EM Environmental Management

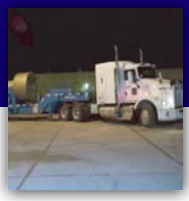
safety ✣ performance ✣ cleanup ✣ closure

Standard Review Plan (SRP) Modules










Technical Framework for EM Projects Critical Decision (CD) Milestones Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

Table of Content[1]

[1] *The SRP is being developed in a phased-approach. Table of Content only lists the developed Review Modules to date (those hyperlinked). Figure 1 and Figure 2 present a listing of key project documents and activities, related tp Critical Decision (CD). These provide a roadmap for a complete listing of Review Modules to be developed as part of the SRP initiative.*

Section	Sub - Section
	e. Environment *i. Additional Review Modules to be developed.*
	f. Security *i. Additional Review Modules to be developed.*
	g. Quality Assurance (QA) *i. Additional Review Modules to be developed.*
5. Critical Decision (CD-3) Review Modules	
	a. Project Management *i. Additional Review Modules to be developed.*
	b. Engineering and Design *i. Final Design* *ii. Construction Readiness* *iii. Commissioning Plan*
	c. Nuclear and Facility Safety *i. Additional Review Modules to be developed.*
	d. Worker Safety *i. Additional Review Modules to be developed.*
	e. Environment *i. Additional Review Modules to be developed.*
	f. Security *i. Additional Review Modules to be developed.*
	g. Quality Assurance (QA) *i. Additional Review Modules to be developed.*
6. Critical Decision (CD-4) Review Modules	
	a. Project Management i. *Additional Review Modules to be developed.*
	b. Engineering and Design *i. Additional Review Modules to be developed.*
	c. Nuclear and Facility Safety *i. Management Self-Assessment* *ii. Additional Review Modules to be developed.*
	d. Worker Safety *i. Additional Review Modules to be developed.*
	e. Environment *i. Additional Review Modules to be developed.*
	f. Security *i. Additional Review Modules to be developed.*
	g. Quality Assurance (QA) *i. Additional Review Modules to be developed.*

Overview: Critical Decision (CD) Technical Framework and Strategy

The Department of Energy (DOE) Office of Environmental Management (EM) Standard Review Plan (SRP) is the corporate technical review framework designed to formalize EM's institutional processes and requirements associated with the review of project activities and key documents prior to Critical Decision (CD) approval[2].

EM is responsible for managing the design, construction, operation, and eventual disposition of high profile, mission critical projects. Effective management of these projects requires multiple technical disciplines to be engaged at various project lifecycle phases. These disciplines include nuclear safety, various design, process, and structural engineering specialties, risk assessment, and safety and health subject matter experts. The project lessons learned to date, both successes and setbacks, have highlighted the need for a more focused, technically in-depth, and standardized approach to project reviews performed at Critical Decision points.

The SRP is a working document planned to be developed in a phased-approach consisting of a series of "Review Modules". The individual Review Modules address key functional areas of project management, engineering and design, safety, environment, security, and quality assurance, grouped per each specific Critical Decision point.

The SRP provides a consistent, stable, and predictable corporate review framework to ensure that issues and risks that could challenge the success of EM projects are identified early and proactively addressed. The internal EM project review process encompasses key milestones established by the DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Asset*, DOE-STD-1189-2008, *Integration of Safety into the Design Process,* and EM's internal business management practices.

In addition to the DOE directives and EM guidance, the Review Modules also incorporate other related technical documents including the recent development of various DOE O 413.3 Guides, lessons learned from current field implementation, and insights gained from previous EM, Office of Engineering and Construction Management (OECM), Office of Science (SC), and the National Nuclear Security Administration (NNSA) project reviews.

Figure 1 depicts the prerequisite activities associated with each Critical Decision approval. Figure 2 presents all of the key documents, and their evolutions, that are needed for corporate review and approval of Critical Decision milestones. It is anticipated that a Review Modules will be developed for the corresponding key document and associated activities presented in Figure 1 and Figure 2. Figure 3 presents a simplified listing of Review Modules developed in FY-08 and planned for development in early FY-09. Additional priority Review Modules are planned for the remainder of FY-09.

[2] James M. Owendoff, Chief Operations Officer for Environmental Management, dated September 8, 2008, *Interim Policy for Environmental Management Capital and Major Operating Project Standard Review Plan*

The intended audiences for the SRP are EM-HQ organizations and Field organizations including the Federal Project Directors (FPDs) responsible for preparation, review, and approval of key documents and associated project activities needed for Critical Decisions. Additionally, the SRP provides the Architect/Engineer (A&E) and operating contractors clarity on DOE expectations, thus promoting a more stable and consistent corporate decision-making framework.

For Critical Decision approval, Table 1 presents a listing of key issues that needs to be considered by the Acquisition Executive, EM HQ and Field Managers. The FPDs can also use the listed issues to gauge the progress of their respective projects.

Table 1. Key Issues for Critical Decision Review and Approval

ISSUES FOR CRITICAL DECISION REVIEW AND APPROVAL[3]	YES	NO
CD-0 (Approval on Mission Need)		
• Have the program's strategic goals and objectives been addressed? (PM)		
• Are project objectives, requirements, priorities, and constraints documented? (PM)		
• Has the Mission Need Statement and pre-project planning activities been completed? (PM)		
• Have all significant project issues been identified, resolved, and documented? (PM)		
• Has a mission need Independent Project Review been completed? (PM)		
• Have technical and functional requirements been identified? (PM)		
• Have the major potential hazards and safety/risk implication been identified and documented in the Mission Need Statement? (NFS, E, S)		
CD-1 (Approval on Alternative Selection and Cost Range)		
• Has a Risk Management Plan been prepared and project risks identified, analyzed, and determined to be either avoidable or manageable? (all project areas)		
• Has an Acquisition Strategy been completed? (PM)		
• Is an Independent Project Team (IPT) been chartered, organized and functioning? (PM)		
• Has the preliminary Project Execution Plan, including baseline range and documents, been submitted for approval? (PM)		
• Have long-lead and special equipment items been identified and documented? (PM)		
• Has Alternative Analysis been prepared and documented? (PM)		
• Is the Conceptual Design Report complete? (ED)		
• Has DOE complete the conceptual design review and prepare a Conceptual Design Review Report? (ED)		
• Has the Project Data Sheet for design been submitted? (ED)		
• Has the requirements basis for the design and engineering phase of the project been identified and is it adequate/appropriate? (ED)		
• Has a Safety Design Strategy been prepared and reviewed and approved by DOE for addressing early integration of safety into design? (NFS)		
• Has the contractor developed a Conceptual Safety Design Report (CSDR) per STD-1189? (NFS)		
• Has DOE prepared a Conceptual Safety Design Validation Report on the review of the CSDR? (NFS)		
• Has a Preliminary Hazard Analysis Report been issued, if the project is non-nuclear? (FS and WS)		
• Has DOE reviewed and approved the Preliminary Hazard Analysis Report, if applicable? (FS and WS)		
• Has Integrated Safety Management process been initiated and documented for the		

[3] PM= Project Management, ED=Engineering & Design, NFS= Nuclear Facility Safety, WS= Worker Safety, E= Environmental, S= Security, QA= Quality Assurance.

ISSUES FOR CRITICAL DECISION REVIEW AND APPROVAL[3]	YES	NO
project? (NFS, WS)		
• Have the High Performance Sustainable Building considerations been evaluated and documented? (E)		
• Have environment documents been prepared, including National Environmental Policy Act strategy and analyses, and permit applications? (E)		
• Has a preliminary security vulnerability assessment been prepared and documented? (S)		
• Has an initial Cyber Security Plan been prepared? (E)		
• Is the site-wide Quality Assurance Program acceptable to the project? (QA)		
CD-2 (Approval on Performance Baseline)		
• Has a performance baseline External Independent Review been conducted by OECM? Are the Corrective Actions been completed? (all project areas)		
• Has a Risk Management Plan been updated to determine if risks have been identified and properly classified? Are appropriate risk mitigation actions incorporated into the baseline? (all project areas)		
• Has an Acquisition Strategy been updated? Is it consistent with the way the project is being executed? (PM)		
• Is an Independent Project Team (IPT) been fully staff and functioning properly? Are there any deficiencies in the IPT that could hinder successfully execution of the project? (PM)		
• Has the Project Execution Plan been updated? (PM)		
• Are detailed Resource Loaded Schedule and Total Project Cost and Project Schedule completed? (PM)		
• Is the Work Breakdown Structure represents a reasonable breakdown of the project work scope? (PM)		
• Has the Value Engineering process been applied and the results been incorporated into the baseline? (PM)		
• Has an Earned Value Management process been employed? (PM)		
• Is the Preliminary Design Report complete? (ED)		
• Are the Systems, Functions, and Requirements documents completed and are in the baseline, including safety, permits, licenses, and regulatory approvals? (ED)		
• Has DOE completed the preliminary design review and prepare a Preliminary Design Review Report? (ED)		
• Has the updated Project Data Sheet for design been submitted? (ED)		
• Has the requirements basis for the design and engineering phase of the project been identified and is it adequate/appropriate? (ED)		
• Has a Safety Design Strategy been updated, reviewed and approved by DOE for addressing early integration of safety into design? (NFS)		
• Has the contractor developed a Preliminary Safety Design Report (PSDR) per STD-1189? (NFS)		
• Has DOE prepared a Preliminary Safety Validation Report on the review of the PSDR? (NFS)		
• Has a Hazard Analysis Report been updated, if the project is non-nuclear? (FS and WS)		
• Has DOE review and approve the Hazard Analysis Report? (FS and WS)		
• Has Integrated Safety Management process been continuously implemented? (NFS, WS)		
• Have the High Performance Sustainable Building considerations been documented and incorporated into the project? (E)		
• Have a National Environmental Policy Act and Record of Decision been documented? (E)		
• Has a security vulnerability assessment been updated and documented? (S)		
• Has a Cyber Security Plan been updated? (E)		
• Is the Quality Assurance Program been updated for the design phase? (QA)		
CD-3 (Approval on Start of Construction)		
• Has DOE completed the final design review and prepare a Final Design Review Report? (ED)		
• Has a construction readiness External Independent Review been conducted by OECM? Are the Corrective Actions been completed? (all project areas)		

ISSUES FOR CRITICAL DECISION REVIEW AND APPROVAL[3]	YES	NO
• Has a Risk Management Plan been updated to determine if new risks have been identified in the final design and the risk been properly classified? (all project areas)		
• Has an Acquisition Strategy been updated? Is it consistent with the way the project is being executed? (PM)		
• Is an Independent Project Team (IPT) been fully staff and functioning properly? Are there any deficiencies in the IPT that could hinder successfully construction execution? (PM)		
• Has the Project Execution Plan been updated to reflect final design and supports the way the project and construction effort is being managed? (PM)		
• Are detailed Resource Loaded Schedule and Total Project Cost and Project Schedule updated? (PM)		
• Has the Value Engineering process been applied and the results been incorporated into the final design process? (PM)		
• Has an Earned Value Management process been employed? (PM)		
• Is the Project Transition to Operation Plan being prepared and completed? (PM)		
• Are Final Design Reports complete, including drawings and specifications? (ED)		
• Are the Systems, Functions, and Requirements documents completed and are in the Performance Baseline, including safety, permits, licenses, and regulatory approvals? Are changes from the final design review incorporated into the Performance Baseline? (ED)		
• Has the Design Code of Record prepared? (ED)		
• Has the contractor prepared a construction readiness execution plan/strategy? Has EM conducted a Construction Readiness Review besides the OECM EIR? (ED)		
• Has the requirements basis for the design and engineering phase of the project been identified and is it adequate/appropriate? (ED)		
• Has a Checkout, Testing and Commissioning Plan been initiated prior to CD-4 approval? (ED)		
• Has the contractor developed a Preliminary Documented Safety Analysis Report (PDSA)? (NFS)		
• Has DOE prepared a Safety Evaluation Report on the review of the PDSA? (NFS)		
• Has a Hazard Analysis Report been updated, if the project is non-nuclear? (FS and WS)		
• Has DOE reviewed and approved the Hazard Analysis Report, if applicable? (FS and WS)		
• Has Integrated Safety Management process been validated for construction activities? (NFS, WS)		
• Has the contractor completed the Construction Project Safety and Health Plan as required by CFR 851? Has the DOE reviewed this plan? (WS)		
• Has Integrated Safety Management process continuously implemented for the project? (NFS, WS)		
• Have the High Performance Sustainable Building evaluations completed and documented? (E)		
• Have NEPA documents been completed? (E)		
• Has a security vulnerability assessment been updated and documented? (S)		
• Has an initial Cyber Security Plan been updated? (E)		
• Is the Quality Assurance Plan been modified for construction activities and testing? (QA)		
CD-4 (Approval on Start of Operations)		
• Has a Post Implementation Review been conducted? (PM)		
• Has a Lesson Learn Report been prepared? (PM)		
• Has a Final Project Closeout Report been prepared? (PM)		
• Have verifications been performed to determine if Key Performance Parameters or Project Completion Criteria have been met and mission requirements achieved? (PM)		
• Have project required Operational documents been prepared? (PM)		
• Has a Management Self-Assessment been performed? (PM)		
• Have contractor and DOE readiness reviews or Operational Readiness Review been conducted and correctives actions have been addressed? (ED and NFS)		
• Have the Documented Safety Analysis (DSA) been finalized and the Technical Safety Requirements (TSR) been established?(NFS)		
• Has DOE reviewed and approved the DSA and TSR and prepared a Safety Evaluation		

ISSUES FOR CRITICAL DECISION REVIEW AND APPROVAL[3]	YES	NO
Report? (NFS)		
• Has the Hazard Analysis Report been finalized and obtain DOE review and approval prior to operations (FS and WS)		
• Are the NEPA documents and the Sustainable Building evaluation documents been finalized and incorporated into the project's Environmental Management System? (E)		
• Is the Security Vulnerability Assessment report finalized? (S)		
• Is the Cyber Security Plan finalized? (S)		
• Has the QA Plan been updated facility operations? (QA)		

In summary, it is expected that the SRP will provide EM senior leadership, Federal Project Directors, and the technical review teams with the following:

1. Added clarity to and streamlining of project roles, responsibilities, accountabilities, and authorities both at the HQ and the Field level.

2. Minimize potential overlaps, redundancy, and duplication in the number and scope of project reviews.

3. Integrated and synergetic project reviews resulting in reduced burden on field site resources and assuring a technically sound, consistent, and focused review process. This has an added benefit of ensuring that EM's expectations and review criteria are clearly conveyed to the contractors.

4. Increased the likelihood that unforeseen design, construction, operational, and decommissioning issues/risks are identified earlier and addressed before posing challenge to project progress and success.

5. A technically objective and defensible basis for Critical Decision approval.

Master Roadmap for EM Projects *(Crtitical Decision Approval Prerequisite Activities)*

Working Document - CNS

	CD-0 Approval on Mission Need	CD-1 Approval on Alternative	CD-2 Approval on Performance Baseline	CD-3 Approval on Start of Construction	CD-4 Approval on Start of Operations
Project Management	Perform Pre-conceptual Planning activities Prepare Mission Need Statement Prepare a Tailoring Strategy if required Perform a Mission Validation Independent Project Review Evaluate projects for Information Technology elements within the Departmental Enterprise Architecture framework	Prepare a preliminary Project Execution Plan Prepare an Acquisition Strategy Comply with the One-for-One Replacement legislation Approve appointment of the Federal Project Director Establish and charter an Integrated Project Team Approve Long-Lead Procurements, if necessary	Update the Project Execution Plan Establish Performance Baseline Employ an Earned Value Management System Perform a Performance Baseline Validation External Independent Review or a Performance Baseline Validation Independent Project Review Develop an Independent Cost Estimate or perform an Independent Cost Review for Major System Projects	Update all CD-2 project documentation and required approvals to reflect any changes resulting from final Design, including Project Data Sheet, etc Perform an External Independent Review for Construction or Execution Readiness (OECM) Issue a Project Transition to Operations Plan	Verify Key Performance Parameters or Project Completion Criteria have been met and mission requirements achieved Perform final administrative and financial closeout and prepare a Final Project Closeout Report Prepare a Lessons Learned Report Conduct Post Implementation Review Complete project required Operational Documentation
Engineering and Design	None at this CD stage	Prepare a Project Data Sheet Prepare a Conceptual Design Report Conduct Conceptual Design Review	Update the Project Data Sheet, if applicable Prepare a Preliminary Design Conduct a Preliminary Design Review	Issue a Checkout, Testing, and Commissioning Plan Prepare Final Design Conduct Final Design Review Develop Design Code of Record	No activities required by DOE O 413.3A
Nuclear and Facility Safety	Determine major potential hazards and safety/risk implication	Prepare a Safety Design Strategy for projects subject to DOE STD 1189 Prepare a Conceptual Safety Design Report for Hazard Category 1, 2, and 3 nuclear facilities Prepare a Conceptual Safety Validation Report Prepare a Preliminary Hazard Analysis Report for facilities that are below Hazard Category 3 threshold Implement Integrated Safety Management	Update the Safety Design Strategy for projects subject to DOE STD 1189 Prepare a Preliminary Safety Design Report Prepare a Preliminary Safety Validation Report Prepare a Hazard Analysis Report and obtain DOE approval	Update the Safety Design Strategy for projects subject to DOE STD 1189 Prepare the Preliminary Documented Safety Analysis Prepare a Safety Evaluation Report Update the Hazard Analysis Report and obtain DOE approval Complete a Readiness Assessment or an Operational Readiness Review. As a precursor to ORR, conduct an Management Self-Assessment	Prepare the Documented Safety Analysis with Technical Safety Requirements Prepare a Safety Evaluation Report Finalize the Hazard Analysis Report and obtain DOE approval
Worker Safety	None at this CD stage	Implement Integrated Safety Management (see nuclear safety)	None defined	Prepare a Construction Project Safety and Health Plan and obtain DOE approval as defined in 10 CFR 851	Update the Construction Project Safety and Health Plan
Environment	Initiate National Environmental Policy Act strategy and analyses	Document High Performance Sustainable Building considerations Prepare environmental documents including National Environmental Policy Act strategy and analyses, and permit applications	Incorporate Preliminary Sustainable Environmental Stewardship-High Performance Sustainable Building provisions into the preliminary design and design review Complete (or obtain approval of) final National Environmental Policy Act documentation, which must be completed prior to the start of final design	Incorporate Sustainable Environmental Stewardship-High Performance Sustainable Building provisions into the Final Design and the External Independent Review Revise the Environmental Management System to ensure that it incorporates new environmental aspects related to turnover and operations	No activities required by DOE O 413.3A
Security	None at this CD stage	Prepare a Preliminary Security Vulnerability Assessment Report Prepare an Initial Cyber Security Plan	Update the Preliminary Security Vulnerability Assessment Report Update the Initial Cyber Security Plan	Update the Preliminary Security Vulnerability Assessment Report Update the Cyber Security Plan	Finalize the Security Vulnerability Assessment Report Finalize the Cyber Security Plan for Information Technology projects and complete the Certification and Accreditation, as required
Quality Assurance	None at this CD stage	Determine that the Quality Assurance Program is acceptable	Determine that the Quality Assurance Program is acceptable and continues to apply	Issue an updated Quality Assurance Plan to address testing, identified deficiencies, and startup, transition, and operation activities	Update the Quality Assurance Program for operations

Figure 1

Master Roadmap for EM Projects *(Key Documents for Critical Decision Approval Review)*

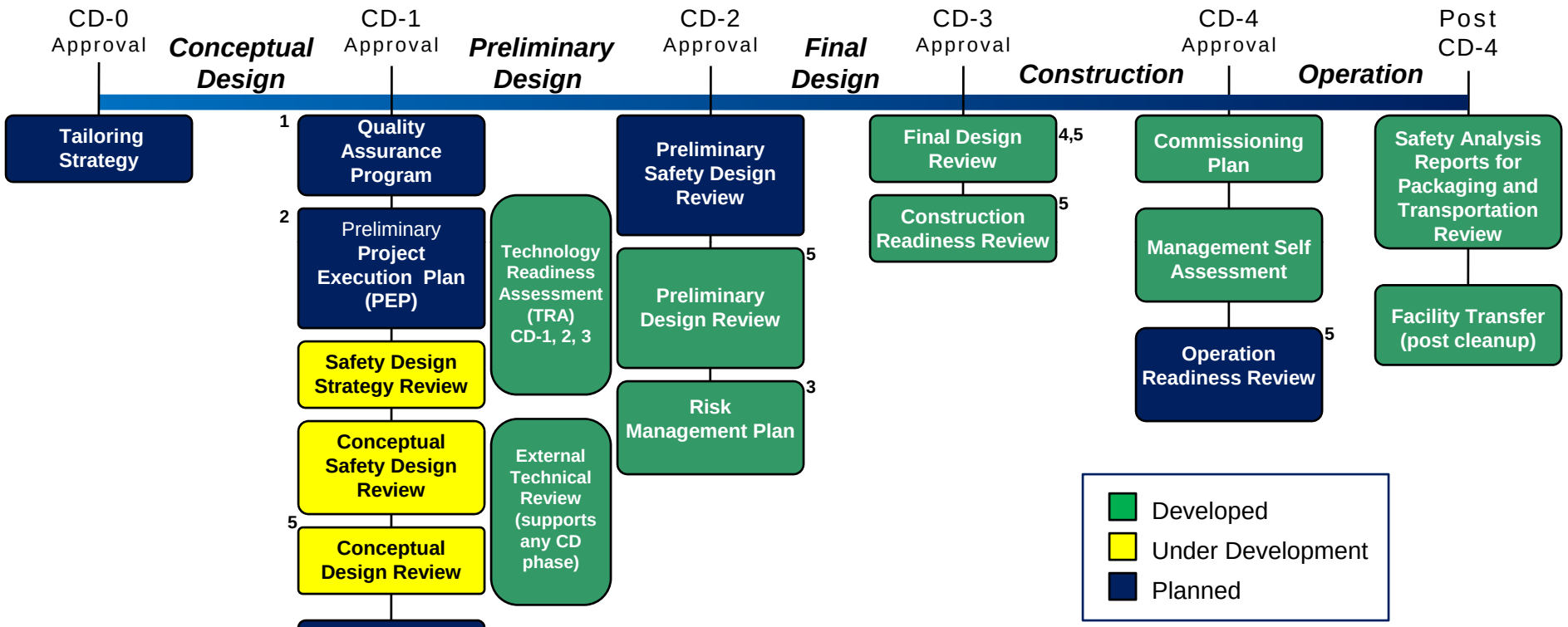
Working Document - CNS

	CD-0 Approval on Mission Need	CD-1 Approval on Alternative	CD-2 Approval on Performance Baseline	CD-3 Approval on Start of Construction	CD-4 Approval on Start of Operations
Project Management	Mission Need Statement	Project Execution Plan Risk Management Plan Alternatives Analysis document Acquisition Strategy Long Lead Procurement documents, if applied Integrated Project Team Charter	Updated Project Execution Plan Detailed Resource Loaded Schedule Detailed Cost and Schedule Estimates Risk Management Plan Contingency Analysis and Plan Earned Value Management System documents Acquisition Strategy/Plan Funding Profile documents Startup Plan, when appropriate EIR report on Performance Baseline Validation	Updated Project Execution Plan Updated Detailed Resource Loaded Schedule Updated Detailed Cost Estimate Updated Risk Management Plan Updated Value Management and Engineering Report Updated Acquisition Strategy Updated Funding Profile documents Updated Startup Plan, when appropriate EIR report on Construction Readiness Review	Documents on verification of Key Performance Parameters or Project Completion Criteria Project Transition to Operations Plan Final Project Closeout Report Lessons Learned Report Documents on operations procedures Post Implementation Review report
Engineering and Design	None at this CD stage	Technology Readiness Assessment Conceptual Design Report Conceptual Design Review Report Project Data Sheet for design	Drawings, specifications and design lists System Functions and Requirements documents (Design Criteria) Preliminary Design Report Preliminary Design Review documents Updated Project Data Sheet	Design Code of Record *(initiated in CD-1)* Construction planning documents Final Design documents, including drawing and specs Final design review documents Checkout, Testing and Commissioning Plan	
Nuclear and Facility Safety	Documentation of major potential hazards and safety/risk implication as part of Mission Need Statement	Safety Design Strategy Conceptual Safety Design Report Conceptual Safety Validation Report Preliminary Hazard Analysis Report for non-nuclear project DOE review of PHA Report ISM documents	Updated Safety Design Strategy Preliminary Safety Design Report Preliminary Safety Validation Report Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report	Updated Safety Design Strategy Preliminary Documented Safety Analysis report Safety Evaluation Report Updated Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report	Documented Safety Analysis with Technical Safety Requirements Safety Evaluation Report Updated Hazard Analysis Report (non nuclear) DOE review of Hazard Analysis Report Readiness Review or Operational Readiness Review Report
Worker Safety	None at this CD stage	ISM documents	Hazard Analysis Report and approval (see Nuclear Safety)	Construction Project Safety and Health Plan Updated Hazard Analysis Report and approval (see Nuclear Safety)	Updated Construction Project Safety and Health Plan Updated Hazard Analysis Report and approval (see Nuclear Safety)
Environment	None at this CD stage	Permit applications NEPA documents High Performance Sustainable Building considerations documents	Final NEPA documents Sustainable Building considerations documents	Final Sustainable Building considerations documents	Environment Management System
Security	None at this CD stage	Preliminary Security Vulnerability Assessment Report, if applied Initial Cyber Security Plan, if applied	Updated Preliminary Security Vulnerability Assessment Report, if applied Updated Cyber Security Plan, if applied	Updated Preliminary Security Vulnerability Assessment Report, if applied Updated Cyber Security Plan, if applied	Security Vulnerability Assessment Report, if applied Cyber Security Plan, if applied
Quality Assurance	None at this CD stage	QA Plan	Updated QA Plan	Updated QA Plan for construction	Updated QA Plan

Note: Long-Term plan is to develop a SRP Review Module for each of the key documents and associated activities listed above.

Figure 2

Partial Listing of Near-Term SRP Review Modules Planned for Development (FY-08/Early FY-09)



[1] Note that the QA Program is a requirement for all CD phases.
[2] The PEP includes the Risk Management Plan and Risk Assessment (CD-1, CD-2).
[3] Risk Management Plan is indicated as a separate element to place more emphasis on it.
[4] The final design review process includes 2 design reviews at 60% and 90% design completion
[5] Design Code of Record (COR) policy and guidance will be an integral part of applicable design review modules, i.e., CDRM, PDRM, and FDRM.

Figure 3

EM Environmental Management

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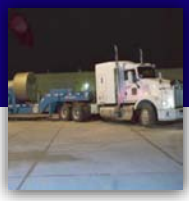
Standard Review Plan (SRP)

Risk Management Plan Module







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OFFICE OF ENVIRONMENTAL MANAGEMENT

RISK MANAGEMENT REVIEW MODULE

September 2008

[This Review Module will be subject to field pilot implementation in FY-09. Any subsequent lessons learned will be captured in the next revision]

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

CD-(N)	Critical Decision – (numbered)
EM	Office of Environmental Management
FPD	Federal Project Director
IPT	Integrated Project Team
LOI	Line of Inquiry
PEP	Project Execution Plan
RMP	Risk Management Plan
RMR	Risk Management Review

I. INTRODUCTION

The focus on project performance has increased significantly due to the legacy of Department of Energy Capital Projects behind schedule and over budget. To improve performance, the Department of Energy has updated and issued DOE Order 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets* to reflect lessons learned and to update requirements to take advantage of better methodologies in project management. The objective of the DOE Order is: "To provide Department of Energy . . . project management direction for the acquisition of capital assets that are delivered on schedule, within budget, and fully capable of meeting mission performance and environmental, safety, and health standards."

One of the major tools needed to meet the objective of DOE Order 413.3A, Change 1, is project risk management. This tool is the process of continuous and iterative identification and control of project risks and opportunities. Risks can be technical, financial, or programmatic. The goal for the risk management system is to either avoid the risk's threat by taking preemptive action or to minimize the risks negative impacts on project performance. Project opportunities identified through the project risk management process can be handled in a similar manner with the goal being to exploit or enhance the realization of that opportunity.

DOE O 413.3A and supporting guidance provides an "approach to managing risk that is integrated, forward-looking, disciplined, iterative, and continuous." In general the outcomes of risk being realized are categorized as either favorable or unfavorable. Risk management is defined in DOE O 413.3A as

> "The DOE risk management concept is based on the principles that risk management must be analytical, forward-looking, structured, informative, and continuous. Risk assessments should be performed as early as possible in the project life cycle and should identify critical technical, performance, schedule, and cost risks. Once risks are identified, sound risk mitigation strategies and actions should be developed and documented."

This approach is further developed in guide DOE G 413.3-7, *Risk Management Guide, Rev Com.*

Risk management is an important part of project definition and execution and as such should begin as soon as possible in a project's lifecycle. Some limited risk identification and analysis is possible and highly desirable as early as the Project Initiation Phase. While the detail of risk identification and changes from qualitative to quantitative analysis is expected to occur as the project moves from the Initiation Phase, through CD-0, and on through CD-4, it is also expected that the nature of the risks facing the project will evolve as well.

For Hazard Category 1, 2, and 3 projects, the Risk and Opportunities Assessment is required as input to the risk management process. Given the potentially significant costs associated with safety decisions, the integration of safety into the design process needs to include a strong link between the development of Safety-in-Design and the Risk Management process. With anticipated risks, early identification of possible opportunities to address potential risks allows the project to define appropriate range estimates. Comprehensive risk identification, coupled with an appropriately conservative safety design posture, affords the project the opportunity to execute within the range estimate with a higher degree of reliability. More guidance on addressing safety risks in is contained in DOE-STD-1189-2008.

II. PURPOSE

This review guide focuses on three areas: A) identifying each project's governing risk management requirements; B) the extent to which the identified requirements implement the DOE O 413.3A, Change 1, and EM policy and procedures; and C) the extent to which the project's requirements are being implemented by the Integrated Project Team (IPT). This information will elicit whether the correct set of risks been identified, and whether the handling strategies for the risks are correct based on the stage of the project and the information available. The outcome will assist the Federal Project Director (FPD) in determining the adequacy and potential effectiveness of the Project's risk management program (i.e., that correct risks are identified and the handling strategies are correct, the adequacy of resources (personnel and funds) assigned to identify and manage the project risk, and potential areas of concern in risk management implementation that could impact mission success.

Periodic assessment of risk management implementation is an important management practice to provide confidence that Field Elements and their contractors have the necessary infrastructure to properly evaluate and manage project risks. A key component of a successful project is that project risks are identified early in the project such that the impacts can be predicted and managed with reasonable confidence by implementing mitigating (for threats) or enhancing (for opportunities) actions as part of an integrated project management strategy. Finally, this provides an opportunity for FPDs to self-identify potential impediments to project performance and to fully take advantage of opportunities and noteworthy practices and lessons learned. The overarching goal of risk management is to bring about a project management culture that is proactive in assessing risks and preventing unnecessary delays and cost overruns on projects.

III. ROLES AND RESPONSIBILITIES

A critical element of risk management reviews (RMR) is the qualifications, training and most importantly the experience of the personnel selected to conduct the review. To the maximum extent possible, the personnel selected to participate in the RMR should have

"on the ground", first-hand experience (as opposed to an oversight role) in project risk management

Additional qualifications and experience may also be selected depending on the current project phase. For example, construction requires a focus on traditional project management risks but also requires a focus on the unique risks presented by construction activities. The following is a partial list of skills to be considered when forming the RMR team.

- Identification of Risks
- Qualitative and Quantitative risk analyses methods
- Management of Risks
- Component and system testing
- Nuclear operations and maintenance
- Industrial Health and Safety
- Nuclear safety
- Design engineering
- Process engineering
- Radiological engineering and control
- Safety basis development and maintenance
- Project Communication/Emphasis on risk communication
- Project management
- Project and program execution and integration, DOE and EM policy strategies

The core team will normally consist of one or more Subject Matter Experts (SMEs) independent of the project. If necessary, each team member will receive indoctrination and training prior to conducting the evaluation. This core team can be augmented with additional technical personnel selected to complement any specific concerns of the project being reviewed (e.g. Chemical, Structural, Seismic, Instrument, Process, Mechanical Engineering, Construction, Decommissioning, Demolition, etc.).

Management support is another necessary component to a successful RMR. Field element managers, as well as the Federal Project Director, must recognize the importance of the RMR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the RMR process.

The structure and roles and responsibilities of the individual review team members and others involved in the RMR must be clear and consistent with the requirements of DOE O 413.3A, Change 1. The table below provides a compilation of risk management assessment roles and responsibilities.

Table 1 - Risk Management Assessment Roles and Responsibilities

Role	Responsibilities
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the RMR
	Facilitates conduct of the RMR. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Coordinates with the Review Team Leader in the selection of technical areas for the review and in developing the review criteria.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the RMR activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the corrective actions resulting from the RMR.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the areas to be reviewed.
	Based on the project activities, complexity, and hazards involved, selects the RMR team members.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the RMR pre-visit. (If a pre-visit is necessary)

Role	Responsibilities
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of and forwards to the Federal Project Director, the data call of documents, briefings, interviews, and presentations needed.
	Forwards the final review plan to the Acquisition Executive for approval.
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review. Coordinates the characterization of the significance of the findings.
	Coordinates the review team handling of factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final RMR report to the manager authorizing the review for approval.
	Remains available as necessary to participate in the closure verification of the findings from the RMR report.
Review Team Member	Refines and finalizes the criteria for appropriate areas of the RMR.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the RMR.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares the review report.

Role	Responsibilities
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.
	Concurs in the findings for his/her area of the review.

IV. REVIEW SCOPE AND CRITERIA

The RMR should be conducted in accordance with the process and criteria outlined in this review module. A project-specific assessment plan, based on the project risk management infrastructure and the scope and nature of project activities will be prepared for each assessment. For consistency, this guide provides general lines of inquiry (LOI) to guide the overall review process. General lines of inquiry/principles for a risk management program are contained in Appendix A. These lines of inquiry have been developed from DOE G 413.3-7 and should be used as guidance when developing the project-specific detailed review plan.

A better understanding of risks will evolve as the project moves from CD-0 through CD-4. Development of project-specific LOIs should be consistent with the level of information expected and available at each critical decision point. For example: a project entering CD-3 should have substantially developed risk management program outputs including quantitative analyses. Recognizing that the maturity of the risk management program varies with project phases, the following is a list of the program elements that should typically be available at various project phases.

Project Initiation

CD-0, Approve Mission Need

- Risks to the facility mission should be defined early and identified in the Mission Needs Statement.
- Lessons Learned from conducting Risk Management are documented and evaluated.

CD-1, Approve Requirements and Alternative Selection and Cost Range

- Risk Register – risks are initially indentified, particularly technical risks known at this point

- Risk Analysis – at this point in the project, qualitative analysis is expected to be performed.
- Risks are rated using a risk analysis matrix or other tool that assigns some relative ranking
- Risk Handling Strategy and Plan – begin to define actions to take and assign risk owners
- Risk Monitoring process defined.
- Method to communicate risks (may be part of the Risk Management Plan or Project Execution Plan or stand alone plan).
- Lessons Learned from conducting Risk Management are documented and evaluated. Evaluation is factored into risk analysis through iterative risk management process.

CD-2, Prepare Performance Baseline

- Risk Register – Risk statements are refined, especially technical risk, and have been periodically updated.
- Risk Analysis – qualitative analysis may be appropriate however, at this point quantitative analysis is expected to support cost and schedule estimates.
- Risks are rated using a risk analysis matrix or other tool that assigns some relative ranking
- Risk Handling Strategy and Plan –actions to prevent or mitigate well defined and assign risk owners implementing those actions.
- Risk Monitoring process implemented.
- Method to communicate risks (may be part of the Risk Management Plan or Project Execution Plan or stand alone plan).
- Lessons Learned from conducting Risk Management are documented and evaluated. Evaluation is factored into risk analysis through iterative risk management process.

CD-3, Approve Start of Construction/Authorization to Complete Implementation

- Risk Register – Risk statements are specifically defined , especially technical risk, and have been periodically updated.
- Risk Analysis – at this point in the project, quantitative analysis is expected.
- Risks are rated using a risk analysis matrix or other tool that assigns some relative ranking
- Risk Handling Strategy and Plan –actions to prevent or mitigate well defined and assign risk owners implementing those actions.
- Risk Monitoring process is implemented.
- Method to communicate risks (may be part of the Risk Management Plan or Project Execution Plan or stand alone plan).

- Lessons Learned from conducting Risk Management are documented and evaluated. Evaluation is factored into risk analysis through iterative risk management process.

CD-4, Approve Start of Operation or Project Transition/Closeout

- Risk Register – Risks associated with executing the project are closed. Open risks are those associated with operating the new/modified facility or Long Term stewardship. Risk Analysis – at this point in the project, quantitative analysis is generally expected.
- Risks are rated-a risk analysis matrix or other tool assigns some relative ranking.
- Risk Handling Strategy and Plan –actions to prevent or mitigate well defined and assign risk owners implementing those actions.
- Risk Monitoring process is implemented.
- Risks Communication Plan (may be part of the Project Execution Plan).
- Lessons Learned from conducting Risk Management are documented and evaluated. Evaluation is factored into risk analysis through iterative risk management process.

V. REVIEW PLANS AND DOCUMENTATION

It is important to clearly document the methods, assumptions, analysis, and results of the RMR. Section 8 of the Standard Review Plan provides guidelines for preparing a Review Plan and a final report.

The following activities should be conducted as part of the Review Plan development and documentation/closure of the review:

- Upon selection, formation and chartering of the review team and receipt and review of the prerequisite documents, assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this guide.
- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provides for a unique identifier for each line of inquiry, arranged by subject area (e.g. organizational structure, risk management process, etc.) such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. The method used, the basis for closure/comment/finding, and the result of the inquiry should all be documented and tracked.

VI. REFERENCES

DIRECT REFERENCES

1. DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets*
2. DOE-STD-1189-2008, *Integrating Safety into the Design Process (Appendix F Safety-In-D*esign Relationship with the Risk Management Plan)
3. DOE G 413.3-7, *Risk Management Guide*, REVCOM
4. DOE G 413.3-8, EM Closure Project
5. EM policies and protocols for risk and contingency management

OTHER SOURCES CONSULTED

1. NAS, "Owners Role in Project Management" (NAS report to DOE on Project and Risk Management)

Other sources: DoD, NASA, PMI's OPM3 guide

Appendix A - Performance Objectives and Criteria

Legend of Safety and Engineering Review Topics

Review Topical Area	Identifier
Risk Management Organizational Structure	RMO
Risk Management Process	RMP
- Risk Planning	RMP-1
- Risk Identification	RMP-2
- Risk Analysis	RMP-3
- Risk Handling	RMP-4
- Risk Monitoring	RMP-5
- Risk Reporting and Feedback	RMP-6
Risk Documentation and Communication	RDC
Lessons Learned	LL

Table A.1 – Performance Objectives and Criteria

ID #	Performance Objectives and Criteria	Met?
Risk Management Organizational Structure		
RMO-1	The Project Baseline includes resources and funding for risk management activities. (Applicable to CD-1 through 4)?	
RMO-2	Project Execution Plan (PEP) contains sufficient detail concerning the personnel assigned to the project and the project work structure to allow a determination of the feasibility of the plan? N/A if PEP not required.	
RMO-3	Risk Management Responsibilities are captured in PEP Duties and Responsibilities? N/A if PEP not required?	
Risk Management Process		
RMP-1	Risk Planning	
	A communication structure has been established or a Federal Risk Management Communication Plan is written and executed as part of the tailoring decisions to be made in regard to the project? (RMP-1.1)	
	Inputs to the planning process have been identified. At a minimum they include the project objectives, assumptions, Mission Need Statement, customer/stakeholder expectations, and site office risk management policies and practices? (RMP-1.2)	
	The risk management approach and reporting structure, including format for documenting risk management products, is established (i.e., documented strategy)? (RMP-1.3)	
	For Hazard Category 1, 2 and 3 facility projects, a Risk and Opportunity Assessment is initiated in the conceptual design stage? (RMP-1.4)	
RMP-2	Risk Identification	
	There is evidence that risk identification is continuously performed throughout the project life cycle (i.e., not just at one project phase)? (RMP-2.1)	
	Project risks are captured using a Risk Breakdown Structure (e.g., Project, Technical, Internal, External), unless the project tailoring strategy justifies other methods for organizing identified risks? (RMP-2.2)	

ID #	Performance Objectives and Criteria	Met?
	Risk elicitation sessions are structured and involve an appropriate representation of IPT members necessary to identify the risks? (RMP-2.3)	
	Risk statements are in affirmative terms, as if the risk will occur? (RMP-2.4)	
	Risks, and any specific causal event(s) or assumption(s), are captured in a Risk Register? (RMP-2.5)	
	Risk Owners are assigned to each risk? (RMP-2.6).	
	Risk statements include both consequence and probability statements for the risk? (RMP-2.7)	
	Risk triggers are identified by event and/or date as appropriate? (RMP-2.8)	
	Technical or safety risks capture issues identified from hazard analyses, Technology Readiness Assessments, and External Technical Reviews? (RMP-2-9)	
RMP-3	Risk Analysis	
	Qualitative risk analysis is performed and includes an estimate of risk probability, risk consequence, and trigger metrics or conditions [NOTE: at project initiation through CD-1 minimum analysis is a cost benefit review]? (RMP-3.1)	
	Quantitative risk analysis is performed to support cost and schedule estimates? (RMP-3.2)	
	Risk analysis activities are inclusive of contractor and DOE related risks and analyze both threats and opportunities? (RMP-3.3)	
RMP-4	Risk Handling	
	The risk handling approach is identified and documented for the Project and is consistent with DOE-EM's Risk Management Policy and protocols, Technology Maturation Plans, and the project specific Risk Management Plan? (RMP-4.1)	
	The Risk Handling Strategy for each risk must be specific in regard to High and Medium ranked risks and how they will be handled for the Project? (RMP-4.2)	

ID #	Performance Objectives and Criteria	Met?
	Risk handling strategy is periodically reviewed and updated, and changes in the project are considered during these reviews? (RMP-4.3)	
	High risks are evaluated for back-up risk handling strategies and when they are used, the costs associated are included in risk analyses? (RMP-4.4)	
	Residual Risk is included and managed after application of risk handling strategies and included in risk analyses? (RMP-4.5)	
	Secondary Risk is included and managed after application of risk handling strategies and included in risk analyses? (RMP-4.6)	
	Risk handling strategies are considerate of the following: feasibility of options being considered in terms of the project's objectives, funding and schedule; expected effectiveness; results of a cost/benefit analysis; impacts on other technical portions of the project; and other analyses deemed relevant to the decision process ? (RMP-4.7)	
RMP-5	Risk Monitoring	
	Risk monitoring is performed for individual risks per the risk metrics and overall project risk status? (RMP-5.1)	
	Risk monitoring process covers one or more of the following strategies for managing risks: risk acceptance, avoidance, mitigation, or transfer? (RMP-5.2)	
	Risk monitoring process is systematic, involves continuous tracking and evaluates the effectiveness and appropriateness of the risk handling strategy techniques and actions established within the Risk Management Plan? (RMP-5.3)	
	The risk monitoring process provides qualitative and quantitative information to decision-makers regarding the progress of the risks and risk handling actions being tracked and evaluated? (RMP-5.4)	
	The Risk Monitoring Process includes a mechanism for the Risk Owner to update information from the Risk Register. Changes to the Risk Register are evaluated to determine if additional Risk Identification actions are needed? (RMP-5.5)	
	Integrated risk monitoring has been implemented in accordance with DOE G 413.3-7? (RMP-5.6)	

ID #	Performance Objectives and Criteria	Met?
RMP-6	Risk Reporting and Feedback	
	Status reports are prepared on a monthly basis and provide risk information consistent with the format and content described in DOE G 413.3-7? (RMP-6.1)	
	There is evidence that participants in the risk management process provide feedback through mechanisms identified in the risk management plan? (RMP-6.2)	
Risk Documentation and Communication		
RDC-1	A risk management plan is prepared and included or referenced in the project execution plan? (RDC-2.1)	
RDC-2	The format and content of the risk management plan is consistent with Risk Management Plan elements of DOE G 413.3-7? (RDC-2.2)	
RDC-3	In cases where the federal/contractor risk management plan and register is combined, it is justified in a tailoring strategy? (RDC-2.3)	
RDC-4	The risk management plan is reviewed and updated, as necessary, on at least an annual basis? (RDC-2.4)	
RDC-5	Risk information is considered and integrated into acquisition strategy documentation ? (RDC-2.5)	
RDC-6	Risk management communication is accomplished either through the PEP, the risk management plan, or a separate risk management communication plan that is consistent with the Risk Management Communication Plan elements of DOE G 413.3-7	
Lessons Learned		
LL-1	Project evaluates for risk management lessons learned at each stage of the project.	
LL-2	Quantitative analyses include a lessons learned section regarding risk realization.	

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

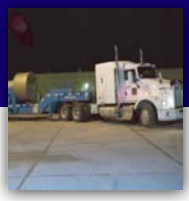
Standard Review Plan (SRP)

Technology Readiness Assessment Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

U.S. Department of Energy
Office of Environmental Management

Technology Readiness Assessment (TRA) / Technology Maturation Plan (TMP) Process Guide

March 2008

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1.0 INTRODUCTION

1.1 Document Purpose

This document has been developed to guide individuals and teams that will be involved in conducting Technology Readiness Assessments (TRAs) and developing Technology Maturation Plans (TMPs) for the U.S. Department of Energy's Office of Environmental Management (DOE-EM). The Process Guide is intended to be a 'living document' and will be modified periodically as the understandings of TRA/TMP processes evolve.

2.0 OVERVIEW OF TECHNOLOGY READINESS ASSESSMENTS AND TECHNOLOGY MATURATION PLANS

2.1 Objectives of TRAs and TMPs

TRAs provide a snapshot in time of the maturity of technologies and their readiness for insertion into the project design and execution schedule. TMPs detail the steps necessary for developing technologies that are less mature than desired to the point where they are ready for project insertion. TRAs and TMPs are effective management tools for reducing technical risk and minimizing potential for technology driven cost increases and schedule delays.

2.2 The TRA

> "A TRA is a systematic, metric-based process and accompanying report that assesses the maturity of certain technologies [called Critical Technology Elements (CTEs)] used in systems." [2003 *DoD Technology Readiness Assessment Deskbook* (updated May 2005)]

The TRA is an assessment of how far technology development has proceeded. It is not a pass/fail exercise, and is not intended to provide a value judgment of the technology developers or the technology development program. A TRA can:

- Identify the gaps in testing, demonstration and knowledge of a technology's current readiness level and the information and steps needed to reach the readiness level required for successful inclusion in the project;
- Identify at-risk technologies that need increased management attention or additional resources for technology development; and
- Increase the transparency of management decisions by identifying key technologies that have been demonstrated to work or by highlighting immature or unproven technologies that might result in increased project risk.

A TRA evaluates technology maturity using the Technology Readiness Level (TRL) scale that was pioneered by the National Aeronautics and Space Administration (NASA) in the 1980s. TRL indicates the maturity of a given technology, as defined in Table 1. Figure 1 provides a schematic of the meaning of the TRLs in the context of DOE EM projects. The TRL scale ranges from 1 (basic principles observed) through 9 (total system used successfully in project operations). TRL is not an indication of the quality of technology implementation in the design. However, technology testing results are critical in determining the TRL. Testing must be done in the proper environment and the technology tested must be of an appropriate scale and fidelity. TRL requirements and definitions regarding testing "scale," "system fidelity," and "environment" are provided in Tables 2 and 3.

Figure 1 Schematic of DOE Technology Readiness Levels

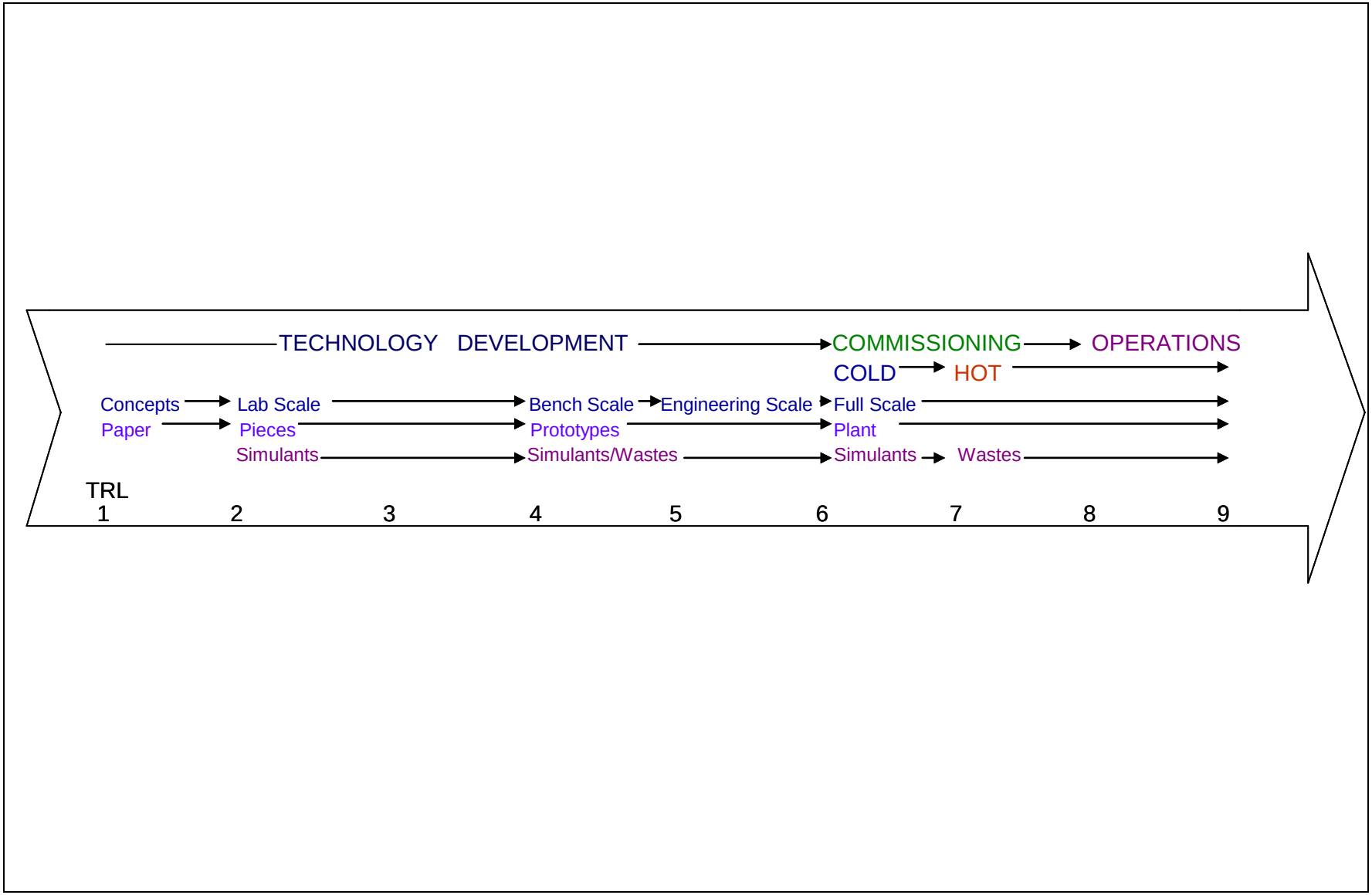


Table 1 Technology Readiness Levels

Relative Level of Technology Development	Technology Readiness Level	TRL Definition	Description
System Operations	**TRL 9**	Actual system operated over the full range of expected conditions.	The technology is in its final form and operated under the full range of operating conditions. Examples include using the actual system with the full range of wastes in hot operations.
System Commissioning	**TRL 8**	Actual system completed and qualified through test and demonstration.	The technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental testing and evaluation of the system with actual waste in hot commissioning. Supporting information includes operational procedures that are virtually complete. An ORR has been successfully completed prior to the start of hot testing.
	TRL 7	Full-scale, similar (prototypical) system demonstrated in relevant environment	This represents a major step up from TRL 6, requiring demonstration of an actual system prototype in a relevant environment. Examples include testing full-scale prototype in the field with a range of simulants in cold commissioning[1]. Supporting information includes results from the full-scale testing and analysis of the differences between the test environment, and analysis of what the experimental results mean for the eventual operating system/environment. Final design is virtually complete.
Technology Demonstration	**TRL 6**	Engineering/pilot-scale, similar (prototypical) system validation in relevant environment	Engineering-scale models or prototypes are tested in a relevant environment. This represents a major step up in a technology's demonstrated readiness. Examples include testing an engineering scale prototypical system with a range of simulants.[1] Supporting information includes results from the engineering scale testing and analysis of the differences between the engineering scale, prototypical system/environment, and analysis of what the experimental results mean for the eventual operating system/environment. TRL 6 begins true engineering development of the technology as an operational system. The major difference between TRL 5 and 6 is the step up from laboratory scale to engineering scale and the determination of scaling factors that will enable design of the operating system. The prototype should be capable of performing all the functions that will be required of the operational system. The operating environment for the testing should closely represent the actual operating environment.
	TRL 5	Laboratory scale, similar system validation in relevant environment	The basic technological components are integrated so that the system configuration is similar to (matches) the final application in almost all respects. Examples include testing a high-fidelity, laboratory scale system in a simulated environment with a range of simulants[1] and actual waste[2]. Supporting information includes results from the laboratory scale testing, analysis of the differences between the laboratory and eventual operating system/environment, and analysis of what the experimental results mean for the eventual operating system/environment. The major difference between TRL 4 and 5 is the increase in the fidelity of the system and environment to the actual application. The system tested is almost prototypical.
Technology Development	**TRL 4**	Component and/or system validation in laboratory environment	The basic technological components are integrated to establish that the pieces will work together. This is relatively "low fidelity" compared with the eventual system. Examples include integration of ad hoc hardware in a laboratory and testing with a range of simulants and small scale tests on actual waste[2]. Supporting information includes the results of the integrated experiments and estimates of how the experimental components and experimental test results differ from the expected system performance goals. TRL 4-6 represent the bridge from scientific research to engineering. TRL 4 is the first step in determining whether the individual components will work together as a system. The laboratory system will probably be a mix of on hand equipment and a few special purpose components that may require special handling, calibration, or alignment to get them to function.
Research to Prove Feasibility	**TRL 3**	Analytical and experimental critical function and/or characteristic proof of concept	Active research and development (R&D) is initiated. This includes analytical studies and laboratory-scale studies to physically validate the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative tested with simulants.[1] Supporting information includes results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. At TRL 3 the work has moved beyond the paper phase to experimental work that verifies that the concept works as expected on simulants. Components of the technology are validated, but there is no attempt to integrate the components into a complete system. Modeling and simulation may be used to complement physical experiments.
Basic Technology Research	**TRL 2**	Technology concept and/or application formulated	Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are still limited to analytic studies. Supporting information includes publications or other references that outline the application being considered and that provide analysis to support the concept. The step up from TRL 1 to TRL 2 moves the ideas from pure to applied research. Most of the work is analytical or paper studies with the emphasis on understanding the science better. Experimental work is designed to corroborate the basic scientific observations made during TRL 1 work.
	TRL 1	Basic principles observed and reported	This is the lowest level of technology readiness. Scientific research begins to be translated into applied R&D. Examples might include paper studies of a technology's basic properties or experimental work that consists mainly of observations of the physical world. Supporting Information includes published research or other references that identify the principles that underlie the technology.

[1] Simulants should match relevant physical and chemical properties.

[2] Testing with as wide a range of actual waste as practicable; and consistent with waste availability, safety, ALARA, cost, and project risk is highly desirable

Table 2 TRL Scale, Fidelity, and Environment Definitions

Scale	
Full Plant Scale	Matches final application
Engineering Scale[1]	Typical (1/10 < system < Full Scale)
Laboratory/Bench[1]	< 1/10 Full Scale
[1] The Engineering Scale and Laboratory/Bench scale may vary based on engineering judgment.	
System Fidelity	
Identical System Configuration	-matches final application in all respects
Similar Systems Configuration	-matches final application in almost all respects
Pieces	-system matches a piece or pieces of the final application
Paper	-system exists on paper (i.e., no hardware system)
Environment (Waste)	
Operational (Full Range)	Full range of actual waste
Operational (Limited Range)	Limited range of actual waste
Relevant	Simulants plus a limited range of actual wastes
Simulated	Range of simulants

Table 3 TRL Testing Requirements

TRL Level	Scale of Testing	Fidelity	Environment[1,2]
9	Full	Identical	Operational (Full Range)
8	Full	Identical	Operational (Limited Range)
7	Full	Similar	Relevant
6	Engineering/Pilot Scale	Similar	Relevant
5	Lab/Bench	Similar	Relevant
4	Lab	Pieces	Simulated
3	Lab	Pieces	Simulated
2		Paper	
1		Paper	

[1] Simulants should match relevant physical and chemical properties
[2] Testing with as wide a range of actual waste as practicable; and consistent with waste availability, safety , ALARA, cost, and project risk is highly desirable

In 1999 the General Accounting Office (GAO) (GAO/NSIAD-99-162) recommended that the DoD adopt NASA's TRLs as a means of assessing technology maturity prior to transition. In 2001, the Deputy Undersecretary of Defense for Science and Technology issued a memorandum that endorsed the use of TRLs in new major programs. Subsequently, the DoD developed detailed guidance for performing TRAs using TRLs, as defined in the 2003 *DoD Technology Readiness Assessment Deskbook* (updated in May 2005 [DOD 2005]). Recent legislation (2006) has specified that the DoD must certify to Congress that the technology has been demonstrated in a relevant environment (TRL 6) prior to transition of weapons system technologies to design or justify any waivers. TRL 6 is also often used as the level required for technology insertion into design by NASA.

In March of 2007, the GAO recommended that DOE adopt the NASA/DoD methodology for evaluating technology maturity. Language supporting the GAO recommendation was incorporated in the House version of the 2008 DOE-EM budget legislation.

2.3 The Technology Maturation Plan

The TMP is a planning document that lays out the activities required to bring immature CTEs up to the desired TRL. It includes preliminary schedules and rough order of magnitude cost estimates that allow decision makers to determine the future course of technology development. Normally the TMP will be followed by detailed test plans that provide more accurate cost and schedule information that can be incorporated into the project baseline. See Section 4.0 for more information on the TMP.

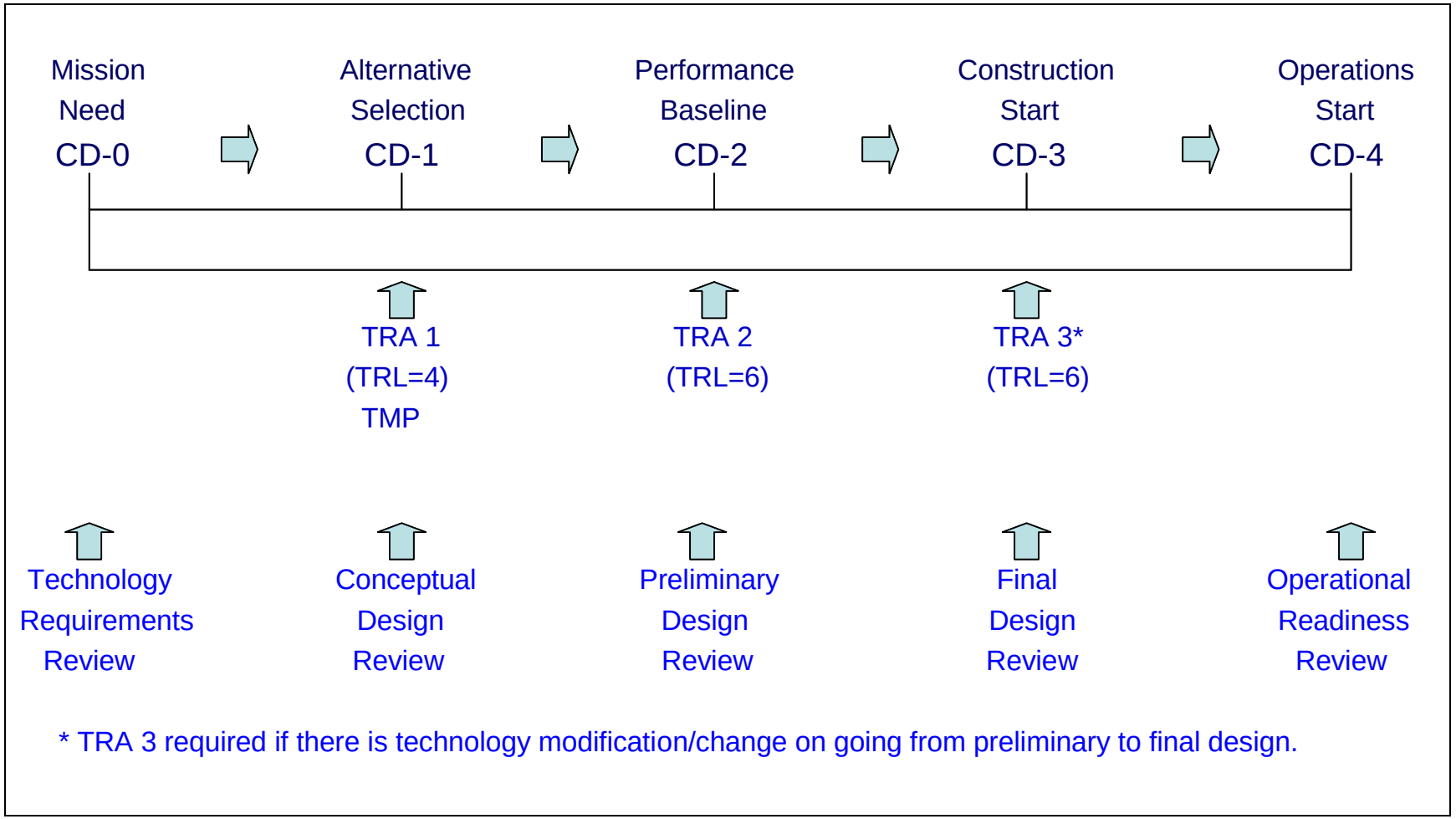
2.4 The Relationship of TRAs and TMPs to DOE Critical Decisions

While the TRA/TMP process is not currently required by DOE Order 413.3A, in the realm of program and project management, the TRA/TMP process can serve as one of the tools employed to help make the Critical Decisions required by DOE Order 413.3A:

> *The five Critical Decisions are major milestones approved by the Secretarial Acquisition Executive or Acquisition Executive that establish the mission need, recommended alternative, Acquisition Strategy, the Performance Baseline, and other essential elements required to ensure that the project meets applicable mission, design, security, and safety requirements. Each Critical Decision marks an increase in commitment of resources by the Department and requires successful completion of the preceding phase or Critical Decision. Collectively, the Critical Decisions affirm the following:*
>
> • *There is a need that cannot be met through other than material means* [CD-0]*;*
> • *The selected alternative and approach is the optimum solution* [CD-1]*;*
> • *Definitive scope, schedule and cost baselines have been developed* [CD-2]*;*
> • *The project is ready for implementation* [CD-3]*; and*
> • *The project is ready for turnover or transition to operations* [CD-4].

The recommended guidance is to conduct TRAs during conceptual design and preliminary design processes; and at least 90 days prior to CD milestones. Figure 2 shows how TRAs and other key reviews support each of the CDs. (There are numerous additional requirements for each CD. See Table 2 of DOE O 413.3A for a complete listing.)

Figure 2 Suggested Technology Readiness Assessments and Other Review Requirements for Critical Decisions



Note: Refer to Doe Order 413.3A for Critical Decision criteria

CD-0, Approve Mission Need: identification of a mission-related need and translation of this gap into functional requirements for filling the need
The mission need is independent of a particular solution and should not be defined by equipment, facility, technological solution, or physical end item (413.3A). The focus for Technology Assessment, at this stage, is on clear statement of the requirements of the input and the desired output of the process. For waste processing, this would include characterization of the waste as well as definition of requirements for the processing and the waste form. A Technology Requirements Review should be performed to assess the adequacy of requirements definition and characterization information and determine if any additional work is necessary. If additional work is necessary to adequately define technical scope of the project, a detailed plan with a proposed schedule should be developed.

CD-1, Alternative Selection and Cost Range: identification of the preferred technological alternative, preparation of a conceptual design, and development of initial cost estimates
A TRA and a TMP should be performed during conceptual design to support the CD-1 approval process. A TRA/TMP supporting CD-1 may be used to (a) assess the relative maturity and maturation requirements of competing technologies and provide a basis for input into the selection amongst them; and/or (b) assess the maturity and maturation requirements of the selected technology. Prior to CD-1 approval, all CTEs of the design should have reached TRL 4 and a TMP that details the strategies for bringing all CTEs to TRL 6 should have been prepared. If a technology is assessed at less than TRL 4, then the TMP and rationale for proceeding with a CTE(s) with a lower TRL(s) should be specifically briefed to the Approval Authority as part of the CD-1 approval process.

CD-2, Performance Baseline: completion of preliminary design, development of a performance baseline that contains a detailed scope, schedule, and cost estimate
The process of technology development, in accordance with the approved TMP, should support all CTEs reaching TRL 6. Attainment of TRL 6 indicates that the technology is ready for insertion into detailed design. If a technology is assessed at less than TRL 6, then the TMP and rationale for proceeding with a CTE(s) with a lower TRL(s) should be specifically briefed to the Approval Authority as part of the CD-1 approval process.

CD-3, Start of Construction: completion of essentially all design and engineering and beginning of construction, implementation, procurement, or fabrication
A TRA is only required if there is significant technology modification as detailed design work progresses. If substantial modification of a technology occurs, the TRA should be performed and a focused TMP developed to ensure that the modified technology has attained TRL 6 prior to its insertion into the detailed design and baseline.

CD-4, Start of Operations: readiness to operate and/or maintain the system, facility, or capability
Successful completion of an Operational Readiness Review (ORR) corresponds to attainment of TRL 7/8.

2.5 The Relationship of TRAs and TMPs to External Technical Reviews (ETRs)

DOE-EM has also recently issued guidance for the conduct of External Technical Reviews (ETRs); as described in the Guide:

> "The purpose of an ETR is to reduce technical risk and uncertainty. ETRs provide pertinent information for DOE-EM to assess technical risk associated with projects and develop strategies for reducing the technical risk, and provide technical information needed to support critical project decisions. Technical risk reduction increases the probability of successful implementation of technical scope. In general, an ETR assesses technical bases, technology development, and technical risk identification and handling strategies."

The use of these two review processes could overlap. In general, it is anticipated that TRAs, and the

associated TMPs, will be focused on the development status of technologies; ETRs, on the other hand are likely to be used for reducing the risk and/or uncertainty associated with a particular technical issue. If there is uncertainty as to which process to use, EM-20 staff should be consulted.

3.0 TECHNOLOGY READINESS ASSESSMENT PROCESS

3.1 Process Overview

The TRA/TMP process diagram is depicted in Figure 3. Associated detailed guidance is provided in Sections 3.4, 3.5 and 4.0. The TRA is divided into two stages: assessment planning and assessment execution.

The Assessment Planning Stage (Section 3.4) begins when it is determined that a TRA is required. Assessment planning involves selection of the TRA team, development of a TRA Plan and review of critical documents. The Assessment Planning Stage ensures pertinent information required to successfully perform the TRA is documented and readily available to the TRA team.

The Assessment Execution Stage (Section 3.5) begins with the onsite assessment activities. Assessment activities involve identification and evaluation of critical technology elements (CTEs), determination of TRLs, TRA reporting and a close-out briefing. The Assessment Stage ensures appropriate data are gathered, appropriate elements are assessed, and assessment results are adequately documented.

The TMP preparation (Section 4.0) begins after the factual accuracy review is conducted on the drafted TRA Report. The TMP ensures the actions required to develop the technologies to the required levels are documented.

A typical timeline for a TRA is provided in Table 4. A typical timeline for a TMP is provided in Table 5. However, the timing for each of these will vary considerably based on the complexity of the project.

Figure 3 Technology Readiness Assessment Process Diagram

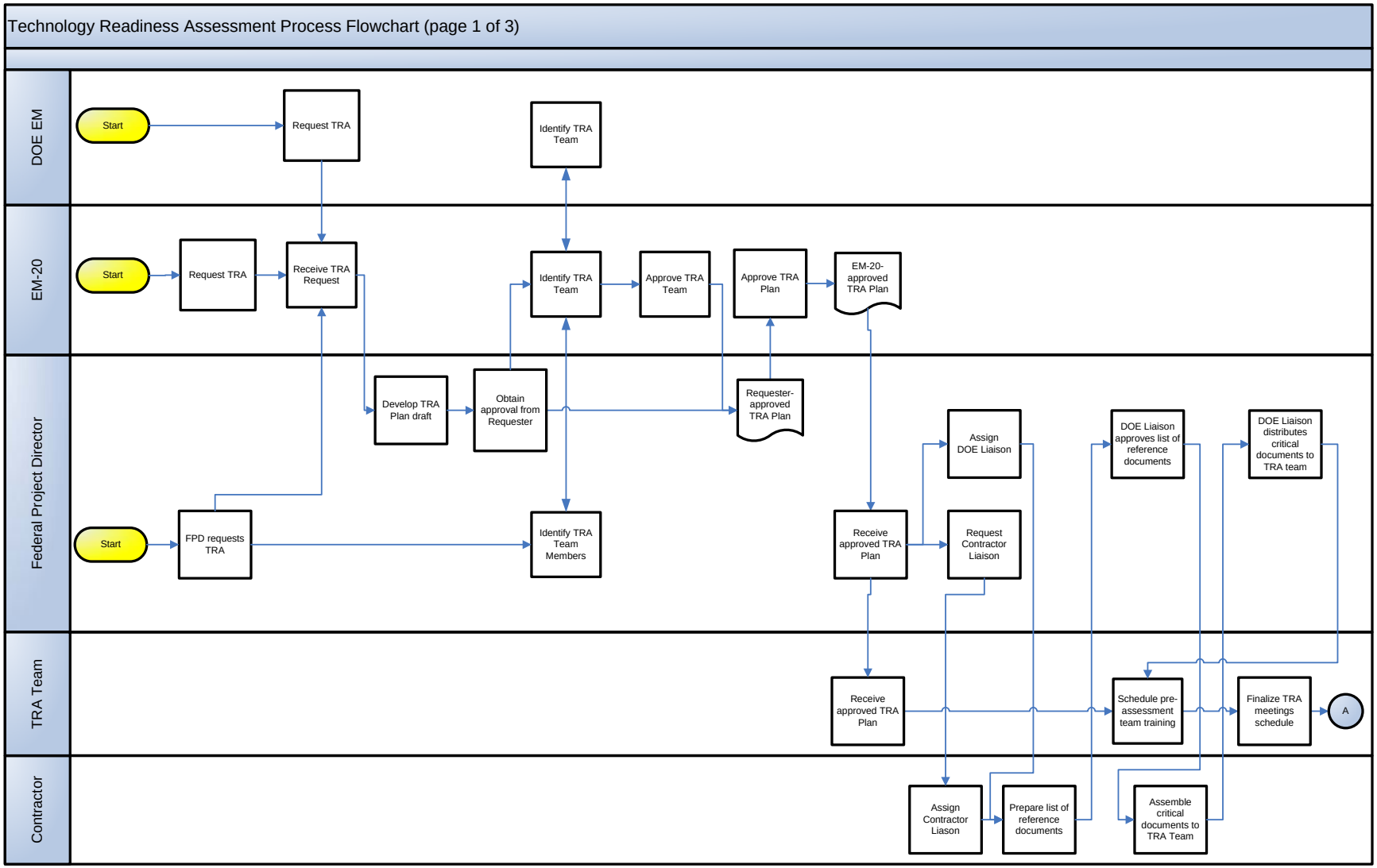


Figure 3 Technology Readiness Assessment Process Diagram (continued)

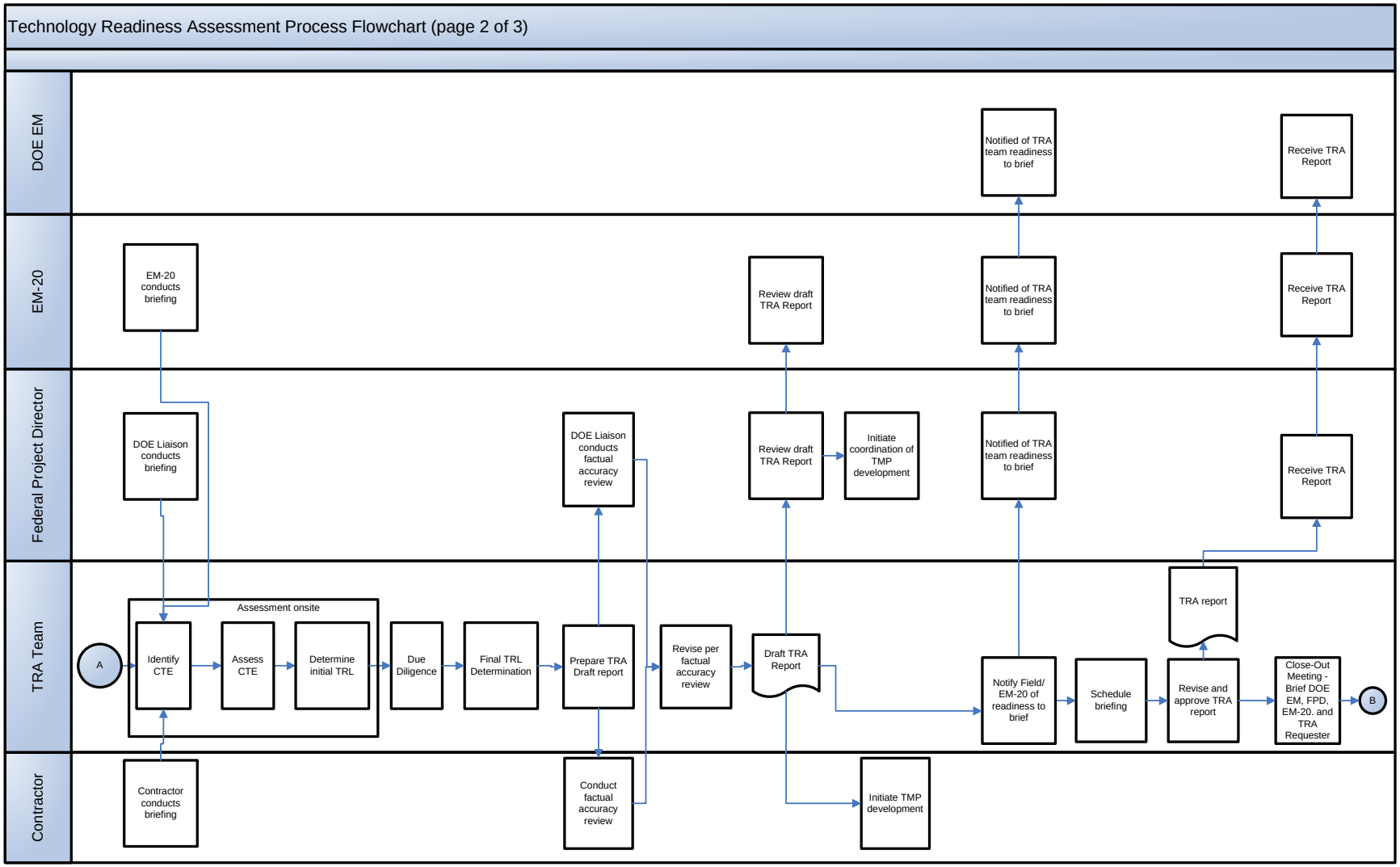


Figure 3 Technology Readiness Assessment Process Diagram (continued)

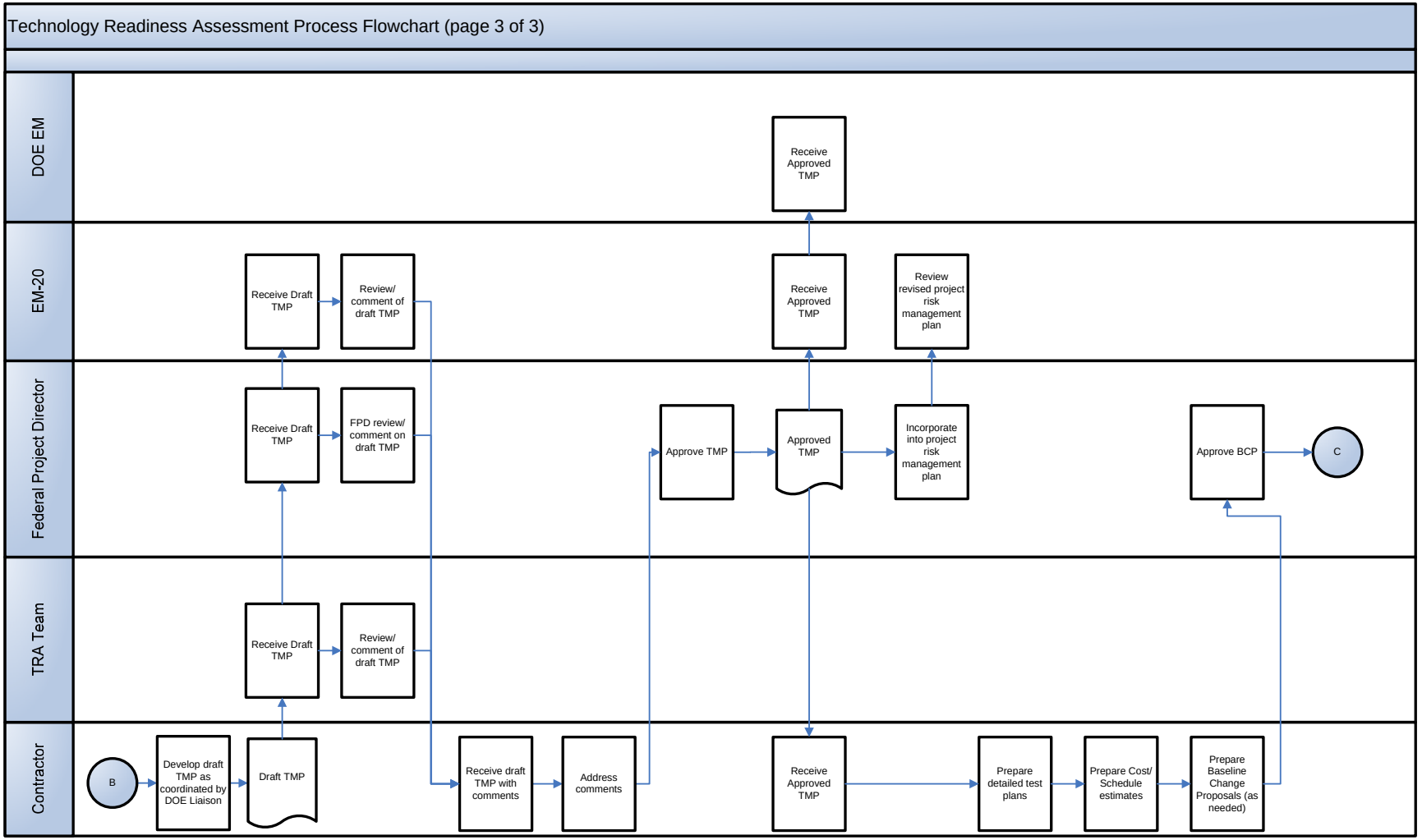


Table 4 Typical TRA Timeline

Activity	Typical Time Frame
TRA Requested	Time 0
TRA Plan Submitted to EM-20	Week 2
TRA Team Established by EM-20	Week 8
Critical Documents Distributed to Team	Week 12
Onsite Assessment Activities Begin	Week 16
Draft TRA Report Issued for Comment	Week 20
Final TRA Report Issued	Week 24

Table 5 Typical TMP Timeline

Activity	Typical Time Frame
Begin TMP	Week 0
Draft TMP Completed	Week 8
Review TMP	Week 10
Final TMP	Week 12
Prepare Test Plans Including Cost and Schedule	Week 20
Approve Test Plans	Week 24
Incorporate Test Plans Into Baseline	Project Dependent

3.2 Key Roles and Responsibilities

3.2.1 DOE EM

- Requests a TRA as appropriate.
- Recommends potential TRA Team candidates to EM-20.
- Approves TRA Plans for TRAs requested by DOE EM.
- Reviews drafted TRA Report for TRAs requested by DOE EM.
- Approves TMP for TRAs requested by DOE EM.

3.2.2 EM-20

- Owns the TRA/TMP process.
- Requests a TRA.
- Provides input to the Requester for development of TRA Plans.
- Identifies, approves and establishes the TRA Team.
- Trains team members on the TRA/TMP process.
- Approves all TRA Plans.
- Reviews all TRA Reports.

- Reviews all TMPs.
- Briefs TRA team at Kickoff Meeting

3.2.3 Federal Project Director

- Requests a TRA.
- Assigns a DOE Liaison.
- Prepares TRA Plans for TRAs requested by the Federal Project Director.
- Requests assignment of Contractor Liaison.
- Performs factual accuracy review of drafted TRA Report.
- Reviews and approves TMP.
- Incorporates TMP details into project risk management plan.

3.2.4 DOE Liaison

- Serves as the primary DOE interface with the TRA Team.
- Reviews and approves the list of reference documents to be provided to the TRA team to ensure completeness and absence of bias.
- Distributes documents assembled by the Contractor Liaison to the TRA Team.
- Conducts TRA Kickoff Meeting jointly with Team Leader.
- Provides administrative and technical editing support to the TRA Team as needed.
- Coordinates the factual accuracy review of the TRA Report.
- Reviews factual accuracy review comments to ensure they are within the factual accuracy scope.
- Assembles factual accuracy review comments and forwards to the TRA Team Leader.

3.2.5 Contractor

- Assigns a Contractor Liaison.
- Provides technology information in the form of tours, briefings, documents and test information.
- Performs factual accuracy review of drafted TRA Report.
- Prepares the TMP.
- Prepares detailed test plans that implement the TMP.
- Implements test plans.

3.2.6 Contractor Liaison

- Compiles and distributes a listing of technology elements to the TRA Team.
- Serves as the conduit for communication between the TRA Team and Contractor.
- Coordinates with the Team Leader on arrangements, facilities and resources at the site for the assessment.
- Coordinates briefings and tours of site facilities for the TRA Team as applicable.
- Coordinates the conduct of the Contractor factual accuracy review of the TRA Report.

- Coordinates the Contractor reviews of the TRA report and TMP.

3.2.7 Team Leader

- Serves as the TRA Team primary point of contact.
- Reviews Team Members' qualifications to ensure that the team has the appropriate expertise and sufficient capability to execute the assessment.
- Develops TRA schedule with input from EM-20 and team members.
- Is accessible during the entire review process, and actively participates in the process described in the TRA plan. This commitment includes development of written input, and participation in team meetings.
- Organizes the team's work and makes assignments so that the Team Members' on-site time is well spent and will provide the required products.
- Reviews the TRA request to assure that specific topics or emphasis requested are properly understood and identified in the TRA plan. Obtains clarification from the requesting DOE official, as appropriate.
- Coordinates arrangements and agenda for the TRA with the DOE Liaison.
- Accepts requests for additional information from team members following initial review of materials provided in advance; communicates these requests to the DOE Liaison; obtains agreement on time for responses to requests.
- Conducts team conference call approximately two weeks prior to beginning the TRA to confirm arrangements and to clarify questions from the team members.
- Coordinates team's arrival at the site of the assessment. Identifies required check-in at site security office and time and place for initial team meeting with project officials.
- Presents initial briefing describing review team charge and review process to on-site project participants.
- Participates as a subject-matter-expert for assigned technology areas.
- Requires team members to provide summary bases for all TRL determinations to allow team review and discussion.
- Establishes responsibilities among team members and timelines for completion of detailed write-ups supporting assessment results.
- Conducts and provides a copy of the exit brief for on-site project participants with support from team members as appropriate.
- Assembles and edits initial and final drafts of the TRA report and all briefings.
- Reviews and consolidates all Team comments to ensure consistency throughout the report.
- Provides a draft copy of the report to all members of the Review Team for final consensus on the content and to the Federal Project Director for a review for factual accuracy of the observations included.
- Incorporates team member comments as appropriate as the final authority on the report content. Corrects errors in fact identified by the project team review. Because a significant level of effort may be required to incorporate comments, the Team Leader may task Team Members to rewrite their sections as appropriate.
- Approves the final report and issues report to the Federal Project Director.

3.2.8 Team Members

- Serve as subject matter experts in technical areas relevant to the technology under review. They are independent from the entities responsible for decision-making and implementation of the technology being reviewed. Specifically, they shall not be individuals who are from offices assigned direct line management responsibility for the work being reviewed.
- Objectively assess technologies, determine associated TRLs and document associated bases for the TRL determinations.
- Review all advanced materials provided prior to the assessment and advise the Team Leader, if additional information is needed.
- Finalize listing of CTEs to be assessed.
- Participate in all pre-assessment conference calls.
- Be willing and capable of staying on-site during assessment execution, and to actively participate in the process described in the Team Meeting.
- Ensure receipt of all advance documentation and advise the Team Leader if other arrangements need to be made.
- Participate in the on-site assessment.
- Submit draft input in accordance with this guidance.
- Prepare questions resulting from review of advanced material received and provide to Team Leader in advance. Only the Team Leader will coordinate with the site.
- Communicate directly with identified project participants to clarify understanding of material review.
- Seek clarification from project participants concerning perceived omissions or deficiencies.
- Prepare written comments on a timely basis as required by the Review.
- Ensure their comments are unclassified and coordinate their comments with an Authorized Derivative Classifier if there is a question.
- Review draft report to assure determinations are accurately described and to identify possible conflicts.
- Ensure availability for follow-up consultations.

3.3 TRA Team Independence

Independence of the TRA Team (Team Leader and Team Members) is a key requirement for conducting TRAs. Ideally, the TRA Team should be comprised of individuals from a different organization and site than is being assessed. In any event, the Team Leader should be a DOE employee (or DOE consultant) from a different organization than is being assessed. However, selection of purely independent TRA Teams may not be possible due to the subject matter being assessed, the availability of subject matter experts, and the timing of assessments. As a minimum, the Team Leader and Team Members must be independent from the project team implementing the technical scope; the Team Leader should not be from the organization responsible for the implementation of the technology being assessed. For example, Team Members should not be DOE employees or contractors affiliated with the project (or competing projects) to be reviewed.

Any exceptions to the guidelines for TRA Team independence require approval by EM-20.

3.4 Assessment Planning

The steps in planning a TRA are summarized below. These steps are illustrated in the Technology Readiness Assessment Process Diagram in Figure 3, and additional information regarding the major steps is provided in the sections that follow.

1. DOE EM, EM-20, or the Federal Project Director requests a TRA. The TRA Request must be written to include a brief description of scope, desired completion date, funding source and the purpose for the request (e.g., upcoming critical decision, technology down selection). An annual schedule of TRAs will be established for DOE EM projects.
2. The Federal Project Director, with input from EM-20, develops a TRA Plan that outlines how the review will be conducted. The TRA Plan contains the elements detailed in Section 3.4.1 and in Attachment A.
3. The TRA Requester and EM-20 approve the TRA Plan and forward the approved plan to the Federal Project Director.
4. EM-20, with input from other entities with a vested interest (e.g., DOE EM, the Federal Project Director), establishes the TRA Team. In establishing the team, EM-20 ensures available funding, approved contractual agreements and Team Member availability. Refer to Section 3.3 for guidance regarding Team independence.
5. The Federal Project Director assigns a DOE Liaison.
6. The Contractor assigns a Contractor Liaison.
7. The Contractor Liaison compiles a listing of reference documents for the technology to be reviewed and distributes critical documents to the DOE Liaison who forwards them to the TRA Team. Considerations for the identification and distribution of critical documentation are provided in Section 3.4.2.
8. The Team Leader conducts a pre-assessment team training meeting. The purpose of the pre-assessment team training meeting is to provide the team an overview of the TRA/TMP process, to review the TRA Plan, and the subject technology.
9. The TRA Team develops and finalizes the TRA meetings schedule.
10. The Contractor Liaison coordinates availability of onsite resources/equipment needed by the TRA Team. Typical considerations regarding onsite meeting facilities and resources are provided in Section 3.4.3.
11. Table 6 provides a listing of implementation tips for Assessment Planning.

3.4.1 TRA Plan

The Federal Project Director is responsible for developing the Plan. The Plan is a detailed working plan for conduct of the TRA. Successful implementation of the plan relies on the Review Team, DOE EM-20, and the Contractor. Therefore, the Federal Project Director should actively seek the input of these entities during development of the plan. The developed Plan is submitted by the Federal Project Director to the TRA Requester and DOE EM-20 for approval. DOE EM-20 ensures allocation of required funding.

The TRA Plan:

- Identifies the TRA requester.
- Identifies the technology (or technologies) being assessed.
- Establishes the scope of the assessment.
- Provides a listing of the TRA Team.
- Identifies the estimated cost for conduct of the TRA.

- Provides a milestone and deliverables schedule.

While the structure of each TRA Plan is the same, the content is specifically tailored for each project. The TRA Plan helps the TRA Team coordinate activities during the assessment.

See Attachment A for additional information regarding the format of the TRA Plan.

3.4.2 Documentation for Review

An important aspect of planning the TRA is the advanced review of critical documentation. The Contractor Liaison is responsible for coordinating the identification and distribution of critical documentation. To the maximum extent possible, the critical documentation should be distributed to Team Members (via the DOE Liaison) at least 4 weeks prior to the scheduled assessment. Submission of the critical documentation is expected to be as an entire package and represent a 'current state' of development.

The critical documentation pertinent to a TRA varies but generally includes: design reports, technology reports, technology bases documents, value engineering studies, technology alternatives studies, relevant regulatory information, and DOE or program reference documents.

3.4.3 Onsite Meeting Facilities, Resources and Logistics

Prior to the onsite assessment, the Team Leader, DOE Liaison and the Contractor Liaison discuss the facilities and equipment needed during the conduct of the TRA. Typical considerations regarding onsite meeting facilities,, resources and logistics are:

- Conference Room in un-cleared area or in area accessible to un-cleared team members with cleared team member escorts, if necessary.
- Office space, two (2) additional offices for small group discussions (accessible to un-cleared team members with cleared team member escorts if necessary).
- Teleconference capability.
- Computer with printing capabilities, Microsoft Word and PowerPoint installed.
- Telephone, internet and Fax access.
- Define site/project clearance requirements for personnel related equipment such as government and non-government owned laptop computers.
- Process site badge(s) as necessary.
- Identify security information for site visit.
- Identify personnel to conduct classification reviews of documentation generated during the review.
- Define training required by Team Members for access to facilities.

The Contractor Liaison ensures that the requested resources are readily available at the start of the onsite assessment. Additional resources identified after the start of Assessment Activities are communicated to the Contractor Liaison by the Team Leader. Proper planning should eliminate the need for additional resources; however, the expectation is that the Contractor Liaison will respond promptly to any additional resource requests.

Table 6 Implementation Tips for Assessment Planning

Planning

- Define the assessment scope clearly and concisely. The definition should describe what is within the scope of the assessment and what is not in the scope of the assessment.
- Up-front review of documents by the Review Team will streamline initial meetings (e.g., Kick-Off meeting) by reducing the need for overviews.
- Early in the assessment, address how responses to assessment criteria and the associated bases will be reported and tracked.

Team Selection

- Team members should be independent of any corporate accountability or responsibilities for managing the technology being assessed.
- Team members should be free of any conflict-of-interest with respect to potential benefit due to recommendations identified during the assessment
- The Team Leader should have demonstrated ability regarding preparation, scheduling, organization and execution of assessment team activities.
- Industrial experts (for technologies that are industrial in size and therefore different than many of the Laboratory technologies) and experts from other laboratories with similar technologies should be considered.
- Ensure that there are firm commitments from the team members and/or identify any conflicts early.
- Allow time and funding for the acquisition of team members through contracts.
- Team size will be dictated by project complexity and size and reviewer expertise. There should be at least 1 assessor with expertise in each major technical area of the project.

Team Readiness

- Conduct team building activities early in the TRA process to improve interactions and communications.
- Establish team communication guides early, i.e. status calls, distribution lists.

3.5 Assessment Execution

The steps in conducting a TRA are summarized below. These steps are illustrated in the Technology Readiness Assessment Process Diagram in Figure 3, and additional information regarding the major steps is provided in the sections that follow.

1. The TRA Team Leader and the DOE Liaison conduct a Kick-Off Meeting at the assessment site location.
2. The Contractor provides briefings and conducts tours of site facilities applicable to the development of the technology being assessed.
3. Based on the process descriptions, the Team finalizes the list of CTEs.
4. The Team reviews pertinent documentation and applies the TRL assessment criteria to determine the TRL for each CTE. The documented bases for the criteria scoring are recorded during the meeting. To aid in review of TRL determinations, each Team Member maintains adequate notes from their information-gathering activities.
5. Team members conduct due diligence reviews of the TRL determinations via detailed document reviews to ensure that the bases for the scoring are fully supported in the appropriate technical reports. TRL determinations are finalized after the due diligence review.
6. The Team Leader is responsible for keeping the Federal Project Director and EM-20 informed of the progress of the TRA and TRL determinations as they are identified. This may include periodic meetings during the onsite assessment period. The frequency and formality of these updates is dependent on the length of the assessment period.
7. The Team prepares the initial draft TRA Report.
8. The Team reviews the draft TRA Report to ensure the report is clear, concise and within the scope of the assessment.
9. The DOE Liaison and Contractor perform a factual accuracy review of the draft TRA Report. Then, the Team revises the draft report as needed based on the factual accuracy review.
10. The Contractor initiates development of the TMP based on the draft TRA report.
11. The revised draft TRA report is submitted to the Federal Project Director, EM-20, and, DOE-EM management (if DOE EM was the TRA Requester) for review. The Team revises the TRA Report based on comments received and approves the final report.
12. The final TRA report is distributed to the Federal Project Director, EM-20, and DOE-EM management.
13. The Team Leader conducts a Close-Out Meeting with Federal Project Director, EM-20, and DOE-EM management on the determined TRLs, their bases, and needs identified to mature the technology.
14. Table 7 provides a listing of implementation tips for Assessment Execution.

3.5.1 Kick-Off Meeting

The Kick-Off Meeting marks the start of Assessment activities. The purpose of the Kick-Off Meeting is to 1) introduce the TRA Team and key project personnel, 2) review the primary objective of the TRA and the identified assessment criteria, 3) convey the logistics for TRA activities, and 4) begin the TRA assessment. The Federal Project Director and the DOE Liaison are responsible for the Kick-Off Meeting. Attendance is usually limited to the Team Members, DOE EM-20, TRA Requestor, Contractor Liaison, and Contractor personnel.

At the Kick-Off Meeting, briefings are presented by EM-20 and Federal Project Director. EM-20 should brief the TRA team to describe 1) related technology experience elsewhere in the DOE complex and ongoing related technology maturation efforts and 2) how the TRA/TMP results will be used in specific future EM decisions. Contractor personnel provide an overview of the technology and its development status. Briefings will be in the form of formal presentations to the Team using support materials such as view graphs, charts, drawings, or photos. Presentations should allow for questions and answers within the allotted time. Detailed information should be transmitted via supplemental handouts. The Team is the primary audience for the presentations, but other individuals may attend, particularly if their presence would be advantageous in answering questions from the Team. When the agenda calls for discussion time, or at the conclusion of a particular topic presentation, a more informal round-table format is appropriate. These presentations should also address questions submitted by the Team in advance. Pre-existing presentations may be utilized if still current.

A sample Kick-Off meeting agenda is provided in Attachment C. As shown in Attachment C, a tour of the facilities should be included if this information will aid the Team's understanding of the project and/or technology being reviewed.

3.5.2 Critical Technology Elements (CTE) Identification

The following is the definition of a CTE as provided by DoD Technology Readiness Assessment (TRA) Deskbook, May 2005:

> A technology element is "critical" if the systems being acquired depend on the technology element to meet operational requirements (with acceptable development cost, and schedule and with acceptable production and operations costs) and if the technology element or its application is either new or novel. Said another way, an element that is new or novel or being used in a new or novel way is critical if it is necessary to achieve the successful development of a system, its acquisition, or its operational utility.

CTE identification is fundamental to the TRA process. The TRA Team is responsible for identifying and documenting CTEs. Early in TRA planning, the Team Leader requests that the Contractor Liaison compile a list of technology elements. This listing should be based on a comprehensive review of the project's established work breakdown structure and process flowsheets. The Team then determines the CTEs using a 2-step process, which utilizes two sets of questions to evaluate each technology element. The questions are provided in Attachment B. A technology element must have a positive response to at least one question in each question set for a determination as a CTE.

Team discussions should be utilized to resolve any disagreements between Team Members on CTE determinations. If consensus cannot be reached, the Team Leader makes the CTE determination. Also, the Federal Project Director has the discretion to add CTEs to the listing generated by the Team.

3.5.3 Technology Readiness Level Assessment

A modified version of the DoD TRL Calculator has been used extensively during the conduct of DOE-EM TRAs. The TRL Calculator is a two-step process. First, a set of top-level questions (Table D1 of Attachment D) is used to determine the anticipated TRL. The anticipated TRL is determined from the question with the first "yes" answer. Second, evaluation of the detailed questions (Tables D2 through D7 of Attachment D) is started one level below the anticipated TRL. To attain a specific TRL, the CTE must receive a "yes" response to <u>all</u> questions at the TRL level. If it is determined from the detailed questions that the technology has not attained the maturity of the starting level, then the next levels down are evaluated in turn until the TRL is determined.

TRLs are documented within the TRA Report. As a minimum, the TRL should be expressed numerically and described in text. Additionally, the basis for the TRL determination should be clearly and concisely documented.

3.5.4 Due Diligence Reviews

Following the initial TRL determination, individual Team Members conduct due diligence reviews by detailed study of reference documents and, if needed, by personal interviews. Even though some Contractor personnel provide presentations to the Team as a whole, individual reviewers may be assigned responsibility for analyzing and assessing assigned CTE TRLs and providing a written report of their TRL determination and supporting basis. To improve efficiency during the interview process, breakout sessions should be scheduled to allow non-related interviews to be held concurrently. To the extent possible, more than one Team Member should be present for all interview sessions.

As interviews and document reviews are completed, the details of the review should be documented. The information collected should provide the Team the ability at a later date to understand the CTE, responses to TRL criteria, the TRL determination, and the associated bases.

3.5.5 TRA Report

The purpose of the report is to document a description of the process used to conduct the TRA and a comprehensive explanation of the assessed TRL for each CTE. The Team Leader is responsible for coordinating the report preparation with detailed input from Team Members. See Attachment F for the format of the report. The report is divided into sections that may be assigned to individual Team Members. The Team Leader compiles an initial draft of the report. A designated editor (not a Team Member) will review the draft report for consistency in writing style and format without changing content. The draft report will then be provided to the Review Team for a final review. It will also go to the Federal Project Director and Contractor for a factual accuracy check as described in Section 3.5.6. To expedite the schedule, these two reviews are often accomplished in parallel. Comments will be resolved by the Team and incorporated by the editor. The Team Leader will issue the revised draft report to the Federal Project Director, EM-20, and DOE-EM management. Comments will be provided to the Team Leader for incorporation into the final TRA report. The Team Leader will enlist Team members to assist in comment resolution as needed. After these comments have been addressed, the Team will review and approve the final TRA report.

Lessons learned that benefit future TRAs and/or technology development projects may be identified during the conduct of a TRA. These lessons learned should be documented within the TRA Report or they may be documented in a separate document. In the case of a separate lessons learned document, the TRA report should be referenced within the document and the document should be filed with the TRA report.

3.5.6 Factual Accuracy

The Federal Project Director and Contractor conduct a factual accuracy review of material presented in the draft report. The purpose of the factual accuracy review is to identify any items of fact that are inaccurate. Factual accuracy reviews do not include challenging the TRL scores and technical issues identified by the Team Members. However, the Team will correct errors in fact that may result in a change in TRL scores or identified technical issues.

3.5.7 Close-Out Meeting

The Close-Out Meeting, conducted after completion of the final TRA report, marks the end of Assessment activities. The Team Leader is responsible for presenting the results of the assessment at the Close-Out Meeting. The purpose of the Close-Out Meeting is to brief the Federal Project Director, EM-20, and DOE-EM management on TRL determinations and associated bases. A sample Close-Out Meeting agenda is provided as Attachment G.

The Team Leader or individual Team Members assigned to each CTE should make informal presentations that describe the assessment results relative to TRL determinations and highlight those CTEs that do not meet the maturity expectations. The Team will respond to any questions raised by the DOE EM-20, the Federal Project Director or the Contractor. Copies of materials presented at the Close-Out Meeting are usually made available to meeting attendees. The Close-out meeting may also include a briefing by the Federal Project Director or Contractor on their path forward for preparing a Technology Maturation Plan, if needed.

Table 7 Implementation Tips for Assessment Execution

Status Meetings

- Maintain a regular form of communication between the Team and the Project such that neither is caught off guard by new information. Typically this is a daily meeting during assessment activities.

Issue Capture and Resolution

- A database or table format is recommended to capture the technology elements assessed, responses to assessment criteria and determined TRLs to facilitate the review and track open items.
- A standard form for capturing information should be used. Standard items should include: name, e-mail, phone number, technology element, document identification, specific criteria, response, and follow-up items.
- The Team should have a process for handling differences in professional opinions.

Report Preparation

- Include a technical editor as a resource to the team to help in finalizing reports.
- Build the assessment report as the review progresses rather than waiting until the assessment activities are complete.

Comment Resolution

- Reviewers are responsible for resolving comments within their assigned technology expertise.
- The Team Leader resolves comments that are not specific to a particular technology area.
- Team Members may document non-resolvable differences of opinion in a “minority report”.

Report Distribution / Approval / Closeout

- The Team Leader should establish the distribution list for the report early in the assessment.

4.0 TECHNOLOGY MATURATION PLAN

4.1 Process Overview

The purpose of the TMP is to describe planned technology development and engineering activities to mature CTEs that did not receive a TRL of 6 or higher. The TMP should provide the relationship between the planned technology development and the status of the project, particularly any upcoming Critical Decisions. In a very limited number of instances, the Federal Project Director may be of the opinion that a CTE receiving a TRL of 5 already has a maturation plan that is well understood, planned, scheduled for timely completion, and adequately funded. In this case, the TMP should reflect the opinion of the Federal Project Director and a TMP briefing should be conducted as part of Critical Decision.

4.2 TMP Preparation

The major steps in preparing a TMP are summarized below and are illustrated in the Technology Readiness Assessment Process Flowchart (Figure 3).

1. The Contractor prepares the draft Technology Maturation Plan. Additional information on the desired content of the plan is provided below and in Attachment G.
2. The Contractor provides the draft report to the TRA Team, Federal Project Director and EM-20 for review. To expedite the schedule, these three reviews are often accomplished in parallel. The reviews verify 1) responsiveness to gaps identified in the draft TRA, 2) reasonableness of the proposed approach, and 3) reasonableness of the proposed schedule and costs associated with technology maturation requirements.
3. As applicable, the Contractor resolves review comments, revises the TMP, and forwards the revised TMP to the Federal Project Director.
4. The Federal Project Director approves and distributes the final report to the Contractor, DOE EM-20, and the DOE-EM management.
5. The Federal Project Director incorporates TMP details into project risk management plan and forwards the revised project risk management plan to EM-20 for review.

As described in Attachment G, the TMP should summarize any previous Independent Technical Reviews, other technical assessments, and any previous TRAs that may have contributed to the need for the TMP. This summary should include the TRLs for each CTE as documented in the latest TRA. Previous technology development activities that brought the technology to its current state of readiness should be described. Also, ongoing technology development must be included because completion of this ongoing work will define the starting point for the TMP. The TMP should describe the approach used in defining the additional, required technology development activities that will be conducted. Approaches may include evaluating incomplete criteria in the TRL calculator, risk assessments, and value engineering.

In preparing the TMP for relatively mature technologies, TRA results should be evaluated using a risk evaluation and value engineering approach. Figure 4 provides a diagram of the technology maturation planning process. An identified technology readiness issue (or technology need) is evaluated using the systems engineering functions and requirements analysis. Then, a first order risk evaluation is conducted to determine whether the current path can be followed with negligible risk or if alternatives (current path with modifications or a new system) should be pursued. A more detailed, second order risk evaluation is conducted to determine if the modifications or new system alternatives have sufficient payoff to be incorporated into the TMP.

In describing the required technology development activities, specific maturation plans must be prepared for each CTE assessed at less than TRL 6. The plans for each CTE must include:

- Key Technology Addressed
- Objective
- Current State of Art
- Technology Development Approach
- Scope
- Schedule
- Budget

The high-level schedule and budget (including the total maturation costs) that incorporate the major technology development activities for each CTE must be provided. Any major decision points such as proceeding with versus abandoning the current technology or selection of a backup technology, should be included in the schedule. More detailed schedules will be prepared for executing and managing the work.

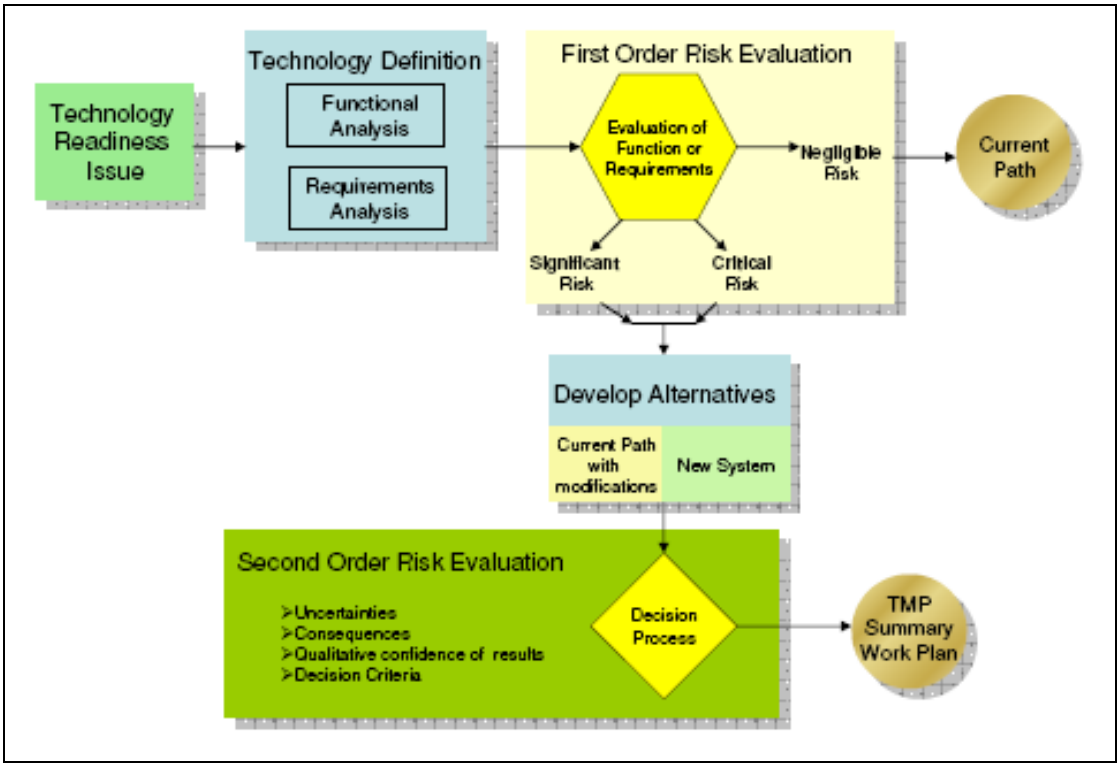
4.3 TMP Execution

After the TMP has been approved, the Contractor will prepare detailed test plans to conduct the technology development activities described in the TMP. These test plans will define the test objectives, relevant environment (stimulant versus actual waste), the scale of the planned tests, and performance targets (or success criteria) for the tests. Then, more detailed cost and schedule estimates will be prepared by the Contractor to support preparation of a Baseline Change Proposal (BCP), if needed. The Federal Project Director will approve any needed BCPs.

The contractor may conduct the technology development in house or work with DOE to select a technology developer by open procurements to industry, solicitations from EM-20, identification of national laboratories with appropriate expertise, etc. Schedule status will be maintained by the contractor based on periodic updates from the technology development performer. Any significant changes in scope and schedule will require formal change control by the contractor and DOE organization providing the funding.

Technical reports will be written as major technology development tasks are completed. A Final Technical Report will be prepared when all of the technology development tasks in the TMP have been completed as required by the TRL 6 criteria.

Figure 4 Technology Maturation Planning Process



5.0 ATTACHMENTS

Attachment A, TRA Plan
Attachment B, CTE Identification Criteria
Attachment C, Kick-Off Meeting Agenda
Attachment D, TRL Assessment Criteria
Attachment E, TRA Report Format
Attachment F, Close-Out Meeting Agenda
Attachment G, Technology Maturation Plan Format

Attachment A, TRA Plan
(Page 1 of 3)

1.0 INTRODUCTION

Briefly state who requested the TRA, what organization is responsible for conducting the TRA, and what technology is to be assessed. State where the technology is being developed (i.e., facility, site).

2.0 PURPOSE

Briefly state the objective of the TRA. Specifically, state how the customer will use the results from the TRA. Additionally, state any other drivers for conduct of the TRA (e.g., Critical Decision milestone support, technology downselect support).

3.0 TECHNOLOGY BACKGROUND

Provide a general description of the technology and the project supported by the technology. The description should include details regarding the function that the technology accomplishes for the project and a brief summary of status of the technology development. Additionally, summarize the results of any previous TRAs conducted on the technology.

4.0 TRA Team

Include a table that lists the position, title, name and area of expertise of each TRA Team Member.

Position	*Title*	*Company*	*Name*	*Area of Expertise*
Team Leader	*Person 1 Title*	*Person 1 company*	*Person 1 name*	*Person 1 expertise*
Team Member	*Person 2 Title*	*Person 2 company*	*Person 2 name*	*Person 2 expertise*
Team Member	*Person 3 Title*	*Person 3 company*	*Person 3 name*	*Person 3 expertise*
Team Member	*Person 4 Title*	*Person 4 company*	*Person 4 name*	*Person 4 expertise*

5.0 TRA ESTIMATED SCHEDULE

Task Number	Projected Duration	Task Description
1	6 weeks	Establish TRA Team
2	4 weeks	Distribute critical documents to Team
3	4 weeks	Conduct onsite assessment activities
4	4 weeks	Draft TRA Report
5	4 weeks	Issue Final Report

6.0 TRA ESTIMATED COST

Provide an estimate of the total man-hours and associated cost for conduct of the TRA. Additionally, state the organization responsible for funding the TRA.

7.0 DEFINITIONS

8.0 REFERENCES

Attachment B, Critical Technology Elements (CTE) Identification Criteria

A CTE is identified if there is at least one positive response for each set of criteria

Set 1 - Criteria	Yes	No
• Does the technology directly impact a functional requirement of the process or facility?		
• Do limitations in the understanding of the technology result in a potential schedule risk, i.e., the technology may not be ready for insertion when required?		
• Do limitations in the understanding of the technology result in a potential cost risk, i.e., the technology may cause significant cost overruns?		
• Are there uncertainties in the definition of the end state requirements for this technology?		

Set 2 - Criteria	Yes	No
• Is the technology new or novel?		
• Is the technology modified?		
• Has the technology been repackaged so a new relevant environment is realized?		
• Is the technology expected to operate in an environment and/or achieve performance beyond its original design intention or demonstrated capability?		

Attachment C, Kick-Off Meeting Agenda

Topic	Presenter
Review Team and Field Office Introductions	Team Leader and Field Office Representative or Contractor Liaison
Purpose of Assessment	Team Leader
Scope of Assessment	Team Leader
TRA Process Overview	Team Leader
Technology overview and status	Field Office Representative or Contractor Liaison
Site tour (as needed)	Field Office Representative or Contractor Liaison
Begin assessment process	Team

Attachment D, Technology Readiness Level Assessment Criteria

Table D1. Top Level Questions for Determining Anticipated TRL

Top-Level Question		Yes/No	If Yes, Then Basis and Supporting Documentation
TRL 9	Has the actual equipment/process successfully operated in the full operational environment (hot operations)?		
TRL 8	Has the actual equipment/process successfully operated in a limited operational environment (hot commissioning)?		
TRL 7	Has the actual equipment/process successfully operated in the relevant operational environment (cold commissioning)?		
TRL 6	Has prototypical engineering scale equipment/process testing been demonstrated in a relevant environment?		
TRL 5	Has bench-scale equipment/process testing been demonstrated in a relevant environment?		
TRL 4	Has laboratory-scale testing of similar equipment systems been completed in a simulated environment?		
TRL 3	Has equipment and process analysis and proof of concept been demonstrated in a simulated environment?		
TRL 2	Has an equipment and process concept been formulated?		
TRL 1	Have the basic process technology process principles been observed and reported?		

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.2. TRL 1 Questions for Critical Technical Element

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		1. "Back of envelope" environment	
T		2. Physical laws and assumptions used in new technologies defined	
T		3. Paper studies confirm basic principles	
P		4. Initial scientific observations reported in journals/conference proceedings/technical reports.	
T		5. Basic scientific principles observed and understood.	
P		6. Know who cares about the technology, e.g., sponsor, funding source, etc.	
T		7. Research hypothesis formulated	
T		8. Basic characterization data exists	
P		9. Know who would perform research and where it would be done	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.3. TRL 2 Questions for Critical Technical Elements

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
P		1. Customer identified	
T		2. Potential system or components have been identified	
T		3. Paper studies show that application is feasible	
P		4. Know what program the technology would support	
T		5. An apparent theoretical or empirical design solution identified	
T		6. Basic elements of technology have been identified	
T		7. Desktop environment (paper studies)	
T		8. Components of technology have been partially characterized	
T		9. Performance predictions made for each element	
P		10. Customer expresses interest in the application	
T		11. Initial analysis shows what major functions need to be done	
T		12. Modeling & Simulation only used to verify physical principles	
P		13. System architecture defined in terms of major functions to be performed	
T		14. Rigorous analytical studies confirm basic principles	
P		15. Analytical studies reported in scientific journals/conference proceedings/technical reports.	
T		16. Individual parts of the technology work (No real attempt at integration)	
T		17. Know what output devices are available	
P		18. Preliminary strategy to obtain TRL Level 6 developed (e.g. scope, schedule, cost)	
P		19. Know capabilities and limitations of researchers and research facilities	
T		20. The scope and scale of the waste problem has been determined	
T		21. Know what experiments are required (research approach)	
P		22. Qualitative idea of risk areas (cost, schedule, performance)	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.4. TRL 3 Questions for Critical Technical Elements

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		1. Academic (basic science) environment	
P		2. Some key process and safety requirements are identified	
T		3. Predictions of elements of technology capability validated by analytical studies	
P		4. The basic science has been validated at the laboratory scale	
T		5. Science known to extent that mathematical and/or computer models and simulations are possible	
P		6. Preliminary system performance characteristics and measures have been identified and estimated	
T		7. Predictions of elements of technology capability validated by Modeling and Simulation (M&S)	
M		8. No system components, just basic laboratory research equipment to verify physical principles	
T		9. Laboratory experiments verify feasibility of application	
T		10. Predictions of elements of technology capability validated by laboratory experiments	
P		11. Customer representative identified to work with development team	
P		12. Customer participates in requirements generation	
P		13. Requirements tracking system defined to manage requirements creep	
T		14. Key process parameters/variables and associated hazards have begun to be identified.	
M		15. Design techniques have been identified/developed	
T		16. Paper studies indicate that system components ought to work together	
P		17. Customer identifies technology need date.	
T		18. Performance metrics for the system are established (What must it do)	
P		19. Scaling studies have been started	
M		20. Current manufacturability concepts assessed	
M		21. Sources of key components for laboratory testing identified	
T		22. Scientific feasibility fully demonstrated	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.4. TRL 3 Questions for Critical Technical Elements (Continued)

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		23. Analysis of present state of the art shows that technology fills a need	
P		24. Risk areas identified in general terms	
P		25. Risk mitigation strategies identified	
P		26. Rudimentary best value analysis performed for operations	
T		27. Key physical and chemical properties have been characterized for a number of waste samples	
T		28. A simulant has been developed that approximates key waste properties	
T		29. Laboratory scale tests on a simulant have been completed	
T		30. Specific waste(s) and waste site(s) has (have) been defined	
T		31. The individual system components have been tested at the laboratory scale	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.5. TRL 4 Questions for Critical Technical Elements

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		1. Key process variables/parameters been fully identified and preliminary hazard evaluations have been performed.	
M		2. Laboratory components tested are surrogates for system components	
T		3. Individual components tested in laboratory~~/~~ or by supplier	
T		4. Subsystems composed of multiple components tested at lab scale using simulants	
T		5. Modeling & Simulation used to simulate some components and interfaces between components	
P		6. Overall system requirements for end user's application are known	
T		7. Overall system requirements for end user's application are documented	
P		8. System performance metrics measuring requirements have been established	
P		9. Laboratory testing requirements derived from system requirements are established	
M		10. Available components assembled into laboratory scale system	
T		11. Laboratory experiments with available components show that they work together	
T		12. Analysis completed to establish component compatibility (Do components work together)	
P		13. Science and Technology Demonstration exit criteria established (S&T targets understood, documented, and agreed to by sponsor)	
T		14. Technology demonstrates basic functionality in simulated environment	
M		15. Scalable technology prototypes have been produced (Can components be made bigger than lab scale)	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment D, Technology Readiness Level Assessment Criteria (continued)

Table D.5. TRL 4 Questions for Critical Technical Elements (Continued)

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
P		16. Draft conceptual designs have been documented (system description, process flow diagrams, general arrangement drawings, and material balance)	
M		17. Equipment scale-up relationships are understood/accounted for in technology development program	
T		18. Controlled laboratory environment used in testing	
P		19. Initial cost drivers identified	
M		20. Integration studies have been started	
P		21. Formal risk management program initiated	
M		22. Key manufacturing processes for equipment systems identified	
P		23. Scaling documents and designs of technology have been completed	
M		24. Key manufacturing processes assessed in laboratory	
P/T		25. Functional process description developed. (Systems/subsystems identified)	
T		26. Low fidelity technology “system” integration and engineering completed in a lab environment	
M		27. Mitigation strategies identified to address manufacturability/ producibility shortfalls	
T		28. Key physical and chemical properties have been characterized for a range of wastes	
T		29. A limited number of simulants have been developed that approximate the range of waste properties	
T		30. Laboratory-scale tests on a limited range of simulants and real waste have been completed	
T		31. Process/parameter limits and safety control strategies are being explored	
T		32. Test plan documents for prototypical lab- scale tests completed	
P		33. Technology availability dates established	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Table D.6. TRL 5 Questions for Critical Technical Elements

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		1. The relationships between major system and sub-system parameters are understood on a laboratory scale.	
T		2. Plant size components available for testing	
T		3. System interface requirements known (How would system be integrated into the plant?)	
P		4. Preliminary design engineering begins	
T		5. Requirements for technology verification established	
T		6. Interfaces between components/subsystems in testing are realistic (bench top with realistic interfaces)	
M		7. Prototypes of equipment system components have been created (know how to make equipment)	
M		8. Tooling and machines demonstrated in lab for new manufacturing processes to make component	
T		9. High fidelity lab integration of system completed, ready for test in relevant environments	
M		10. Manufacturing techniques have been defined to the point where largest problems defined	
T		11. Lab-scale, similar system tested with range of simulants	
T		12. Fidelity of system mock-up improves from laboratory to bench-scale testing	
M		13. Availability and reliability (RAMI) target levels identified	
M		14. Some special purpose components combined with available laboratory components for testing	
P		15. Three dimensional drawings and P&IDs for the prototypical engineering-scale test facility have been prepared	
T		16. Laboratory environment for testing modified to approximate operational environment	
T		17. Component integration issues and requirements identified	
P		18. Detailed design drawings have been completed to support specification of engineering-scale testing system	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Table D.6. TRL 5 Questions for Critical Technical Elements (continued)

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		19. Requirements definition with performance thresholds and objectives established for final plant design	
P		20. Preliminary technology feasibility engineering report completed	
T		21. Integration of modules/functions demonstrated in a laboratory/bench-scale environment	
T		22. Formal control of all components to be used in final prototypical test system	
P		23. Configuration management plan in place	
T		24. The range of all relevant physical and chemical properties has been determined (to the extent possible)	
T		25. Simulants have been developed that cover the full range of waste properties	
T		26. Testing has verified that the properties/performance of the simulants match the properties/performance of the actual wastes	
T		27. Laboratory-scale tests on the full range of simulants using a prototypical system have been completed	
T		28. Laboratory-scale tests on a limited range of real wastes using a prototypical system have been completed	
T		29. Test results for simulants and real waste are consistent	
T		30. Laboratory to engineering scale scale-up issues are understood and resolved	
T		31. Limits for all process variables/parameters and safety controls are being refined	
P		32. Test plan for prototypical lab-scale tests executed – results validate design	
P		33. Test plan documents for prototypical engineering-scale tests completed	
P		34. Risk management plan documented	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Table D.7. TRL 6 Questions for Critical Technical Elements

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
T		1. The relationships between system and sub-system parameters are understood at engineering scale allowing process/design variations and tradeoffs to be evaluated.	
M		2. Availability and reliability (RAMI) levels established	
P		3. Preliminary design drawings for final plant system are complete	
T		4. Operating environment for final system known	
P		5. Collection of actual maintainability, reliability, and supportability data has been started	
P		6. Performance Baseline (including total project cost, schedule, and scope) has been completed	
T		7. Operating limits for components determined (from design, safety and environmental compliance)	
P		8. Operational requirements document available	
P		9. Off-normal operating responses determined for engineering scale system	
T		10. System technical interfaces defined	
T		11. Component integration demonstrated at an engineering scale	
P		12. Scaling issues that remain are identified and understood. Supporting analysis is complete	
P		13. Analysis of project timing ensures technology will be available when required	
P		14. Have established an interface control process	
P		15. Acquisition program milestones established for start of final design (CD-2)	
M		16. Critical manufacturing processes prototyped	
M		17. Most pre-production hardware is available to support fabrication of the system	
T		18. Engineering feasibility fully demonstrated (e.g. would it work)	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Table D.7. TRL 6 Questions for Critical Technical Elements (continued)

T/P/M	Y/N	Criteria	Basis and Supporting Documentation
M		19. Materials, process, design, and integration methods have been employed (e.g. can design be produced?)	
P		20. Technology ”system” design specification complete and ready for detailed design	
M		21. Components are functionally compatible with operational system	
T		22. Engineering-scale system is high-fidelity functional prototype of operational system	
P		23. Formal configuration management program defined to control change process	
M		24. Integration demonstrations have been completed (e.g. construction of testing system)	
P		25. Final Technical Report on Technology completed	
M		26. Process and tooling are mature to support fabrication of components/system	
T		27. Engineering-scale tests on the full range of simulants using a prototypical system have been completed	
T		28. Engineering to full-scale scale-up issues are understood and resolved	
T		29. Laboratory and engineering-scale experiments are consistent	
T		30. Limits for all process variables/parameters and safety controls are defined	
T		31. Plan for engineering-scale testing executed - results validate design	
M		32. Production demonstrations are complete (at least one time)	

T-Technology, technical aspects; M-Manufacturing and quality; P-Programmatic, customer focus, documentation

Attachment E, TRA Report Format
(Page 1of 1)

REPORT CONTENT:

EXECUTIVE SUMMARY

Briefly state who requested the TRA, what organization was responsible for conducting the TRA, what technology was assessed. Provide a summary table of the CTEs and corresponding TRLs determined during the review

INTRODUCTION

Technology Reviewed
Provide a detailed description of the technology that was assessed.

TRA Process
Provide an overview of the approach used to conduct the TRA. Reference applicable planning documents.

RESULTS
Provide the following for each Critical Technology Element assessed:

- ***Function***
  Describe the CTE and its function.
- ***Relationship to Other Systems***
  Describe how the CTE interfaces with other systems.
- ***Development History and Status***
  Summarize pertinent development activities that have occurred to date on the CTE.
- ***Relevant Environment***
  Describe relevant parameters inherent to the CTE or the function it performs.
- ***Comparison of the Relevant Environment and the Demonstrated Environment***
  Describe differences and similarities between the environment in which the CTE has been tested and the intended environment when fully operational.
- ***Technology Readiness Level Determination***
  State the TRL determined for the CTE and provide the basis justification for the TRL.
- ***Estimated Cost/Schedule***
  State the estimated cost and time requirements, with associate uncertainties, and programmatic risks associated with maturing each technology to the required readiness level.

ATTACHMENTS
Include the following planning documents:

- *TRA Plan*
- *Supporting documentation for identification of Critical Technology Elements*
- *Completed tables:*
  - *Top Level Questions for Determining Anticipated TRL (Attachment D Table D1)*
  - *TRL Questions for Critical Technical Element (Attachment D Tables D.2 through D.7)*
- *List of support documentation for TRL determination*
- *Technology Readiness Level Summary table*
- *Team biographies*

Attachment F, Close-Out Meeting Agenda

Topic	Presenter
Purpose of Meeting	Team Leader
Presentation of TRA results ▪ Summary of TRLs Recommendations	 Team Leader Responsible Team Member(s)
▪ Conclusions	Team Leader
Discussion	All
Path Forward for TMP issuance	Team Leader

Attachment G, Technology Maturation Plan Format

(Note: The TMP is a high level summary document. It is not a collection of detailed test plans.)

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LIST OF TABLES
LIST OF FIGURES
ABBREVIATIONS AND ACRONYMS

1.0 INTRODUCTION

- Purpose of the Project
  Provide a brief summary of the project's mission, status, technology(s) being deployed, etc.
- Purpose of the Technology Maturation Plan
  Describe the objectives and content of this Technology Maturation Plan (TMP) and relate it to the status of the project and any upcoming Critical Decisions.

2.0 TECHNOLOGY ASSESSMENTS OF THE PROJECT

- Summary of Previous Independent Technical Reviews
  Summarize any previous Independent Technical Reviews or other technical assessments that may have contributed to the need for a Technology Readiness Assessment (TRA) and this TMP.
- Summary of Previous Technology Readiness Assessment(s)
  Describe the results of previous TRAs with particular emphasis on the latest TRA that is driving this TMP. Include the definition of Technology Readiness Levels as used in the TRA. Discuss the Critical Technology Elements (CTEs) that were determined for the project.
- Technology Heritage
  Summarize the previous technology development activities that brought the technology to its current state of readiness. Include discussions of any full-scale plant deployments of the technology in similar applications.
- Current Project Activities and Technology Maturation
  Describe ongoing technology development activities (if any) that were initiated prior to this TMP. Completion of these activities should define the starting point for this TMP.
- Management of Technology Maturity
  Indicate the DOE and contractor organizations that will be responsible for managing the activities described in this TMP. Include a brief discussion of key roles and responsibilities.

3.0 Technology Maturation Plan

- Development of Technology Maturation Requirements
  Describe the approach used in defining the required technology development activities that will be conducted as described in this TMP. These could include evaluating incomplete criteria in the TRL Calculator, risk assessments, and value engineering.
- Life-Cycle Benefit
  Briefly discuss life-cycle benefits to the project that will result from successful completion of the TMP technology development activities.

ATTACHMENT G, Technology Maturation Plan Format continued

- Specific Technology Maturation Plans
  Maturation plans for each CTE will be described following the format below for each CTE that was defined in the latest TRA.
  - CTE A
    - Key Technology Addressed *(Describe the function that the CTE carries out in the project.)*
    - Objective *(Succinctly state the objective of the CTE)*
    - Current State of Art *(Describe in one paragraph the current status of the CTE including the specific TRL assigned in the latest TRA.)*
    - Technology Development Approach *(In paragraph form, describe how the needed technology development work to reach TRL 6 will be performed. This could include the performing organization, location, simulant versus actual waste, etc.)*
    - Scope *(Provide a list of the key steps to be taken in performing the work. Include a table that gives milestones, performance targets, TRL achieved at milestones, and a rough order of magnitude cost of development.)*
  - CTE B
    - Key Technology Addressed
    - Objective
    - Current State of Art
    - Technology Development Approach
    - Scope
  - CTE C (etc., as needed)

4.0 TECHNOLOGY MATURITY SCHEDULE
Provide and briefly discuss a high-level schedule of the major technology development activities for each CTE. Any major decision points such as proceeding with versus abandoning the current technology, selection of a back-up technology, etc. should be included. Detailed schedules should be given in test plans or used for status meetings during implementation.

5.0 SUMMARY TECHNOLOGY MATURITY BUDGET
Present the rough order of magnitude costs to reach TRL 6 for each major technology development activity for all CTEs in the project. Include the total technology maturation costs.

6.0 REFERENCES

Appendix A. Crosswalk of identified in previous independent reviews and assessments (if applicable)
Appendix B. Technology Readiness Level Calculator As Modified For DOE Office of Environmental Management
Table 1. Technology Readiness Levels Used in this Assessment (taken from DoD)
Table 2, etc. Table(s) for each CTE, listing of test activities, planned completion date, performance targets, resulting TRL level as each increment of testing is completed, and rough order of magnitude costs.
Table X. Technology Maturity Budget for Project
Figure 1. Process Flow Diagram (for technology being assessed)
Figure 2. Technology Maturity Schedule
Figure 3. Project Execution Strategy Diagram

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

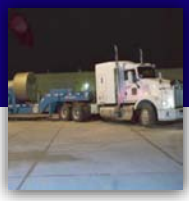
Standard Review Plan (SRP)

External Technical Review Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

U.S. Department of Energy
Office of Environmental Management

External Technical Review (ETR) Process Guide

September 2008

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1.0 INTRODUCTION

1.1 Purpose of Process

This document has been developed to guide individuals and teams who will be involved in External Technical Reviews (ETR) of U.S. Department of Energy's Office of Environmental Management (DOE-EM) projects. This Process Guide is intended to provide Program Offices, Site Offices, and site contractors as well as external technical review teams an understanding of the review process, requirements, and expectations. The guidance herein supplements implementation of Standing Operating Policies and Procedure (SOPP) 26, which was issued in April 2008 for ETRs. This Process will be modified periodically as guidance for ETRs evolves.

ETRs will be requested by the Federal Project Director or Headquarters EM staff and approved by EM-1, EM-2, EM-3, or EM-20. ETRs should be conducted to reduce the technical risk and uncertainty of DOE-EM projects. This Guide and SOPP 26 should be used when planning and conducting ETRs.

This guide provides general policy guidance regarding initiation and approval of ETR requests. Detailed guidance is provided for the remainder of the ETR process (i.e., after the ETR request is approved and before the ETR issues are submitted for tracking). The detailed guidance defines objectives, supporting activities, and responsible personnel/organizations for the three major components of the ETR process. Specifically, these components are:

- Pre-assessment planning
- Onsite Activities
- Reporting

1.2 Background

The DOE-EM was established in 1989 to achieve the safe and compliant disposition of legacy wastes and facilities from defense nuclear applications. A large majority of these wastes and facilities are 'one-of-a-kind' and unique to DOE. Many of the programs to treat these wastes have been 'first-of-a-kind' and unprecedented in scope and complexity. This has meant that many of the technologies needed to successfully disposition these wastes were not yet developed or required significant re-engineering to be adapted for DOE-EM's needs. Thus, throughout its existence, DOE-EM has required a strong technology component – focused on developing and adapting technologies to enhance safety, effectiveness, and efficiency – to accomplish its mission.

Although the Department has made great progress toward safely disposing of the legacies of the Cold War (e.g., the cleanup of the Fernald, Rocky Flats, and Mound sites), much remains to be done. While past accomplishments often provide a guide for future success, the unique nature of many of the remaining challenges will require a strong and responsive applied research and engineering program. To address this need, DOE-EM has placed this responsibility within the DOE-EM Engineering & Technology Program.

The objective of the DOE-EM Engineering & Technology Program is to reduce the technical risk and uncertainty in the Department's clean-up programs and projects. Risks are known technical issues that could prevent project success. Uncertainties are indefinite or unpredictable technical aspects of a project. To reduce those risks and uncertainties, the Applied Research and Technology Development and Deployment component of this program will provide technical solutions where none exist, improved solutions that enhance safety and operating efficiency, or technical alternatives that reduce programmatic risks (cost, schedule, or effectiveness).

Technical risks are identified by the projects, programmatic and external technical reviews, technical readiness assessments, and the DOE sites.

DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, provides the DOE with project management direction for the acquisition of capital assets. The accompanying goal of this Order is delivering projects on schedule, within budget, and fully capable of meeting mission performance, safeguards and security, and environmental, safety, and health standards. The Order recognizes that reviews are an important project activity and must be planned as an integral part of the project and tailored as appropriate to project risk, complexity, duration, and Critical Decision or phase. These key reviews include:

- Mission Validation Independent Project Review
- Mission Need Statement Review
- Acquisition Strategy Review
- Technical Independent Project Review
- External Independent Review (EIR)
- External Independent Readiness Review
- Operational Readiness Review or Readiness Assessment

ETRs are not required by DOE O 413.3A. However, Section 9.5 of DOE Manual 413.3-1 states that "technical reviews are necessary when there is uncertainty in the outcome of a project effort. If a design [technology, process, or system] is new, untried, or unproven….then a review by….knowledgeable peers is in order." The focus of the ETR is different than the DOE O 413.3A reviews. The DOE O 413.3A EIRs are focused on broad-based project management aspects (i.e., scope, cost, and schedule). ETRs are focused on technical risks and uncertainties.

The DOE-EM program believes strongly in reducing the technical risk of its projects and has initiated external technical reviews as one of several steps to ensure the timely resolution of engineering and technology issues. EM is working closely with Federal Project Directors to review such issues as technology development, systems integration, design, operations, maintenance, and nuclear safety. Cyber and physical security could also be reviewed, as needed. EM has completed several successful reviews using expert engineers and scientists from private industry and academia. Additional external technical reviews will be conducted to support key project decisions and will be a mainstay of the EM program.

In the National Academies of Science (NAS) 2007 report, *Assessment of the Results of External Independent Reviews for U. S. Department of Energy Projects*, it was acknowledged that projects benefit from the effort expended in preparing for external independent reviews and independent project reviews. This benefit increases as the size, complexity, and inherent risks of the project increase. The report stated the value and cost-effectiveness of external independent reviews would be enhanced if they were (1) planned more carefully with the broader involvement of all stakeholders, (2) tailored in a more flexible manner using a collaborative process, and (3) integrated into the complete portfolio of peer reviews that are used to monitor and support DOE projects. These conclusions and recommendations resulting from the NAS 2007 report can be applied to External Technical Reviews.

Feedback from the ETRs completed to date indicated that the ETR process could be improved through the development of general guidance and standard formats by which technical issues may be readily compared, summarized, trended and tracked in support of reducing technical risk across all projects. Existing review processes (DOE EM & SC, NNSA, NASA, and NAS), common ETR practices within DOE-EM, and the former Tiger Team Assessment process (Reference *Tiger Team Guidance Manual*, February 1990) were considered during the

development of this standard ETR process.

2.0 OVERVIEW OF EXTERNAL TECHNICAL REVIEWS

2.1 Purpose

The purpose of an ETR is to reduce technical risk and uncertainty. ETRs provide pertinent information for DOE-EM to assess technical risk associated with projects and develop strategies for reducing the technical risk, and provide technical information needed to support critical project decisions. Technical risk reduction increases the probability of successful implementation of technical scope. In general, an ETR assesses technical bases, technology development, and technical risk identification and handling strategies.

Objectives of Reviews

The three key objectives of an ETR are:

1. To determine if the technology, process, system, or design under review will meet project objectives and requirements,

2. To identify any issues (showstoppers) preventing successful implementation of the technology, process, system, or design under review, and

3. To identify issues or data needed to support critical or other project or program decisions.

The specific objectives of ETRs may vary, but generally include:

- Determining if technical objectives are well known and defined
- Determining if alternatives have been identified and effectively evaluated
- Determining if technology development is well planned and executed
- Determining the adequacy of quality assurance and scientific investigation
- Determining if technical bases are substantial and adequately documented
- Validating the technical basis and appropriateness of the technology, process, system, or design to technical risk reduction
- Determining if the technology can be deployed and implemented.

An ETR is not a contract or management review, nor is it an External Independent Review of a project baseline.

2.2 External Technical Reviews Defined

External Technical Reviews are independent reviews advisory to DOE (i.e., not the site or project contractor) that focus on technical scope and risk. The ETR is conducted by personnel who are independent from the project team implementing the technical scope and external to the office responsible for the technical scope. Rigorous ETRs enable DOE-EM to trend technical risk and implement technical risk reduction strategies. ETRs enhance project execution through timely identification of technical issues and corresponding response actions. Further, ETRs bolster assurance that technical issues have been thoroughly addressed and thereby support project management's bases for critical decision approvals. While not an explicit ETR objective, ETRs afford another opportunity to identify safety issues.

ETRs can be conducted at any stage of a project, but the scope of those ETRs will vary depending on the stage of the project. For example, to support Critical Decision (CD)-0, an ETR could be conducted to identify technical risks and the need for new technologies and applied research. To support a CD-1 decision, an ETR of the project's technical alternatives or conceptual design could be conducted. To support CD-2/3, an ETR of the project preliminary and/or final design could be conducted. To support CD-4, an ETR of certain operations or safety issues could be conducted.

The value of conducting ETRs is recognized throughout DOE-EM and requests originate directly from EM or the Field Office. At that point, EM or the Field Office will define the general scope and key lines of inquiry for the ETR. Requests initiated by the Field Office are routed to the Office of Engineering and Technology (EM-20), the Chief Operations Officer (EM-3), and the Principal Deputy Assistant Secretary (EM-2), respectively, for approval. EM-20 notifies the Field Office when an ETR request has been fully approved. (This does not preclude the Field Office from conducting independent reviews of project issues, as needed.) Requests initiated by EM-1 require no additional approvals and are routed directly to EM-20 who notifies the Field Office of the requested ETR. EM-20 assigns a sponsor for the ETR, who participates as an active member of the ETR team and/or acts as a liaison between the team and DOE-Headquarters. The ETR team completes its work with the issuance of the final team report. However, closeout of an ETR does not occur until all issues identified by the team are compiled in an approved Issue Response Plan. DOE EM-20 has the responsibility for tracking and validating the closure of ETR issues. The expectation is that Field Offices and Projects will forecast, schedule and fund all ETRs as a general policy.

The ETR process diagram, an EM Standing Operating Policy and Procedure, is depicted in Figure 1. Associated detailed guidance is provided in Section 3.0 of this document. The ETR process is divided into three stages: Pre-Assessment Planning, Onsite Activities and Reporting. Table 1 correlates these three stages to steps in the SOPP. The remainder of this section provides a summary of the three stages.

Table 1 Comparison of ETR Guide Stages to ETR SOPP

ETR Stage	Corresponding SOPP Step
Pre-Assessment Planning	*Begin* – Notify Field of ETR *End* – ETR Team Begins Work
Onsite Activities	*Begin* – ETR Team Begins Work *End* – Notify field/EM-20/EM management of readiness to brief
Reporting	*Begin* – Prepare ETR draft report *End (ETR Team)* – Distribute ETR Report *End (ETR)* – Issue(s) closeout document

Figure 1 ETR Standing Operating Policies and Procedures Diagram

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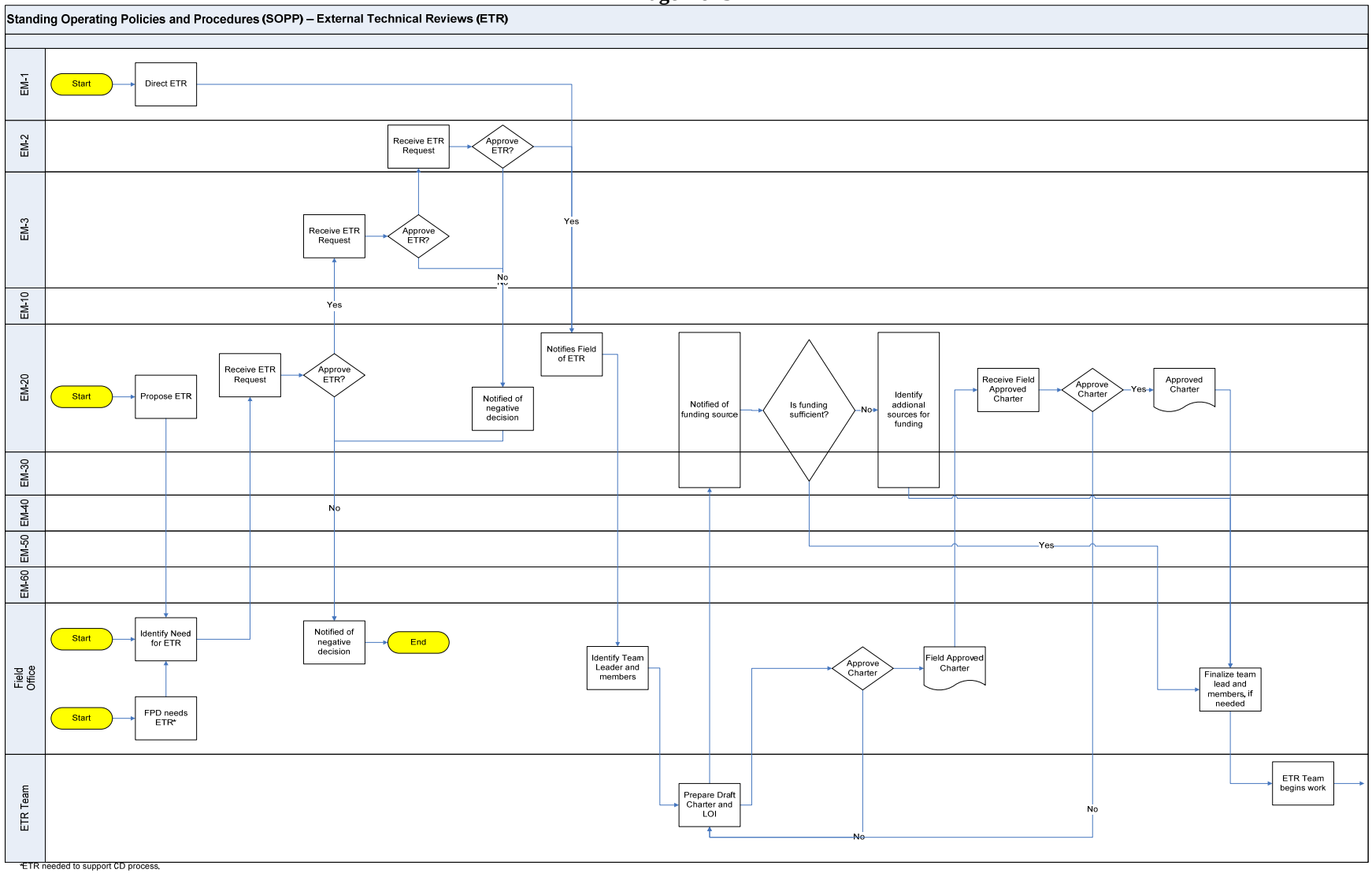


*ETR needed to support CD process.
** Briefing will be held before final report is issued.

Figure 1 ETR Standing Operating Policies and Procedures Diagram

(Page 2 of 3)

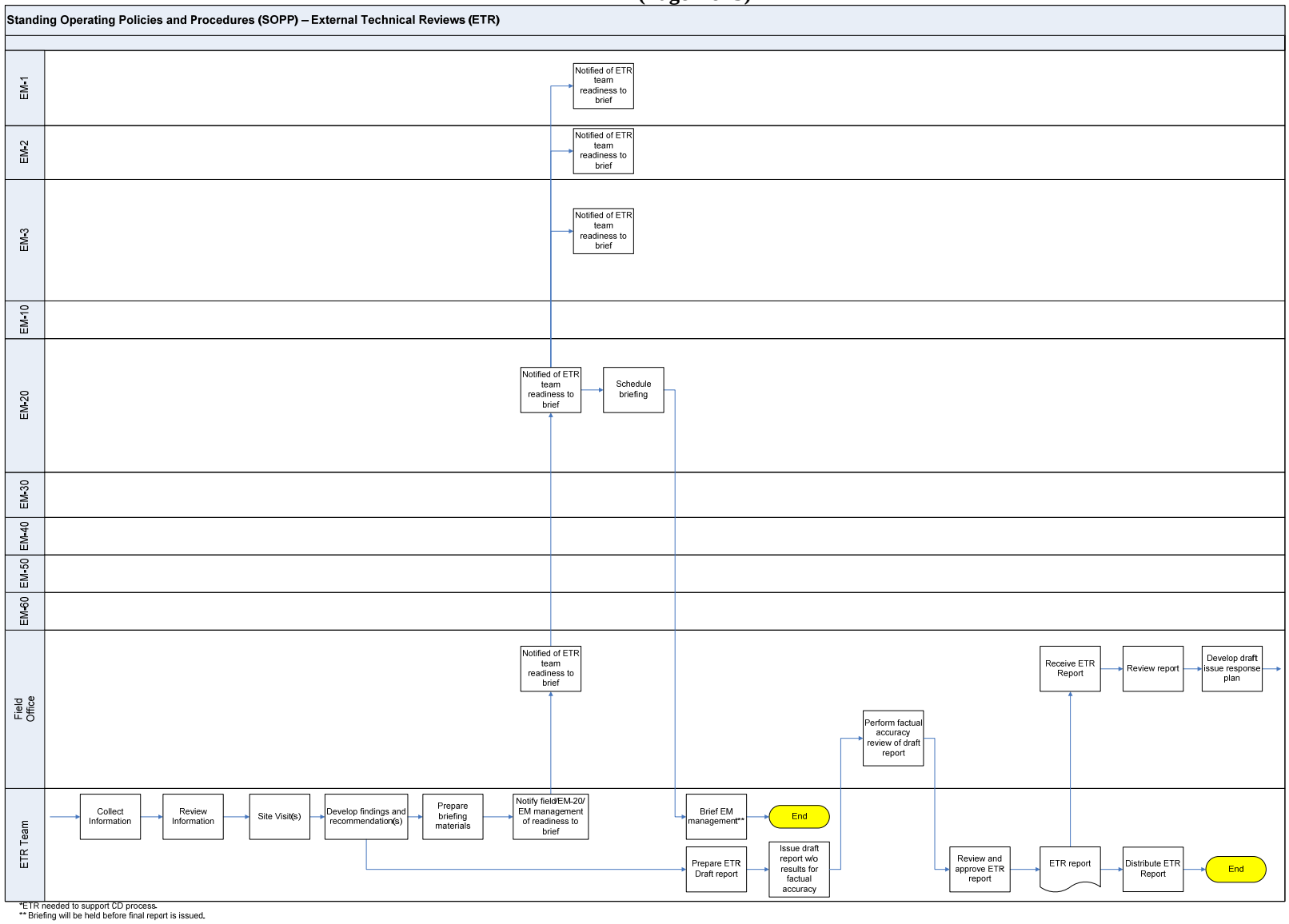
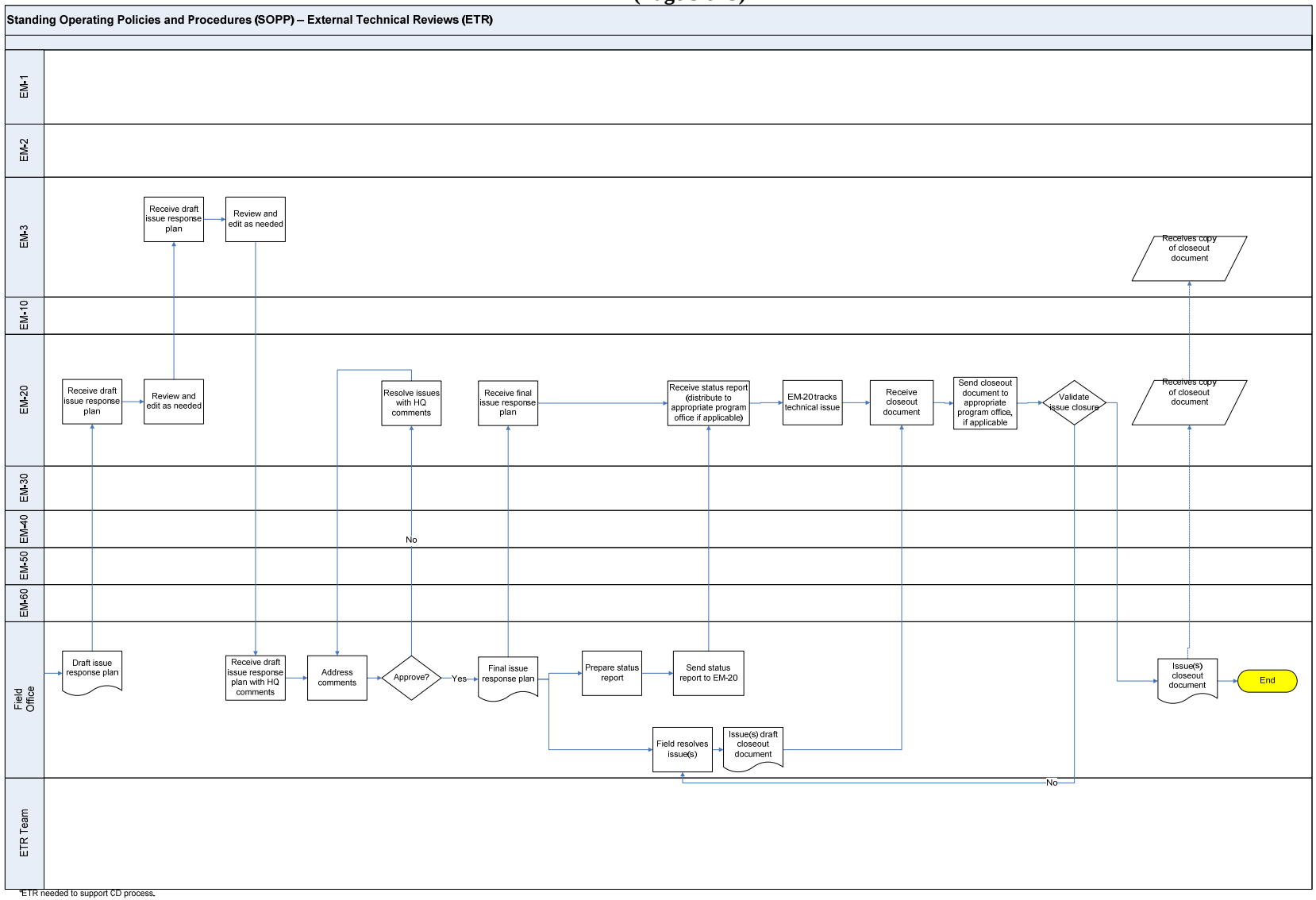


Figure 1 ETR Standing Operating Policies and Procedures Diagram

(Page 3 of 3)



*ETR needed to support CD process.
**Briefing will be held before final report is issued.

The pre-assessment planning stage (Section 3.1) begins when EM-20 notifies the Field Office that an ETR request has been approved or that EM-1 has requested the initiation of an ETR. Pre-assessment planning involves selection of the ETR team, development of a Charter and Lines of Inquiry, and reviewing pertinent technical scope documentation. The pre-assessment planning stage ensures pertinent information is documented and communicated to the requester and the Field Office responsible for implementation of the technical scope. This pertinent information includes but is not limited to:

- Goals and objectives of the review
- ETR team membership
- Primary points of contact
- Period of performance
- Funding
- Technical scope documentation required prior to the onsite review
- Agenda and general process for conduct of ETR
- Lines of inquiry
- ETR Deliverables to be provided at conclusion of the review

The Onsite activities stage (Section 3.2) begins when the team arrives at the site to conduct the review. Onsite activities involve conducting a Kick-Off Meeting, conducting interviews and documentation reviews, drafting a list of identified issues, briefing DOE EM management on the results, and conducting a Close-Out Meeting. The onsite activities stage ensures appropriate data is gathered to assess the technical scope and identify associated technical issues. At the conclusion of the onsite activities stage, the ETR team provides a list of issues/recommendations. These recommendations are focused on reducing the technical risk associated with the reviewed technical scope.

The Reporting stage (Section 3.3) begins after onsite activities are completed. Reporting involves the ETR team drafting and issuing the final ETR report. The field office prepares the Issue Response Plan for all issues identified by the ETR team. The reporting stage ensures that technical issues identified during the ETR are accurately documented and the action plan for responding to the issues is documented.

2.3 Key Roles and Responsibilities

ETRs are conducted by teams comprised of personnel who are subject matter experts in technical areas relevant to the technical issue under review. Expertise required for the ETR should consider the following: 1) process or technology functionality and efficacy (e.g., engineering, chemistry or other science basis), 2) nuclear and chemical safety, and 3) environmental requirements. Additionally, ETR team personnel are independent from the entities responsible for decision-making and implementation of the technical scope being reviewed. Team membership should include individuals (subject matter experts) from a variety of sources (federal, contractor, academia, industry, etc.). The key is to find the best people available.

There are two functions within the ETR team: Team Leader and Team Member.

The Team Leader is selected by the Field Office, in consultation with EM-20, to organize and direct the conduct of the ETR. Consequently, the Team Leader should have participated in previous technical reviews.

Team Members are selected by the Field Office to objectively review the technical scope

and identify issues within their specific areas of expertise. For an ETR of significant technical scope, Team Members may serve as focus area leads for a subteam of reviewers.

In addition to the ETR team, a project liaison function in the field is crucial to ETR success. The Project Liaison is assigned by the Field Office and serves as the conduit for communication between the Field Office and the ETR team.

DOE EM-20 has ownership of the ETR process and tracking technical issues resulting from the conduct of ETRs. To facilitate their role, DOE EM-20 should assign a sponsor who will be responsible for review ETR documents, coordinating the interfaces between the ETR team and DOE EM organizations, and tracking technical issues.

Specific roles and responsibilities of the ETR Team Leader, Team Members and the Project Liaison are provided in Section 3.1.1.

2.4 Tailoring and Timeline for External Technical Review

The guidance provided in this document is generic to all ETRs. Specifically, all ETRs will be formally planned, executed and documented. Planning is documented in a Charter. Lessons learned from previous ETR indicate that upfront planning is essential to having a successful ETR. Execution consists of Kick-Off/Close-Out meetings, interviews and documentation reviews. Documentation includes an ETR Report of issues/recommendations and an accompanying Issue Response Plan. However, there are instances that require tailoring of the process. Conduct of an ETR under a compressed schedule and untimely availability of appropriate reviewer expertise are instances requiring tailoring. The following are considerations when tailoring the ETR:

- Is the scope manageable for review within the constrained time?
- Are there uncertainties applied to the ETR results?
- Is there uncertainty associated with ETR conclusions due to limited review time or limited availability of reviewers?
- Can appropriate reviewer expertise be acquired (contracted) to meet the compressed schedule?

A typical timeline for the ETR process is provided in Figure 2. This timeline assumes ETRs are forecast on an annual schedule.

Figure 2 Typical ETR Timeline

Activity	Typical Time Frame (relative to 'Begin Review')
Team Selection	-8 weeks
Consultant contract & funding (as required)	-8 to -6 weeks
Charter issued	-8 to -6 weeks
Pre-Assessment Meeting (optional)	-6 weeks
Advanced Material Reviewed	-2 weeks
Begin Review (onsite activities)	0
Complete Onsite Review/ Presentation to Field Office	+1 to +2 weeks
Summary to DOE-EM	+2 weeks
Draft Report	+4 weeks
Review and Comment resolution	+6 weeks
EM Management Exit Briefing	+6 weeks
Final Report issued	+8 weeks
Issue Response Plan completed for tracking	+10 weeks

3.0 EXTERNAL TECHNICAL REVIEW PROCESS

3.1 Pre-Assessment Planning

1. An ETR is requested by DOE Program Office or the Field Office for a specified project or technical issue. It is expected that an annual schedule of ETRs will be established. EM approves ETR.
2. The Field Office selects a Team Leader and Team Members for conduct of the review. The Team Leader and Team Members are independent from the project team implementing the technical scope and external to the office responsible for the technical scope. The Team Leader should have participated or led a previous technical review, and should be knowledgeable of the technical area. Selection of Team Members is based on the scope of the review. Refer to Team Leader and Team Member roles and responsibilities in Section 3.1.1. Refer to Team Selection criteria in Section 3.1.2.
3. The Team Leader assesses the need for additional reviewers and initiates the appropriate acquisition actions to ensure the additional support is available for the review.
4. The Team Leader assesses the need for a pre-assessment onsite visit. The purpose of the pre-assessment onsite visit is to provide the team an overview of the technical issue and request documentation for advance review. However, if this purpose can be accomplished by some other means (e.g., teleconference, emails, or the team's existing familiarity with the technical issue), the Team Leader may determine that a pre-assessment onsite visit is not needed. An on-site visit should be required for Team Members unfamiliar with the site and its issues.
5. If a pre-assessment onsite visit is needed, the Team Leader contacts the Field Office (the organization to be reviewed) and schedules a visit.
6. The Team Leader requests in writing the documentation needed for advance review from the Field Office.
7. The Team Leader, with input from Team Members, develops a Charter containing the elements detailed in Section 3.1.3 and Attachment A.
8. The Team develops lines of inquiry (LOI) to ensure the scope of the charter is adequately addressed. Attachment B provides suggested lines of inquiry. Additional guidance regarding lines of inquiry is provided in Section 3.1.4.
9. The Team confers with the Field Office and DOE EM-20 to determine the funding source for the ETR. It is expected that funding for ETRs will be provided by the Project or Field Office.
10. The Team Leader submits the Charter and LOI to the Field Office and DOE EM-20 for approval.
11. If previously scheduled, the Team attends the pre-assessment onsite visit.
12. Upon receipt of requested advance review documentation, the Team conducts document reviews.
13. Table 3 provides a listing of implementation tips for the pre-assessment planning stage.

3.1.1 Review Team Roles and Responsibilities

Team Leader

- Serve as the ETR Team primary point of contact
- Develops the ETR Charter and lines of inquiry in partnership with the Team
- Be willing and capable of staying onsite during the entire review process, and actively participate in the process described in the Charter. This commitment includes development of written input, and participation in team meetings.
- Organize the team's work and make assignments so that the Team Members' onsite time is well spent and will provide the required products. This will ensure that no single team member, including the Team Leader, will be left to complete a disproportionate amount of work.
- Review the ETR request to assure that specific topics or emphasis requested are properly understood and identified in the Charter. Obtain clarification from the requesting DOE official, as appropriate.
- Support Field Office with recommendations for members of the review team having expertise that is appropriate for the type of review and the project to be reviewed.
- Assign responsibility to Team Members to act as subteam leaders.
- Coordinate arrangements and agenda for review with the Field Office.
- Identify written materials to be provided to Team Members in advance of the onsite visit and required date by which these materials will be available.
- Accept requests for additional information from Team Members following initial review of materials provided in advance; communicate these requests to the Field Office; obtain agreement on time for responses to requests.
- Conduct team conference calls approximately one week (or as needed) prior to onsite visit to confirm arrangements and to clarify questions and potential lines of inquiry among Team Members.
- Coordinate team's arrival. Identify required check-in at site security office and time and place for initial team meeting with project officials.
- Present initial briefing describing review team charge and review process to onsite project participants.
- Participate as a subject-matter-expert as needed.
- Require Team Members to provide summary statements of observations and significant concerns approximately one day before the planned exit briefing to allow team review and discussion.
- Establish responsibilities among Team Members and timelines for completion of detailed write-ups supporting significant concerns and observations, and for submittal of other observations.
- Assign responsibilities and timelines for preparation of summaries and for consistency of comments.
- Conduct and provide a copy of the exit brief for onsite project participants with support from Team Members as appropriate.
- Review and consolidate all Team comments to ensure consistency throughout the report.
- Provide a draft copy of the report to all members of the Review Team for final consensus on the content and to the Field Office for a review for factual accuracy of the observations

included.

- Incorporate team member comments as appropriate as the final authority on the report content. Correct errors in fact identified by the project team review. Since a significant level of effort may be required to incorporate comments, the Team Leader may task Team Members to rewrite their sections as appropriate.
- Approve and issue the final report.
- Conduct exit briefing to key DOE personnel (i.e., EM-1, EM-2, EM-3, Field Office, Federal Project Director) after conclusion of the ETR.

Team Members

- Review all advanced materials provided prior to site review and advise the Team Leader if additional information is needed.
- Conduct a thorough review of the document(s) and personnel interviews. Focus efforts on specified areas and responsibilities.
- Advise Team Leader of project personnel that Team Members will want to interview on site.
- Participate in pre-review conference calls and onsite interviews.
- Be willing and capable of staying onsite during the entire review process, and to actively participate in the process described in the Team Meeting.
- Ensure receipt of all advance documentation and advise the Team Leader if other arrangements need to be made.
- Submit draft input in accordance with this guidance
- Prepare questions resulting from review of advanced material received and provide to Team Leader in advance. Only the Team Leader will coordinate with the site.
- Communicate directly with identified project participants to clarify understanding of material review.
- Seek clarification from project participants concerning perceived omissions or deficiencies.
- Prepare written comments on a timely basis as required by the Review
- Ensure all comments are unclassified and coordinate their comments with an Authorized Derivative Classifier if there is a question.
- Review draft report to assure individual observations are accurately described and to identify possible conflicts with other observations.

Remote Reviewers (if any):

- The Remote Reviewer write-ups/concerns/questions (unclassified) must be provided to the Team Leader prior to the Kick-Off Meeting as outlined in the Review Schedule.
- Review draft report to assure individual observations are accurately described and to identify possible conflicts with other observations.

Project Liaison Roles and Responsibilities:

- Serve as the project and site primary point of contact
- Facilitates ETR logistics (e.g., Coordinates with the Team Leader on arrangements, facilities and resources at the site for the review)
- Ensures site access to ETR Team Members

- Coordinates the project's review of the ETR report

DOE EM-20 Roles and Responsibilities:

- Approves ETR requests
- Approves the ETR Team charter and LOI
- Consults with the Field Office regarding designation of Team Leader and Team Members
- Works with the field office to ensure funding is sufficient for the ETR
- Assigns EM-20 ETR team sponsor. The sponsor may also be a member of the ETR Team.
- Reviews Issue Response Plan
- Tracks technical issues in Issue Response Plan

EM-20 ETR Team Sponsor Roles and Responsibilities:

- Review ETR documents
- Coordinate the activities between the ETR team and the DOE EM organization [i.e. the Office of Regulatory Compliance (EM-10); the Office of Acquisition and Project Management (EM-50), and the Office of Safety Management and Operations (EM-60)]
- Track issues identified during ETR scoping, execution, and closeout, and coordinate with the appropriate EM office
- Validate the closure of issue response plans
- Periodically visits the ETR team to monitor review activities

3.1.2 Team Selection

Key criteria for the selection of the ETR Team are independence and expertise. Team selection should utilize all resources available to DOE. The number of individuals on an ETR Team is based on the scope of the review. The Team Leader and Team Members are independent from the project team implementing the technical scope and external to the office responsible for the technical scope. For example, Team Members should not be contractors affiliated with the project (or competing projects) to be reviewed. Additionally, Team Members should satisfy the following criteria:

(a) no substantial obligations, reporting responsibilities or financial ties (either through current or employment within the past 2 years, or contractual relationships, or otherwise) with the contractors responsible for the project being reviewed,

(b) no substantial obligations, reporting responsibilities or financial ties with contractors responsible for directly competing technologies, projects or proposals with the project being reviewed. All potential conflicts should be disclosed through a "conflicts and bias" statement or form (similar to that used by the National Academies).

In determining the expertise required by Team Members, industrial experts (for operations that are industrial in size and therefore different than many of the Laboratory operations) and experts from other laboratories with similar operations should be considered.

3.1.3 Charter

The ETR Team provides its first formal response to the ETR request via the Charter. The purpose of the Charter is to convey intended technical focus, team membership, lines of inquiry,

cost and schedule. The ETR Team Leader is responsible for developing the charter based upon the general scope of the review provided by DOE. It is expected that the Team Leader will solicit, receive and incorporate input from Team Members. Team member input ensures relevant technical perspectives are reflected in the charter and strengthens team buy-in/support of the path forward. The developed Charter is submitted to DOE EM-20 for approval and allocation of required funding. The Charter should be approved by the EM-20 Deputy Assistant Secretary (DAS) and the responsible Field Office Manager by signing the Approval section of the Charter. DOE approval indicates 1) all relevant subject areas are covered; 2) team membership has been reviewed for conflict of interest regarding particular technology solutions; and 3) lines of inquiry have been reviewed for adequacy. The responsible EM-20 Office Director should also agree, but would not sign the Charter.

To establish the review schedule a typical review timeline is provided in Table 2 and an example list of schedule activities is provided in Attachment C.

As a minimum, the Charter should contain the elements described in Attachment A.

3.1.4 Lines of Inquiry (LOI)

LOI are the basic set of focused questions utilized during the conduct of the ETR to acquire data that will be used to formulate the conclusions of the review. Development of LOI is a collaborative effort with input from all Team Members. Properly identified LOI support the overall objective of the review and can be reasonably assessed in the time allotted for the review. Typically, a single set of LOI are developed for use by all Team Members. In this instance, individual reviewers perform their assessment from the perspective of their area of expertise. In some instances, it may be necessary to include LOI that are unique to a particular area of expertise. Possible areas for LOI include: the assumptions, methods for selecting an alternative, constraints to possible options, basis for the risk(s), the technical development plan and status, and information supporting key decisions.

There are federal directives that influence the engineering and technical requirements defined for projects. Engineering and technical requirements are inherent concerns of external technical reviews. Consequently, federal directives may be good resources for the development of appropriate LOI. The listing in Table 2, though not all inclusive, is provided to assist Team Members in developing LOI from federal directives.

The phase of the project may be a determining factor when developing LOI. The Review Team should be wary of asking questions about data that does not exist based on the phase of the project. The Review Team may need to revise or add to the LOIs as the review progresses. Attachment B provides a sampling of suggested LOI and the relevant phase of the project.

Table 2 Federal Directives for Consideration during LOI Development

DOE Policies
450.4 Safety Management System Policy
DOE Orders
413.3A Project & Program Management for Capital Assets
414.1C Quality Assurance
420.1B Facility Safety
435.1 Radioactive Waste Management
430.1B Real Property Asset Management
450.1 Environmental Protection Program
460.1B Packaging & Transportation Safety
DOE Manuals
413.3-1 Project Management for the Acquisition of Capital Assets
450.4-1 Integrated Safety Management System Manual
DOE Standards
1189-YR (DRAFT) Integration of Safety into the Design Process
Code of Federal Regulations
10 CFR 830 Nuclear Safety Management
10 CFR 835 Occupational Radiation Protection
10 CFR 851 Worker Safety and Health Protection Program

3.1.5 Documentation for Review

An important aspect of preplanning the ETR is the advance review of pertinent documentation. The Team Leader formally requests the documentation for advance review via the Charter or direct communication. The field Project Liaison is responsible for coordinating the distribution of the requested documentation to the ETR Team. To the maximum extent possible, the requested documentation should be provided to Team Members at least 2 weeks prior to the scheduled review. Submission of the project documentation is expected to be as an entire package and represent a 'static state' of development.

Documentation requested for an ETR varies but generally includes scope documents, technical bases documents, value engineering studies, technology alternatives studies, relevant regulatory information, and DOE or program reference documents. Information provided to the ETR Team should include (a) project objectives and requirements, (b) definition of process interfaces (e.g., initial conditions or feed characteristics, requirements for primary process outputs or endpoints, environmental discharge or emission requirements, project schedule constraints), (c) supporting development and testing data, (d) basis of design and design information to the extent available and relevant. Additionally, proper citations should be listed for each document provided

3.1.6 Onsite Meeting Facilities and Resources

Prior to the onsite review, the Team Leader and the Project Liaison discuss the facilities and equipment needed for the review. Typical considerations regarding onsite meeting facilities and resources are:

- Conference Room (or two) in un-cleared area or in area accessible to un-cleared Team Members with cleared team member escorts if necessary.
- Office space, two (2) additional offices for small group discussions (accessible to un-cleared Team Members with cleared team member escorts if necessary).
- Teleconference capability.
- Two computers with printing capabilities, Microsoft Word and PowerPoint installed.
- Telephone, internet and Fax access.
- Site/project clearance requirements for personnel related equipment such as government and non-government owned laptop computers.
- Site badging process as necessary.
- Security information for site visit.
- Personnel to conduct classification reviews of documentation generated during the review.
- Training required by Team Members for access to facilities.

Table 3 Implementation Tips – Pre-Assessment Planning

Planning

- The Pre-Assessment phase may be compressed, but lessons learned from past reviews indicate the need for detailed up-front planning.
- Define the scope: clearly and concisely, focused on the real problem/issue, and delineate the review scope based on mission or contract objectives.
- Define what is not in the scope.
- Up-front review of documents by the Review Team will streamline the initial meetings at the Project by reducing the need for overviews.
- Establish the report format early in the review.
- Early in the review address how responses to recommendations will be reported and tracked.

Team Selection

- Team Members should be independent of any corporate accountability or responsibilities for managing the project or technical issue being reviewed.
- Team Members should be free of any conflict-of-interest with respect to potential benefit due to recommendations identified during the review.
- Teams are comprised of experts in a variety of disciplines such that the Team can adequately review all relevant issues of the Project or technical issue being reviewed
- The Team Leader should have demonstrated ability regarding preparation, scheduling, organization and execution of review team activities.
- Ensure that there are firm commitments from the Team Members and/or identify any conflicts early.
- Allow time and funding for the acquisition of Team Members through contracts.
- Team size should meet the needs of the review scope.

Team Readiness

- Develop a required reading list for the Team Members and ensure it is completed prior to the on site activities. Allow 1 working day of advanced review per 100 pages of documentation.
- Establish team communication guides early i.e. status calls, distribution lists.

Pre-Assessment Onsite Visit (As needed)

- The purpose is to orient the review team on the technical issue to be reviewed and request documentation for advance review.
- Schedule as early as practical to ensure adequate time for advance review of documentation and team familiarization with the technical issue.
- Scheduled for at least 2 full days.

3.2 Onsite Activities

1. The Team Leader and the Project Liaison conduct a Kick-Off Meeting at the review site location. Additional information regarding Kick-Off Meetings is provided in Section 3.2.2.
2. If necessary, the Field Office conducts a tour of site facilities applicable to the scope of the review.
3. The Team reviews pertinent documentation and conducts personnel interviews to assess the identified lines of inquiry. To aid in compilation of issues, each Team Member maintains adequate notes from their information-gathering activities. Additional information regarding interviews is provided in Section 3.2.3.
4. Reviewers submit their identified technical issues to the Team Leader or the subteam leads.
5. The Team Leader is responsible for keeping DOE, the Field Office and Project personnel informed of technical issues as they are identified. This may include periodic meetings during the onsite review period. The frequency and formality of these updates is dependent on the length of the review period and the availability of data and personnel.
6. The Team compiles a list of the technical issues identified during the review.
7. The Team Leader reviews the issues and recommendations to ensure they are within the scope of the charter.
8. The Team Leader conducts a Close-Out Meeting to present the technical issues identified during the ETR. Additional information regarding the Close-out Meeting is provided in Section 3.2.4.
9. The Team Leader conducts an exit briefing with DOE HQ on the identified technical issues.
10. Table 4 provides a listing of implementation tips for the onsite activities stage.

3.2.1 Resources

The Project Liaison ensures that the requested resources are readily available at the start of Onsite Activities. Additional resources and documentation identified after the start of Onsite Activities are communicated to the Project Liaison by the Team Leader. Proper planning is expected to eliminate the need for additional resources; however, the expectation is that the Project Liaison will respond promptly to any additional resource requests.

3.2.2 Kick-Off Meeting

The Kick-Off Meeting marks the start of Onsite Activities. The purpose of the Kick-Off Meeting is to 1) introduce the ETR Team and key project personnel, 2) review the primary objectives of the ETR and the identified lines of inquiry and 3) convey the logistics for onsite activities. The Team Leader and the Project Liaison are responsible for the Kick-Off Meeting. Attendance is usually limited to the Team Members, DOE EM-20, and Project Personnel.

At the Kick-Off Meeting, Project Personnel provide an overview of the Project and its status. This will be in the form of formal presentations by appropriate Project Personnel to the Review Team using support materials such as view graphs, charts, drawings, or photos. Presentations should be concise, allowing for questions and answers within the allotted time. View graphs should be structured consistently from presenter to presenter and be clear and not excessive with information. Detailed information should be transmitted via supplemental handouts. The Review Team is the primary audience for the presentations, but other individuals may attend, particularly

if their presence may be advantageous to any line of questioning from the Review Team. When the agenda calls for discussion time, or at the conclusion of a particular topic presentation, a more informal round-table format is appropriate. These presentations should also address questions submitted by the Review Team in advance. Pre-existing presentations may be utilized if still current.

A sample Kick-Off meeting agenda is provided in Attachment D.

3.2.3 Interviews

During the Review, each individual Team Member conducts his or her own review of documents and personnel interviews. Even though some project personnel provide presentations to the Review Team as a whole, the individual reviewers are responsible for analyzing and assessing the assigned subject matter and providing a written report of their assessed technical issues. To improve efficiency during the interview process, breakout sessions should be scheduled to allow non-related interviews to be held concurrently. To the extent possible, more than one Team Member should be present for all interview sessions.

As interviews and document reviews are completed the details of the review should be documented. The information collected should provide the Review Team the ability at a later date to understand the subject, the observations and enable follow-up if needed.

3.2.4 Close-Out Meeting

The purpose of the Close-Out Meeting is to provide and exit briefing to the Field Office and Project personnel on issues identified through document reviews and personnel interviews during the onsite visit.

At the Close-Out Meeting, the Review Team presents the results of the review in the form of bullets. Comments and recommendations are presented and the Review Team responds to any questions raised by the DOE EM-20, the Field Office or the Project. The Team Leader or individual Team Members assigned to each subject area should make informal presentations that describe the reviews results relative to the Charter, and highlight all technical issues identified during the review. A separate exit briefing with the Field Office may also be arranged as appropriate. Copies of materials presented at the Close-Out Meeting are usually made available to meeting attendees.

The Close-out meeting may also include an exit briefing by the Project of their proposed responses.

A sample Close-Out meeting agenda is provided as Attachment E.

Table 4 Implementation Tips- Onsite Activities

Status Meetings

- Maintain a regular form of communication between the team and the Project such that neither is caught off guard by new information. Typically this is a daily meeting during onsite activities.
- Once issues have been reviewed by the Review Team they should be forwarded to the Project Team. This allows time for communication between the Review Team and the Project Team to clarify the issue.

Issue Capture and Resolution

- Use of a database or tables to capture the issues and responses will facilitate the ability to analyze the review and track open items.
- A standard form for capturing information should be used. Standard items should include: name, e-mail, phone number, scope area / LOI, document identification, specific questions, response, and follow-up items.
- The Review Team should have a process for handling differences in professional opinions.

Observation Categories

- Observations should be categorized based on their significance. Suggested observation categories could be:
    - Severe Technical Issues – Observations that would prevent the technology from being fully developed to meet mission needs. These observations should be considered fatal flaws that cannot be resolved.
    - Technical Issues – Observations requiring resolution to ensure the technology will successfully meet mission needs.
    - Areas of Concern – Observations that may require design modifications to the technology deployment or additional testing to resolve technical concerns.
    - Opportunities for Improvement – Observations that would improve the ability to meet mission needs or offer alternative solutions to technical problems.
    - Good Practices - Items that are commendable and deserve recognition.

3.3 Reporting

1. The Team prepares the draft ETR Report. Additional information on the content of the Report is provided in Section 3.3.1 and Attachment F.
2. Team Members review the draft report to ensure identified issues have been accurately captured in the report.
3. The Team Leader provides the report to the Field Office for a factual review. Additional information regarding factual review is provided in Section 3.3.3.
4. As applicable, the Team Leader revises the draft report based on the factual review.
5. Team Members review the revised draft report.
6. The Team Leader conducts an EM Management exit briefing.
7. The Team Leader approves and distributes the final report to DOE EM-20, the Field Office, and other appropriate parties
8. The Field Office drafts an Issue Response Plan and forwards to DOE EM-20. Additional information regarding Issue Response Plans is provided in Section 3.3.4 and Attachment G.
9. DOE EM-20 reviews and edits the drafted Issue Response Plan before forwarding to DOE EM-3. The DOE EM-20 review should include review(s) by select ETR Team Members if needed to determine if the Issue Response Plan adequately addresses ETR recommendations.
10. DOE EM-3 reviews and edits the drafted Issue Response Plan before forwarding to the Field Office.
11. The Field Office approves the Issue Response Plan and forwards the approved plan to DOE-EM-20.
12. The Field Office provides periodic status of Issue Response Plan item(s) to DOE EM-20.
13. DOE EM-20 validates closure of Issue Response Plan item(s).
14. Upon completion of all Issue Response Plan items, the Field Office issues a closeout document to DOE EM-20 and EM-3.
15. Table 5 provides a listing of implementation tips for the reporting stage.

3.3.1 Report Preparation

The purpose of the report is to document the conduct and results of the review. The Team Leader is responsible for preparing the report with detailed input from Team Members. The report is divided into sections that are assigned to individual Team Members. The intention is to provide the DOE EM-20 and the Field Office, at a minimum, a list of technical issues before the Review Team leaves the site. If possible, the Team Leader will also provide an initial draft of the report. A designated editor should review the draft report to provide consistency without changing content. The draft report will then be provided to the Review Team for a final review. It will also go to the Field Office for a factual accuracy check as described in Section 3.3.3. To expedite the schedule, these two reviews are often accomplished in parallel. Comments will be resolved and incorporated by the editor and a final report generated. The Team Leader will issue the report to the Field Office and Headquarters. See Attachment F for the minimum suggested content for the report.

Lessons learned may be identified during the conduct of an ETR that benefit future ETRs and/or

projects. ETR Teams are encouraged to document these lessons learned. These lessons learned may be documented within the ETR Report or they may be documented in a separate document. In the case of a separate lessons learned document, the ETR report should be referenced within the document and the document should be filed with the ETR report.

3.3.2 General Report Guidance

Technical issues and recommendations identified in the report align with the subject matter expertise of the reviewers and the chartered scope of the ETR. During the conduct of the review, key information should have been gathered to support the identification of the technical issue/recommendation. Supporting information to be included in the report for each technical issue/recommendation is:

- A description of the condition encountered during the review.
- Acknowledgement of the requirement(s) that govern the condition.
- Applicable industry or EM benchmarks.
- The benefit derived from resolving the technical issue and/or implementing the recommendation.

3.3.3 Factual Accuracy

The Field Office is responsible for conducting a factual accuracy review of material presented in the draft report. The purpose of the factual accuracy review is to identify any items of fact that are inaccurate. Factual accuracy reviews are not applied to the technical issues identified by the Team Members. The Review Team will correct errors in fact that may result in a change in identified technical issues. However, if the information provided is factual, the technical issues will not be changed as a result of this review.

3.3.4 Issue Response Plan

The Field Office should complete an Issue Response Plan which should:

- List the “Recommendation” for each "Technical Issue" from the ETR report.
- Provide a discussion of the required action.
- Propose start and end dates for the corrective action.
- Identify the office to which the corrective action has been assigned.
- Determine an open or closed status remark.

An example of an Issue Response Plan is provided in Attachment G. The responses should be entered into the existing Field Office action tracking system. The Issue Response Plans are statused by the Field Office as issues are addressed. The Field Office sends status reports to DOE EM-20. DOE EM-20 monitors the status of action items, validates closure of action items and issues the closeout document for the Issue Response Plan.

3.3.5 Closeout Document

The Closeout Document is the final document issued in the ETR process. The purpose of the Closeout Document to certify that all actions identified in the Issue Response Plan(s) are complete. The Field Office is responsible for issuing the Closeout Document with a Field Office

signature. The signature indicates that the actions have been verified as complete and meet the intent of the Issue Response Plan. The signed Closeout Document is then issued to EM-20 and EM-3.

As a minimum, the Closeout Document contains:

- a statement attesting to the completion of all Issue Response Plan actions,
- the initiating ETR report document reference
- the associated Issue Response Plan(s) document reference(s),
- associated action closure document references

An example Closeout Document is provided in Attachment H.

Table 5 Implementation Tips - Reporting

Report Preparation

- Include a technical editor as a resource to the team to help in finalizing the report.
- Begin report preparation in the beginning of the review. Develop an outline for the report immediately and discuss with the team during an early planning conference call and/or during the onsite visit.
- Build the report as review progresses rather than waiting until the onsite activities are complete.
- Each team member should complete their section of the report, including observations and recommendations, before they leave the site. Edits can be made later.

Comment Resolution

- Reviewers are responsible for resolving comments within their assigned subject area.
- The Team Leader resolves comments that are not specific to a particular subject area.
- Project Team should develop responses as issues are communicated to them. This will help ensure the issue is understood prior to the Review Team leaving the site.
- Caution should be exercised in having the Review Team Members review responses to avoid any implication they are identifying scope they could be retained to resolve.
- Efforts should be made to resolve comments/issues to the satisfaction of all reviewers. However, an individual reviewer may document caveats/concerns regarding report conclusions/recommendations in “minority reports” that are included as appendices to the report.

Report Distribution / Approval / Closeout

- Early in the review, the Team Leader should establish the distribution list for the report with input of the site and DOE.

4.0 ATTACHMENTS

Attachment A, Charter
Attachment B, Suggested Lines of Inquiry
Attachment C, Example Review Schedule
Attachment D, Kick-Off Meeting Agenda
Attachment E, Close-Out Meeting Agenda
Attachment F, Report Format
Attachment G, Issue Response Plan
Attachment H, Closeout Document

Attachment A, ETR Charter
(Page 1 of 3)

OUTLINE:

- **Title**
- **Introduction/ Background**
- **Scope of Review**
- **Team Membership**
- **Period of Performance**
- **Lines of Inquiry**
- **Approvals**
- **Attachment: List of initial information needed**

TITLE: *<insert text>*

The title uniquely identifies the subject of the review. The subject may be the name of a project or technical issue. The title established in the Charter is retained for all other ETR deliverables. Further, attempts should be made to make the title unique and descriptive enough to facilitate ease of retrieval via key word search.

Example:
TITLE: External Technical Review – Demonstration Bulk Vitrification System

INTRODUCTION/BACKGROUND

The introduction/ background clearly and concisely state the following:

- ***the originator of the ETR request***
- ***the organization accepting responsibility for completing the ETR***
- ***a brief summary description of the project or technical issue being reviewed.***
- ***Any other background material***
- ***A statement on how the results of the ETR will be used***

Example
As directed by the US Department of Energy, the Washington Savannah River Company (WSRC) is preparing to engage a team of independent technical reviewers to assess SRS consideration of alternatives and selection of preferred methods for disposition of the tetraphenylborate (TPB) contamination and restoration of Tank 48H to service.

Attachment A, ETR Charter
(Page 2 of 3)

SCOPE OF REVIEW

The scope should describe the technical areas of the project or technical issues that will be reviewed. Additionally, provide explanation of any aspects of the project or technical issue that are notably excluded from the review.

Example
The review will focus on these five primary technical subject areas:

- Mission Integration – This subject area review is intended to focus on the overall integration of the DBVS project into the Hanford Site's mission supporting tank waste treatment. This part of the review scope is intended to focus on the flowdown of mission performance requirements that the DBVS project has been tasked to demonstrate.

- Flowsheet – This subject area review is intended to focus on the DBVS overall flowsheet. This review shall be limited to those systems that are specific to the internal boundaries of the DBVS project, and is not intended to include secondary support systems such as effluent treatment or utility supply. The need to extend the review to any of the secondary support systems will be evaluated on an individual basis as the need arises.

- Vitrification System – This subject area review is intended to focus on the design of the vitrification system, and shall include specific evaluations of the following areas:
  - o Testing and Scale-Up Program
  - o Waste Package and Glass Recipe Formulation
  - o Refractory and Container Design

- Primary Supporting Equipment – This subject area review is intended to focus on the design of the major supporting equipment needed to ensure functionality of the vitrification system, and shall include specific evaluation of the following areas:
  - o Feed Mixer and Dryer Equipment
  - o Off Gas Treatment Equipment

- Nuclear Safety and Operations – This subject area review is intended to focus on the ability of the system to meet nuclear safety and operational standards required for a RCRA permitted research and development pilot scale facility. This review shall include specific evaluation of the following areas:
  - o Nuclear Safety and Authorization Basis Requirements
  - o Operations and Maintenance Feasibility

Attachment A, ETR Charter
(Page 2 of 3)

MEMBERSHIP

The Membership section contains details regarding the review team and team member biographies. Specifically, list each team member's name, subject area expertise and employment affiliation. Further, the list must clearly identify the designated Team Lead and Subteam leads, as needed.

Example:

Position	Name	Subject Area Expertise	Company
Team Leader	Person 1 name	Vitrification technology	DOE Office XYZ
Team Member	Person 1 name	Chemistry	DOE Office XYZ
Team Member	Person 2 name	Nuclear fuel and waste management	DOE Office XYZ
Team Member	Person 3 name	Technology integration	XYZ Laboratory
Team Member	Person 4 name	Requirements management	ABC Consulting

PERIOD OF PERFORMANCE

The period of performance provides estimated start and finish dates for the review. The start date is the expected date that the Kick Off meeting will be held. The finish date is the expected date for delivery of the final report. Other key intermediate milestones should also be included.

Example
The ETR is expected to begin in May 2006 and be completed by the end of September 2006. The primary deliverable for this work will be a final report of ETR review activities and recommendations delivered no later than September 29, 2006.

LINES OF INQUIRY (LOIs)

The LOIs established by the Review Team to address the scope of the review.

APPROVALS

Attachment B, ETR Suggested Lines of Inquiry

The three key objectives of an ETR are:

1. To determine if the technology, process, system, or design under review will meet project objectives and requirements,
2. To identify any issues (showstoppers) preventing successful implementation of the technology, process, system, or design under review, and
3. To identify issues or data needed to support critical or other project or program decisions.

These objectives should become the key lines of inquiry of the ETR, tailored to meet the specific scope of the review.

Technical Scope Considerations
1. Have alternatives been identified and effectively evaluated?
▪ Major alternatives have been identified and analysis of these alternatives is in the work scope of the conceptual design.
▪ Alternative analysis includes comparisons of LCC, Feasibility (including technology development requirements), stakeholder values, safety, regulatory compliance, and other factors as appropriate.
▪ The preferred alternative is identified and justified.
2. Are technical objectives well known and defined?
▪ Functional and performance requirements for the project are documented, approved (by users, key stakeholders, and DOE program office as appropriate) and are under configuration control.
▪ Trade-off studies are performed as needed to reach a reasonable level of project risk consistent with project phase and overall project cost/schedule.
▪ The trade-off studies include alternative design and process control and optimization approaches with consideration of technical safety requirements.
3. Is technology development well planned and executed?
▪ The technology development requirements for each alternative are identified and documented.
▪ The maturity of new technology to be used on the project has been evaluated and factored into risk analysis.
▪ New technology has been tested and determined to meet project objectives (technical, cost and schedule).
▪ Simulation and/or mockup facilities are defined and established as necessary.
4. Are quality assurance and scientific investigation adequate?
▪ Equipment and material needs for processing and production, including availability and reliability, are defined.
5. Are technical bases substantial and documented?
▪ The design basis will be subject to peer review by appropriate technical experts.

Attachment C, Example Review Schedule

Dates	Week	XYZ Recovery System External Technical Review (ETR)
5/8 – 5/12		ETR Team Leader finalize and submit to Field Office complete ETR planning package, including review process, charter, proposed membership and tentative schedule
5/15 – 5/19		– Field Office review, approve and submit the planning package to Program Office for review and approval – Program Office concur with charter and personnel selection
5/22 – 5/26		– ETR Team Leader let contracts for approved Team Members – Project submit proposed review package, for Program Office approval
5/29 – 6/2 (Holiday week)		– Project distribute review packages to review Team Members – Conference call with review team to resolve any outstanding questions – Finalize and issue agenda for kickoff meeting – Release members to travel
6/5 – 6/8	1	**Review Team on site (T-F)** – Kickoff Meeting – Technical briefings and tours – Agreement on scope, level of detail, sub-assignments and rough outline of report – Identification of any additional specialty skills required
6/12 – 6/16	2	– External technical review – Conference call meeting(s)
6/19 – 6/23	3	**Team on site (M-F)** – Continued reviews, discussions, interviews – Establish completeness and validity of prior XYZ Recovery System assessments and responses – Mid-point review with Project and DOE management
6/26 – 6/30	4	– External technical review – Conference call meeting(s)
7/3 – 7/7 (Holiday week)	5	– External technical review – Conference call meeting(s)
7/10 – 7/14	6	**Team on site (T-F)** – Final discussions with Project, DOE, team interactions and determination of recommendations
7/17-21	7	– Conduct DOE EM-20 briefing
		– Close-Out Meeting
		Approve & Issue Final Report
7/24 – 7/28	8	– Submit report draft material, as assigned
7/31 – 8/3	9	– Issue draft report for team review
8/7-8/10 8/14 – 8/18 8/21 – 8/25	10 11 12	– Team comments on draft – Conference call meeting(s) to resolve open comments – Incorporate all comment resolutions and prepare final report
8/28 – 9/1	13	– EM Management Exit Briefing – Issue Final Report

Attachment D, ETR Kick-Off Meeting Agenda

Topic	Presenter
Review Team Introductions	Team Leader
Purpose of Review	Team Leader
Scope of Review	Team Leader
Review Process Overview	Team Leader
Field Office Introductions	Field Office Representative or Project Liaison
Technical Issue overview and status	Field Office Representative or Project Liaison
Site tour (as needed)	Field Office Representative or Project Liaison

Attachment E, ETR Close-Out Meeting Agenda

Topic	Presenter
Purpose of Meeting	Team Leader
Presentation of technical issues ▪ General Overview of Recommendations ▪ Area 1 ▪ Area 2 ▪ Conclusions	 Team Leader Responsible Team Member Responsible Team Member Team Leader
Discussion	All
Path Forward for report issuance	Team Leader

Attachment F, ETR Report Format

REPORT CONTENT:

ACRONYMS

EXECUTIVE SUMMARY

Briefly state who requested the review, what organization was responsible for conducting the review, what project/technical scope was reviewed. Provide a summary table of the technical issues/recommendations identified during the review.

INTRODUCTION/BACKGROUND

Review Process
Provide an overview of the approach used to conduct the review. Reference planning documents.

Technical Scope Reviewed
Provide a detailed description of the technical scope that was reviewed

Provide the following for each technical issue identified during the review:

- ***Subject Area***
  Identify the applicable subject area reviewed
- ***Condition at Review***
  State the contributing factors that were observed during the review that lead to the identification of the technical Issue
- ***Technical Issue***
  State the technical issue identified during the review.
- ***Recommendation***
  State the review team's recommendation for addressing the identified technical issue.
- ***Benefit of Action***
  State how the technical scope will be benefited by adequately addressing the identified technical issue.

RESULTS
Provide results and recommendations in summary narrative and in terms of the five observation categories listed in Table 4.

ATTACHMENTS
Include the following planning documents:
- *References*
- *Charter*
- *Definitions*
- *Review Team biographies*

Attachment G, ETR Issue Response Plan

ID	Recommendation	Response	Action Office	Target Complete Date
6-2	A program to investigate processes that will dissolve the material and could be processed through the Saltstone systems should be initiated to address the risk that the water and salt flushes are not sufficiently effective in achieving compliance with the TPD acceptance criterion established	Initiate pilot testing with surrogate material. (SST-GES-2006-00014)	Field Office	mm/dd/yy

ID
Provide a unique identifier for each recommendation to be addressed by the issue response plan. Use the same identifiers as established in the External Technical Review report.

Recommendation
Provide a descriptive statement for each recommendation to be addressed by the issue response plan. Recommendations listed in the issue response plan are those identified in the External Technical Review Report.

Response
Indicate the identified actions to be taken to address the recommendation. If the response to the recommendation is provided in a separate report, the report may be referenced here.

Action Office
Indicate which office (i.e., Field Office, EM-20, etc.) has responsibility for responding to the recommendation and ensuring actions are completed to address the recommendation.

Target Complete Date
Provide the expected data by which the identified response actions will be completed.

Attachment H, Closeout Document

<Document Number>

<Date>

TO: ***<EM-20 recipient>***
<EM-3 recipient>

FROM: ***<Enter Name of Field Office>***

This document certifies that the issues identified in ETR Report *<reference document #>* and addressed in Issue Response Plan(s) *<list applicable document # references>* have been verified to be complete.

REFERENCE

<Enter applicable document # references e.g., action closure documents>

Field Office Certification:

Signature	**Date**

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

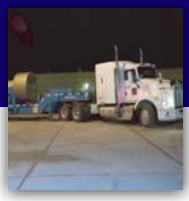
Standard Review Plan (SRP)

Preliminary Design Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

PRELIMINARY DESIGN REVIEW MODULE

September 2008

[This Review Module was used to develop the Review Plan for Oak Ridge Bldg. 3019 30% Design Review. Lessons learned from Oak Ridge Bldg. 3019 30% Design Review have been incorporated in the current version of the Module.]

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

CD-(N)	Critical Decision – (numbered)
EM	Office of Environmental Management
IPT	Integrated Project Team
ISM	Integrated Safety Management
MEL	Master Equipment List
NFPA	National Fire Protection Association
NPH	Natural Phenomena Hazards
PDSA	Preliminary Documented Safety Analysis
PDR	Preliminary Design Review
PEP	Project Execution Plan
P&ID	Piping and Instrumentation Diagram
PDRI	Project Definition Rating Index
PSDR	Preliminary Safety Design Report
QA	Quality Assurance
SDD	System Design Description
SDS	Safety Design Strategy
SRD	Systems Requirements Document
SSC	Structures, Systems and Components
SQA	Software Quality Assurance

I. INTRODUCTION

Design Reviews are an integral part of the contractor and federal project management process. As stated in DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets:*

> *Beginning at CD-1 and continuing through the life of the project, as appropriate, Design Reviews are performed by individuals external to the project. Design Reviews are performed to determine if a product (drawings, analysis, or specifications) is correct and will perform its intended functions and meet requirements. Design Reviews must be conducted for all projects and must involve a formalized, structured approach to ensure the reviews are comprehensive, objective, and documented.*

The preliminary design stage is of special interest because it is the first step in the project execution phase, when the conceptual design is evolved to a depth and level of detail that supports establishment of a Performance Baseline. This is an important stage in the project that has large cost implications associated with technical decisions, and the potential impacts of revising these decisions later in the project can be significant[1].

In preparation for the CD-2 approval, the Federal Project Director must ensure that the contractor is ready to proceed with final design. This involves verification that the preliminary design is sufficiently mature, such that it provides an adequate basis for safety, cost, and schedule decisions/estimates. The preliminary design review (PDR) supports this goal by evaluating the technical adequacy of the engineering design, as well as safety and quality assurance related activities[2].

II. PURPOSE

The PDR Module is a tool that assists DOE federal project review teams in evaluating the technical sufficiency of the preliminary design prior to CD-2 approval. The PDR Module focuses on the maturity of engineering design, safety, and quality assurance to determine whether it meets overall design commitments, and technical/safety requirements. It also evaluates whether the design supports performance of the established facility functions. A PDR's principal focus is on the effectiveness of the design in meeting safety, health, and engineering standards, addressing technical risks, and ensuring successful constructability. Additionally, PDR's should concentrate, as appropriate on the design aspects associated with interfaces that rely on existing site infrastructure. PDRs may include project Quality Assurance program effectiveness in addressing a project's design and configuration management needs as well as effectively implementing requirements established in 10CFR830, Subpart A and DOE O 414.1C.

[1] Decisions at other stages of design can have similar impacts and also warrant a technical review. These activities are addressed in DOE-EM review modules for conceptual and final design.

[2] The PDR does not include safety evaluations performed in support of DOE-STD-1189-2008, though it does consider interfaces and outputs from facility safety basis activities.

This Module does not explicitly target other project areas, including cost and schedule, security, and environmental protection. The safety basis review in the PDR is focused on the interface between safety basis development and design at the preliminary design stage. Safety basis review guidance is established by DOE directives, including DOE-STD-1104.

III. ROLES AND RESPONSIBILITIES

A successful PDR depends on an experienced and qualified team. The team should be augmented with appropriate subject matter experts selected to complement the specific technical concerns of the project being reviewed (e.g., Structural, Seismic, Mechanical Engineering, Quality Assurance, etc.). The specific types of expertise needed will be dependent on the type of facility being reviewed, as well as other factors such as complexity and hazards/risks.

It is preferred that personnel selected to participate in a design review have design experience. This is particularly relevant for reviewers who evaluate engineering design elements against industry standards or other regulatory design requirements. It may not be practical or necessary for some other subject matter experts, such as various safety disciplines, to have this experience.

Management support is another necessary component to a successful PDR. Field element managers, as well as the Federal Project Director, must recognize the importance of the PDR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the PDR process.

The roles and responsibilities for all involved in the PDR must be clear and consistent with various requirements of DOE O 413.3A and the DOE FRAM. The table below provides a compilation of design review roles and responsibilities.

Table 1. PDR Roles and Responsibilities

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the design review.
	Facilitates the conduct of the design review. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Identifies the need for a PDR and determines the scope of the review effort.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.

Position	Responsibility
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the completion of corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the areas to be reviewed.
	Based on the areas selected for review, project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the design review pre-visit.
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of the data call and forwards to the Federal Project Director, a list of documents, briefings, interviews, and presentations needed to support the review.
	Forwards the final review plan to the Acquisition Executive for approval.
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review and characterizes the findings.
	Coordinates incorporation of factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the Acquisition Executive for approval.
	Participates, as necessary in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for assigned area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares input to the review report.

Position	Responsibility
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.

IV. REVIEW SCOPE AND CRITERIA

A primary objective of the preliminary design is to provide sufficient information to support development of the project's Performance Baseline for CD-2 approval. The Federal Project Director will have to determine whether the preliminary design is at the appropriate level of maturity to proceed with a design review. This typically occurs at some point after the design contractor declared that certain milestones described in the project schedule have been achieved.

Specific objectives of the PDR that may be appropriate depending on the project include:

- Ensure that the design will meet program requirements as defined in the contract
- Ensure that the design is compliant with the requirements of DOE Order 420.1B, or applicable exemptions have been initiated and accepted by the appropriate approval authority.
- Ensure that the design is compliant with applicable codes and standards, and
- Ensure that the design incorporates the approach to minimize or remove hazards, or if that cannot be achieved, to provide a robust engineered controls, relying on administrative controls as a last resort.

The preliminary design for new construction projects is generally accepted around 30% of the total design effort. General guidance is given in DOE M 413.3-1 for the level of design completion expected to support the CD-2 phase of the project, and is described as follows:

> *When the project is less complex, such as a facility repair with single design, the percent complete is generally equivalent to 20 to 35 percent of the total design effort. For complex projects, the percentage of design may not be definitive because these projects may have many subsystems undergoing concurrent designs that may be at various stages of completion.*

Establishing whether the preliminary design milestone has been achieved is to some degree subjective and judgment based. On the one hand, expected safety decisions and supporting analyses/documentation appropriate at the preliminary design stage are well described in DOE-STD-1189-2008. Likewise, project cost and schedule related items expected to be completed at this stage are described in DOE O 413.3A. Maturity of the engineering design is not as straightforward in terms of explicitly completed deliverables.

The status of the engineering design is the main determining factor as to whether a preliminary design review should be conducted. One approach to evaluating progress is to examine specific engineering disciplines and the design actions/documents that are completed. Collectively, this will give an approximation of whether the project has achieved adequate progress in the range of 30% completion. Guidelines that support this approach are provided in Table 2 and are meant to be rough approximations.

Table 2, Preliminary Design Completion Goals

Engineering Discipline	Preliminary Design Goals
Process Engineering	All process equipment identified and sized
	Layouts and flow diagrams complete
	Effluents qualified
	Safety systems identified
Architectural	Plans at 85%, except for notes, dimensions, and sections
	Sections-70% completion
	Elevations-70% completion
	Details-40% completion
	Schedules -80%
Civil	Grading Plan-50% completion
	Site Plan with utilities -90%
	Calculations -75%
Structural	Calculations-85% to match architectural progress
	Drawings show basic framing system
Piping	Calculations-70% completion
	Schematics showing major components; general arrangements and flow patterns of each system-90% completion
	Brief tabulation of major equipment data: equipment size, capacity, physical data, etc; materials of construction; brief functional requirements;
Electrical	Initial start of one-line diagram, legend, notes
	Basic power and lighting plan
	General layout of electrical distribution, both interior and exterior
	Locations of substation feeders, switchgear, panelboards
	Preliminary typical layout of lighting and receptacle arrangements, location of control devices, motors, fire alarm devices
Instrumentation	Instrumentation system diagram and tabulation
	Control room layout and general instrumentation system field layout
	Design calculations

Another tool that is helpful in evaluating progress is the Environmental Management Project Definition Rating Index (PDRI). This evaluation is used by the IPT in evaluating the progress of the project at each critical decision established in DOE O 413.3A. Although PDRI scores are not used as a "go/no-go" requirement for CD approval, the scores are an important factor in the decision to proceed to the next project phase. PDRI scores can provide insight on preliminary design progress. Additional information on the PDRI can be found in http://www.em.doe.gov/Pages/pdri.aspx.

Once it has been determined that the design is sufficiently mature for the review, the scope of a PDR is determined by factors such as the types and magnitude of hazards, the complexity of the facility or process, current stage of the design, and the project mission. These influences are considered when the PDR is commissioned, and they are reflected in the final review criteria selected by the review team. Once selected, the review criteria define the planned scope of the PDR.

This PDR Module provides a set of review criteria that are organized into several technical/safety areas and engineering disciplines. These review areas are summarized below and include general requirements, radiation protection, criticality safety, fire protection, safety basis, integrated safety management, quality assurance (including software quality assurance), civil/structural, engineering design (process design/layout, mechanical and piping, electrical, instrumentation and control, HVAC), and configuration management. For each review area, Appendix A of this Module provides overall performance objectives and then a subset of review criteria that satisfy each performance objective.

These performance objectives and review criteria provide consistent guidance to project-specific design review teams to tailor to their respective review areas. In some cases, review criteria may not be applicable to a particular project for a valid reason (e.g., conscious decision to accept immature design because of complex technical issues still to be evaluated). In these cases, the review team member should document the rationale supporting such assertions in order to provide completeness in the review process.

General Requirements

This area of the review is intended to capture the overall progress with respect to completion of design documents and deliverables associated with the preliminary design stage. This includes various management documents, progress of required technical studies, design criteria, design reports, system descriptions, and other higher tier planning documents. The focus of the PDR is to ensure that the design supports safe operation in all disciplines and that engineered control features are included in the design where appropriate. The review should also verify that the project has a mechanism to capture and manage important assumptions that could result in design changes if not supported through later stages of design. Subsequent evaluation of the process used to validate assumptions may be included in follow-on reviews.

Radiation Protection

This area is focused on ensuring that the preliminary design supports safety of operations and activities involving radiological material through engineered controls and barriers. A major emphasis of the review is concerned with 10 CFR 835 Subpart K – Design and Control elements and with physical design elements (e.g., confinement, shielding) rather than overall radiological control program requirements. Other aspects of 10 CFR 835, as well as DOE-STD-1098-99, *Radiological Control*, and the contractor's ALARA Program also require verification within the preliminary design.

Criticality Safety

The intent of this review area is to ensure that the preliminary design adequately considers the potential for criticality in planned activities and that the design implements the necessary and appropriate controls consistent with DOE O 420.1B and related ANSI/ANS Standards. The PDR is focused on the physical design elements rather than the overall criticality safety program

Fire Protection

The purpose of this review area is to ensure that the preliminary design adequately considers fire safety in the planned activities and the design implements the necessary and appropriate controls consistent with DOE O 420.1B, DOE-STD-1066-99, NFPA standards, and other applicable regulatory requirements. The areas of review are derived from these requirements as related to physical design elements rather than the overall the fire protection program.

Safety Integration

Two primary aspects of safety integration are evaluated in the PDR. The first is on the overall management philosophy and approach to integrating safety into design. This review area establishes whether an Integrated Safety Management Description Document has been prepared and updated to address the preliminary design activities. A major component of this review area is also to establish that workplace hazards have been identified and incorporated into the facility design.

The second aspect is related to Safety Basis review area for Hazard Category 1, 2 or 3 nuclear facilities. This review area is not intended to conflict with other ongoing reviews of the Preliminary Safety Design Report, which is prepared in accordance with DOE-STD-1189. Rather, it focuses on verifying that controls derived from the safety basis are adequately captured in the preliminary design. This includes verification that appropriate safety classifications are assigned to SSCs within design documentation and that design commitments are consistent with DOE O 420.1B. The DOE review of the contractor's safety basis programs and activities is covered in DOE-STD-1104. This should include consideration of site characterization, including NPH elements (e.g., seismic, wind,

flood), and appropriate performance criteria, integrated with the Civil/Structural elements below.

Quality Assurance

This review is primarily derived from the requirements of ASME NQA-1- 2000 or later edition and 10 CFR 830 Subpart A and focuses on the design elements rather than the overall QA program. The primary objectives are to ensure that (1) design inputs are correctly selected and translated into design documents in a timely manner; (2) design methods are appropriate; (3) organizational and physical interfaces are identified and controlled; (4) suitable materials, parts processes, and inspections and testing criteria have been specified; (5) changes to design are controlled in a manner commensurate with the original design; (6) the design is independently verified to be adequate; and (7) documentation and records of the design and design verification processes are maintained in accordance with the QA program. A software quality assurance (SQA) review should also be conducted as part of the overall QA review. This includes any software used to classify, design, or analyze structures, systems and components relied on to protect workers, the public and environment.

The requirements identified in 10 CFR830.122, Criterion 6 addresses QA for the design process and form the primary basis for the performance objectives. Also of relevance to the preliminary deign are requirements from DOE Order O 414.1C, Quality Assurance, and the contractor's project specific Quality Assurance Plan.

Civil/Structural

The purpose of this review area is to ensure that progress of the geotechnical/seismic studies, structural design and associated calculations, drawings and specifications are on track with the preliminary design stage. Requirements from DOE O 420.1B and the DOE standard 1020 series related to NPH design form a major emphasis for the PDR. Some level of validation associated with design calculations (depending on availability) will be involved, though not to the extent of the final design review process. Proper use of national standards, such as those promulgated by the American Concrete Institute (ACI), American Institute of Steel Construction (AISC), American Welding Society (AWS), etc. throughout project civil/structural specifications, will be confirmed.

Engineering Design

A major emphasis of the PDR is on the engineering functions that relate to facility systems necessary for confining hazardous and radioactive materials, either as a direct barrier or supporting a critical function of a safety system. The PDR Module addresses performance objectives and criteria according to process design/layout, mechanical and piping, electrical, instrumentation and control, and HVAC. A number of DOE directives and industry standards provide good engineering principles, as well as functional design requirements, that form the basis for the PDR. Some examples are as follows:

- DOE Order O 420.1B, Facility Safety
- DOE-STD-3024-98, Content of System Design Descriptions (SDD)
- DOE-HDBK-1169-2003, Nuclear Air Cleaning Handbook
- DOE-STD-1189-2008, Integration of Safety into the Design Process
- DOE-HDBK-1132-99, Design Considerations
- DOE-HDBK-1092-2004, Handbook on Electrical Safety

Configuration management

Although Configuration Management is normally managed from within the Engineering Organization, its application to a construction project begins very early in the project planning and continues throughout the life of the project. For this reason, as well as for its importance in satisfying facility safety requirements it should be reviewed as a separate area. The review focuses on configuration management requirements found in DOE Order O 420.1B, *Facility Safety*; DOE STD-1073-2003, *Configuration Management Program*; and the Site/Contractor Configuration Management Program

V. REVIEW PLANS AND DOCUMENTATION

The results of a PDR will be used by the DOE Federal Project Director and ultimately the Acquisition Executive to help determine whether project funds may be authorized to conduct final design activities. It is important to clearly document the methods, assumptions and results of the PDR. Section 8 of the SRP provides guidelines for preparing a Review Plan and a final report.

The following activities should be conducted as part of the Review Plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents, assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this Module.
- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provided for a unique identifier for each line of inquiry, arranged by subject area (e.g. Management-Personnel and Qualifications, Management-Processes and Systems, Technical-Civil, etc.) such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. The method used the basis for closure/comment/finding and the result of the inquiry should all be documented and tracked.

The Review Plan should be broken down to provide coverage of the following topics.

Review Coverage

The physical areas of the facility operations that are subject to the PDR should be presented, along with subject areas that are being reviewed. Any areas that are excluded from the review should be discussed, along with the rationale for exclusion.

Design Assumptions

Design assumptions include any process decisions that frame the scope of the design effort and must be considered by reviewers when validating performance. This may include assumptions such as final product forms or performance characteristics related to operational steps or processes. Any explicit expectations imposed on the contractor by DOE, above and beyond those requirements and standards contained in the design contract, are also important assumptions that should be conveyed so that actions to modify the contract can be initiated to support document submittal/approval.

Performance Baseline Documents

The primary documents that form the project technical requirements and that are the basis for review criteria should be referenced in this section. At a minimum this should list the DOE contract that commissions the design, Facility and Design Description Documents, and DOE Order 420.1B and associated review guides/standards.

Design Documents

Design documents include facility documents expected to be provided to the Review Team. A detailed inventory list of all documentation is not necessary in this section. Rather, it should focus on document types expected. Where applicable, this includes the following types of documents: Facility and Design Description Documents; process flow diagrams; Preliminary Safety Design Report; structural drawings, calculations and specification; electrical drawings, calculations and specifications; instrumentation and controls drawings, calculations and specifications; mechanical drawings, calculations and specification; process system drawings, calculations, and specifications.

Performance Objectives and Criteria

The performance objectives and criteria that apply to the review process will be selected and presented in this section, or attached as an appendix to the Review Plan. These should be based on the EM Preliminary Design Review Module, Appendix A, as applicable based on specific project characteristics. The rationale for selection should be presented.

VI. REFERENCE MATERIAL

REFERENCES

1. DOE Order DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*
2. DOE Manual DOE M 413.3-1, *Project Management for the Acquisition of Capital Assets*
3. DOE Standard DOE-STD-1189-2008, *Integration of Safety into the Design Process*.
4. DOE Order DOE O 420.1B, *Facility Safety*
5. DOE Guide DOE G 420.1-1, *Nonreactor Nuclear Safety Design Criteria and Explosives*
6. DOE G 420.1-1, *Nonreactor Nuclear Safety Design Criteria and Explosives Safety Criteria Guide for use with DOE O 420.1, Facility Safety* DOE Order DOE O 430.1B, Real Property Asset Management
7. DOE Guide DOE G 430.1-1, Chapter 3, Stages of Project Development
8. DOE Standard DOE STD -3024-98, *Content of System Design Descriptions*
9. DOE Standard DOE-STD-3006-2003, *Handbook for the Conduct of Operational Readiness Reviews*
10. DOE Handbook DOE-HDBK-1132-99, *Design Considerations*
11. DOE O 414.1C, *Quality Assurance*
12. DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1C, Quality Assurance*

OTHER SOURCES CONSULTED

1. SPD-SWPF-217, Salt Waste Processing Facility Independent Technical Review
2. U-233 Material Downblending and Disposition Project 60% Design Review Report, January 2008, Revision 0
3. NUREG-1718, *Standard Review Plan for the Review of a Mixed Oxide (MOX) Fuel Fabrication Facility*
4. DOE Order O 6430.1A, *General Design Criteria* [Archived]

Appendix A - Performance Objectives and Criteria

Legend of Safety and Engineering Review Topics

Review Topical Area	Identifier
General Requirements	GR
Radiation Protection	RP
Criticality Safety	CS
Fire Protection	FP
Safety Integration	SI
Quality Assurance	QA
Civil/Structural	NPH
Engineering Design	ED
-Process Design/Layout	ED-1
-Mechanical and Piping	ED-2
-Electrical, Instrumentation and Control	ED-3
-HVAC	ED-4
Configuration Management	CM

Table 3 – Performance Objectives and Criteria

ID #	Performance Objectives and Criteria	Met?
General Requirements		
GR-1	Design progress on the facility meets preliminary design expectations, as defined in site procedures and meets Performance Requirements developed in the Design Requirements Document?	
	Preliminary design addresses safety and health standards, technical risks, construction and operability requirements? (GR-1.1)	
	Clear and complete system for tracking design assumptions, to assure their resolution prior to issue of final design? (GR-1.2)	
	Design incorporates adequate provisions for the safe removal, treatment, and disposition of secondary waste and other byproducts of the process? (GR-1.3)	
	Where process equipment will be exposed to demanding environmental conditions, is the equipment expected to survive the environment long enough to fulfill its mission? (GR-1.4)	
	The project has identified all assumptions and requirements that are required to be carried forward to ensure that the final design, construction, and administrative controls are developed? (GR-1.5)	
GR-2	System Description documentation properly integrates the Facility design with the Process design?	
	Structural design for the facility has been coordinated with the process design effort to ensure adequate space is available for installation and operation of all the equipment that is designated to be installed? (GR-2.1)	
	System Design Descriptions prepared for safety related systems and meet the requirements of DOE Order O 420.1B and DOE Standard DOE STD -3024-98, Content of System Design Descriptions? (GR-2.2)	
	Facility envelope contains adequate space to accommodate alternative process technology decisions? (GR-2.3)	
GR-3	A process is in place to resolve any remaining technical uncertainties and to validate design assumptions and calculations?	
	All elements of the process demonstrated at full scale and production throughput verified by demonstration or calculation? (GR-3.1)	
	Prototypes being acquired for any machine or process which has not previously been used in this application? Does the testing schedule provide confidence that the project schedule can be met? (GR-3.2)	
	Design assumptions are identified and there is a process in place to verify them with actual field measurement or modeling? (GR-3.3)	
	New fluid systems are being tested with mock-ups or with surrogate material to verify flow rates, hold up issues, or capacity? (GR-3.4)	
Radiation Protection		
RP-1	The preliminary facility design meets the requirements of 10 CFR 835 Subpart K – Design and Control?	
	The primary measures taken to maintain radiation exposure in controlled areas ALARA accomplished through physical design features (e.g.,	

ID #	Performance Objectives and Criteria	Met?
	confinement, ventilation, remote handling, and shielding)? (RP-1.1)	
	Design features adequate to meet design objectives for controlling personnel exposure (concrete walls of sufficient thickness; penetrations and galleries adequately designed)? (RP-1.2)	
	Administrative controls employed only as supplemental method to control radiation exposure where use of physical design features is demonstrated to be impractical? (RP-1.3)	
	Optimization methods used to assure that occupational exposure is maintained ALARA in developing and justifying facility design and physical controls? (RP-1.4)	
	Design objectives for controlling personnel exposure from external sources of radiation in areas of continuous occupancy (2000 hours per year) to maintain exposure levels below an average of 0.5 mrem (5 microsieverts) per hour and as far below this average as is reasonably achievable? The design objectives for exposure rates for potential exposure to a radiological worker where occupancy differs from the above shall be ALARA and shall not exceed 20 percent of the applicable standards in Sec. 835.202. (RP-1.5)	
	Confinement and ventilation design features are relied on for control of airborne radioactive material, consistent with a design objective to avoid releases to the workplace atmosphere and in any situation, and then to control the inhalation of such material by workers? (RP-1.6)	
	Design or modification of a facility and the selection of materials include features that facilitate operations, maintenance, decontamination, and decommissioning? (RP-1.7)	
RP-2	The preliminary facility design meets the requirements of 10 CFR 835 Subpart E, Monitoring of Individuals and Areas?	
	Provides for : (1) Adequately documenting radiological conditions. (2) Detecting changes in radiological conditions. (3) Detecting gradual buildup of radiological material. (4) Verifying the effectiveness of engineering and process controls in containing radioactive materials and reducing radiation and/or radioactive material (5) Identifying and controlling potential sources of individual exposure to radiation and/or radioactive material (RP-2.1)?	
	Identifies instruments that are: (1) Appropriate for the type(s), levels, and energies of the radiation(s) encountered (2) Appropriate for existing environmental conditions. (RP-2.2)	
RP-3	The facility design is consistent with the requirements of 10 CFR 835 Subpart F – Entry Control Program?	
	Preliminary facility design provides for entry control commensurate with the existing and potential radiological hazards within the area including one or more of the following methods: a. Signs and barricades	

ID #	Performance Objectives and Criteria	Met?
	b. Control devices on entrances; c. Conspicuous visual and/or audible alarms; d. Locked entrance ways; or e. Administrative controls? (RP-3.1)	
	No control(s) are installed at any radiological area exit that would prevent rapid evacuation of personnel under emergency conditions? (RP-3.2)	
	Preliminary facility design provides for entry control for high and very high radiation areas? Such areas shall be monitored as necessary during access to determine the exposure rates to which the individuals are exposed (RP-3.3)	
	One or more of the following features are used for each entrance or access point to a high radiation area where radiation levels exist such that an individual could exceed a deep dose equivalent to the whole body of 1 rem (0.01 sievert) in any one hour at 30 centimeters from the source or from any surface that the radiation penetrates: f. A control device that prevents entry to the area when high radiation levels exist or upon entry causes the radiation level to be reduced below that level defining a high radiation area; g. A device that functions automatically to prevent use or operation of the radiation source or field while individuals are in the area; h. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; i. Entryways that are locked. During periods when access to the area is required, positive control over each entry is maintained; j. Continuous direct or electronic surveillance that is capable of preventing unauthorized entry; k. A control device that will automatically generate audible and visual alarm signals to alert personnel in the area before use or operation of the radiation source and in sufficient time to permit evacuation of the area or activation of a secondary control device that will prevent use or operation of the source. l. Very high radiation area physical controls. In addition to the above requirements, additional measures shall be implemented to ensure individuals are not able to gain unauthorized or inadvertent access to very high radiation areas. m. No control(s) shall be established in a high or very high radiation area that would prevent rapid evacuation of personnel. (RP-3.4)	
Criticality Safety		
CS-1	The preliminary design ensures that operations with fissionable material remain subcritical under all normal and credible abnormal conditions?	
	The preliminary design satisfies the requirements of revisions to the consensus nuclear criticality safety standards of American National Standards Institute (ANSI)/American Nuclear Society (ANS) 8 in effect at the time of the approval of DOE O 420.1B? (CS-1.1)?	
	The preliminary design is such that no single credible event or failure can	

ID #	Performance Objectives and Criteria	Met?
	result in a criticality (DOE O 420.1B)? (CS-1.2)	
	Preliminary criticality safety evaluations for fissionable materials operations have been performed in accordance with DOE-STD-3007-2007, *Guidelines for Preparing Criticality Safety Evaluations at Department of Energy Non-Reactor Nuclear Facilities***,** or they are approved by DOE (e.g,. parameters, limits and controls required to maintain sub-criticality for all normal and credible abnormal conditions)? (DOE O 420.1B) (CS-1.3)	
	The preliminary design includes controls that are derived from the criticality safety evaluation in the preferred order of passive engineered controls, active engineered controls, or lastly administrative controls? (DOE 420.1B) (CS-1.4)	
	The preliminary design implements the double contingency principle defined in ANSI/ANS 8.1, *Nuclear Criticality Safety in Operations with Fissionable Material outside Reactors*? (CS-1.5)	
	The preliminary design provides an explanation whenever an ANSI/ANS standard or other DOE O 420.1B requirement is not planned to be implemented? (CS-1.6)	
CS-2	The preliminary design ensures that nuclear criticality safety is controlled by one or more parameters of the system(s) within sub critical limits and by allowances for process contingencies?	
	The preliminary design demonstrates controls through one or more of the following as appropriate***:*** ***a.*** Physical constraints ***b.*** Use of instrumentation ***c.*** Chemical means ***d.*** Reliance on natural or credible course of events ***e.*** Administrative procedures ***f.*** Other means? (CS-2.1)	
	All controlled parameters and their limits are specified and the influence of variations of these parameters on the k_{eff} is understood and documented in the preliminary design supporting documents? (CS-2.2)	
	The preliminary design relies upon equipment design, where practicable, in which dimensions are limited rather than administrative controls? (CS-2.3)	
	The preliminary design relies upon the use of neutron absorbers, if such reliance is consistent with the requirements of section 4.2.4 of ANSI/ANS 8.1, 8.5 (rashig rings) and 8.14 soluble neutron absorbers? (CS-2.4)	
	Subcritical limits derived from experiments or calculations are in accordance with the requirements of sections 4.2.5 and 4.3 of ANSI/ANS 8.1? (CS-2.5)	
CS-3	The design and use of a criticality alarm system(s) is in accordance with the requirements of ANSI/ANS 8.3?	
	The alarm system coverage meets the requirements of section 4.2 of ANSI/ANS 8.3? (CS-3.1)	
	The criticality alarm system design supports the requirements of section 4.3 of ANSI/ANS 8.3? (CS-3.2)	
	Dependability of the preliminary design for a criticality alarm system is	

ID #	Performance Objectives and Criteria	Met?
	consistent with the requirements of ANSI/ANS 8.3 section 4.4? (CS-3.3)	
	The criticality alarm system(s) meet the criteria identified in ANSI/ANS 8.3 section 5? (CS-3.4)	
	The system supports testing and maintenance as identified in ANSI/ANS 8.3, Section 6? (CS-3.5)	
Fire Protection		
FP-1	The preliminary design ensures that it provides a level of safety sufficient to meet DOE goals and objectives?	
	Fulfills requirement of highly protected risk (HPR) (DOE O 420.1B) (FP-1.1)?	
	Prevents loss of safety functions and safety systems as determined in the preliminary hazards analysis and provides defense in depth (DOE O 420.1B) (FP-1.2)?	
	Prevents fires and related effects that cause an unacceptable release of hazardous or radiological materials (FP-1.3)?	
	Prevents fires and related effects that cause vital DOE program to suffer an unacceptable interruption (FP-1.4)?	
	Prevents fires and related effects that result in the loss of critical process controls (FP-1.5)	
FP-2	The preliminary design meets or exceeds applicable fire protection and emergency response provisions of the governing local building code (the International Building Code if no local code applies), applicable regulations, DOE fire safety criteria, and industry standards, such as those promulgated by the NFPA?	
	The design identifies and reflects the full spectrum of applicable facility related fire protection and emergency response criteria as delineated by DOE and as adopted when the design criteria are / were approved. (FP-2.1)?	
	The design reflects and conforms to the provisions of the following chapters/sections of the local building code (International Building Code (IBC) if no local code applies): • Use and Occupancy Classification • Special Fire Safety Design Requirements for Unique Structures • Height and Area Limitations • Types of Construction • Fire-resistance Design Requirements • Combustibility of Interior Finishes • Fire Protection Systems • Means of Egress • Access for Emergency Vehicles • Fire resistance of Exterior Walls and Roofs • Protection of Structural Steel • Fire Protection and Emergency Services during Construction (FP-2.2)?	
	The design reflects and conforms to the provisions of the following chapters/ sections of the local fire code (International Fire Code if the IBC applies):	

ID #	Performance Objectives and Criteria	Met?
	• Fire Service Features • Building Services and Systems • Fire-resistance Rated Construction • Fire Protection Systems, Including Fire Water Supply • Means of Egress • Fire Exposures, including Wild Land Fire Risk • Flammable and Combustible Liquids and Gases • Hazardous Materials • Emergency Vehicle Accessibility to Facilities (FP-2.3)?	
	The design reflects and conforms to the facility specific provisions of Section 2 *Fire Protection* of Appendix A to 10 CFR Part 851 (FP-2.4)?	
	The design reflects and conforms to the following facility specific provisions of 29 CFR 1926, *Construction Industry Regulations*: • Subpart C, *General safety and Health Provisions* (Fire Safety and Emergency Services) • Subpart D, *Occupational Health and Environmental Controls* (Emergency Medical-related) • Subpart F, *Fire Protection and Prevention* • Subpart Z, *Toxic and Hazardous Substances* (FP-2.5)?	
	The design reflects and conforms to the facility specific provisions of Chapter II, *Fire Protection*; Section 3.c. *Fire Protection Design* of DOE O 420.1B, *Facility Safety*. (Specific review elements are delineated in P.O. 3.) (FP-2.6)?	
	The design reflects and conforms to the following facility specific provisions of DOE G 420.1-3, *Implementation Guide for DOE Fire protection and Emergency Services Programs:* • Section 4.2, *Highly Protected Risk Status* • Section 4.5, *Program Documentation* (construction-related) • Section 4.6, *Fire Hazards Analysis* (preliminary design stage) • Section 4.9, *Baseline Needs Assessment* (emergency services) • Section 4.15, *Exemptions, Variances, Equivalencies* • Section 4.17, *Fire Protection Design* • Section 4.20, *Fire Suppression System Confinement or Containment* • Section 4.21, *Fire Protection System Classification* (FP-2.7)?	
	The design reflects and conforms to the following facility specific provisions of DOE-STD-1066-99, *Fire Protection Design Criteria*: • Chapter 5, *General Criteria* • Chapter 6, *Water Supply and Distribution System Criteria* • Chapter 7, *Automatic Sprinkler System Criteria* • Chapter 8, *Fire Alarm Systems* • Chapter 10, *Life Safety Criteria* • Chapter 11, *Electrical Equipment Criteria* • Chapter 12, *Protection Criteria for General Process Hazards*	

ID #	Performance Objectives and Criteria	Met?
	• Chapter 13, *Protection Criteria for Special Hazards* • Chapter 14, *Nuclear Filter Plenum Fire Protection* • Chapter 15, *Glovebox Fire Protection* (if included in scope) (FP-2.8)?	
	The design reflects and conforms to the following facility specific provisions of NFPA-801, *Standard for Fire Protection for Facilities Handling Radioactive Waste*: • Nuclear Safety Considerations • Identification of Hazards • General Plant Design • Life Safety Design Features • Fire Protection and Notification Systems • Equivalencies (FP-2.9)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1, *Uniform Fire Code* (Construction and Emergency Services Provisions) (FP-2.10)?	
	The design reflects and conforms to the facility specific provisions of NFPA-70, *National Electrical Code.* (FP-2.11)?	
	The design reflects and conforms to the facility specific provisions of NFPA-72, *National Fire Alarm Code* (FP-2.12)?	
	The design reflects and conforms to the following facility specific provisions of NFPA-80, S*tandard for Fire Doors and Fire Windows* (FP-2.13)?	
	The design reflects and conforms to the facility specific provisions of NFPA-90A, *Standard for the Installation of air Conditioning and Ventilating Systems* (FP-2.14)?	
	The design reflects and conforms to the facility specific provisions of NFPA-101, *Life Safety Code* (FP-2.15)?	
	The design reflects and conforms to the facility specific provisions of NFPA-241, *Standard for Safeguarding Construction, Alteration and Demolition Operations* (FP-2.16)?	
	The design reflects and conforms to the facility specific provisions of NFPA-780, *Standard for the Installation of Lightning Protection Systems* (FP-2.17)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1144, *Standard for Protection of Life and Property from Wildfire* (FP-2.18)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1141, *Standard for Fire Protection in Planned Building Groups* (FP-2.19)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1221, S*tandard for the Installation, Maintenance and Use of Emergency Services Communications Systems* (FP-2.20)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1710, *Standard for the Organization and Deployment of Fire Suppression Operations, Emergency Medical Operations, and Special Operations to the Public by Career Fire Departments* (FP-2.21)?	
FP-3	The preliminary design for the facility and supporting systems meets or exceed the following overarching facility-specific fire protection design criteria:	

ID #	Performance Objectives and Criteria	Met?
	A reliable and adequate supply of water for fire suppression. For preliminary design purposes, documentation (text and / or drawings) must include a commitment to conform to applicable criteria, as delineated above, and should also include a conceptual design description that encompasses; fire water storage (quantity and duration), pumps, distribution piping, materials, and other available details (FP-3.1)?	
	Noncombustible construction material for facilities exceeding the size limits established by DOE (see DOE-STD-1066-99, *Fire Protection Design Criteria)*. For preliminary design purposes, documentation must include a commitment to conform to applicable criteria, as delineated above, and should also include the type(s) of construction that will be featured for each facility and reference to the listed structural assemblies that are intended to meet the construction classifications (FP3.2)?	
	Complete fire-rated construction and barriers, commensurate with the applicable codes and fire hazards, to isolate hazardous areas and minimize fire spread and loss potential consistent with limits as defined by DOE. Design documents should describe in general terms the subdivision of each facility into fire areas, as defined in DOE-STD-1066-99. The description should include a summary of how penetrations of fire area boundary construction will be protected. This description should address doorways, ventilation penetrations, cable and conduit penetrations and any anticipated unprotected openings in fire area walls and floor/ceiling assemblies (FP-3.3)***?***	
	Automatic fire extinguishing systems throughout all significant facilities and in all facilities and areas with potential loss of safety class systems (other than fire protection systems), significant life safety hazards, unacceptable program interruption, or fire loss potential in excess of limits defined by DOE. For preliminary design purposes, documentation (text and drawings) should describe which fire areas will be protected by fire extinguishing systems, the extent of protection, the governing NFPA Standards and relevant DOE criteria, and any anticipated design issues (such as high vaulted ceilings or areas with high ventilation rates). There must be a firm commitment to use listed materials which must be encompassed by a QA / QC program (FP-3.4)?	
	Redundant fire protection systems in areas where ***a.*** Safety class systems are vulnerable to fire damage, and no redundant safety capability exists outside of the fire area of interest, or ***b.*** The maximum possible fire loss (MPFL) exceeds limits established by DOE. An initial Maximum Possible Fire Loss (MPFL) calculation is provided to support the need for redundant systems. (FP-3.5)?	
	In new facilities, redundant safety class systems (other than fire protection systems) are located in separate areas and design documents identify those fire areas (such as a control room or automatic electric power transfer area) where redundant safety systems may be located. The description should	

ID #	Performance Objectives and Criteria	Met?
	include the nature and extent of redundant fire protection in these areas (FP-3.6)?	
	A means to notify emergency responders and building occupants of a fire (e.g., fire alarm or signaling system). The design should provide a conceptual description of a fire alarm / signaling system, with a commitment to conform to applicable criteria, to use listed components, and to subject the components to a QA / QC program (FP-3.7)?	
	Emergency egress and illumination for safe facility evacuation in the event of fire as required by applicable codes or fire standards. The design demonstrates that two remote exits are available from all occupied areas, except where permitted by the Life safety Code. Design documents provide an overview of the egress concept, including lighting and signage. Issues that might affect egress, such as security measures, should be identified without mentioning specific provisions (FP-3.8)?	
	Physical access and appropriate equipment that is accessible for effective fire department intervention (e.g., interior standpipe systems in multi-story or large, complex facilities). Design documents show access roads, location of fire hydrants, standpipe systems and fire department connections, entryways into facilities, and other design features (congested areas) that might adversely affect emergency services (FP-3.9)?	
	A means to prevent the accidental release of significant quantities of contaminated products of combustion and fire fighting water to the environment, such as ventilation control and filter systems and curbs and dikes. Such features would only be necessary if required by the preliminary FHA or preliminary safety analysis in conjunction with other facility or site environmental protection measures. The design provides a conceptual description of confinement and containment issues and their mitigation (FP-3.10)?	
	A means to address fire and related hazards that are unique to DOE and not addressed by industry codes and standards. Mitigation features may consist of isolation, segregation or the use of special fire control systems (water mist, clean agent, or other special suppression systems) as determined by the preliminary FHA. The design identifies atypical fire hazards (such as chemicals or processes) and the fire protection means intended to mitigate their corresponding fire risk (FP-3.11)?	
	That the fire protection systems are designed such that their inadvertent operation, inactivation, or failure of structural stability will not result in the loss of vital safety functions or inoperability of safety class systems as determined by the preliminary safety analysis or preliminary DSA. A description of processes is provided that will be used to evaluate for such risk and the possible means (physical safeguards such as shielding or barriers) that would likely be used to minimize the threat from inadvertent operation, inactivation, or other failure. (FP-3.12)?	
FP-4	The preliminary design shall identify conditions for which literal compliance with the above-referenced criteria cannot be met in a cost-effect manner and where	

ID #	Performance Objectives and Criteria	Met?
	alternative (equivalent) fire safety and emergency response features will be proffered.	
	Design documentation (text) manifests a process for identifying conditions for which literal conformance is not feasible or cost-effective. This description should include a requirement for an engineering analysis by qualified fire protection engineers, review and approval by engineers, review and approval by appropriate contractor management, and a commitment to submit all such equivalency determinations to the DOE Authority Having Jurisdiction (AHJ). (FP-4.1)?	
	Design documentation (text) manifests a system for identifying, tracking, and record keeping of all pending decisions regarding fire safety and emergency services equivalencies (FP-4.2)?	
	Design documentation (text) manifests a commitment to implement a design that conforms to governing fire safety criteria when there is no agreement with the DOE AHJ regarding a pending equivalency. (Default decisions regarding design are to literal conformance.) (FP-4.3)?	
FP-5	Where required by Paragraph 3.b. (5) of DOE O 420.1B a (Preliminary) Fire Hazards Analysis (FHA) has been completed and documented.	
	The PFHA has been completed under the supervision of a qualified (as defined by DOE) *or (as defined in DOE STD-1066-99)* fire protection engineer (FP-5.1)?	
	The scope and content of the PFHA are in conformance with the guidelines delineated in Section 4.6 of DOE G 420.1-3 (September 27, 2007 or current equivalent) (FP-5.2)?	
	The conclusions of the PFHA are incorporated into Design Safety Analysis documentation and integrated into design basis and beyond design basis accident conditions (FP-5.3)?	
	Provisions exist for updating the PFHA over time as significant changes occur (FP-5.4)?	

Safety Integration		
SI-1	Safety Basis Documents are prepared and consistent with preliminary design documents?	
	A Safety Design Strategy is prepared by the Safety Design Integration Team (SDIT) (SI-1.1)	
	A Preliminary Safety Design Report (PSDR) is prepared by the SDIT (SI-1.2)	
	The PSDR has been reviewed by DOE and verified to meet expectations of DOE-STD-1189-2008, Appendix I, or where deficient, explicit conditions of approval established. (SI-1.3)	
	The SDS has been reviewed by DOE and verified to meet expectations of DOE-STD-1189-2008, Appendix E, or where deficient explicit conditions of approval established? (SI-1.4)	
	Design criteria are consistent with design commitments and requirements identified in the SDS? (SI-1.5)	
SI-2	The preliminary design incorporates sufficient defense in depth consistent with preliminary safety analysis?	
	The design includes multiple layers of protection to prevent or mitigate the unintended release of radioactive materials to the environment (e.g., isolation, confinement, successive physical barriers, minimizing material at risk, etc)? (DOE O 420.1B) (SI-2.1)	
SI-3	The preliminary design meets the requirements and objectives of DOE O 420.1B? This includes:	
	The preliminary design ensures that the facility is sited and designed in a manner to ensure adequate protection to health and safety of the public, workers, and the environment from the effects of accidents involving radioactive materials release. (SI-3.1)?	
	The preliminary design ensures that safety SSCs are designed commensurate with the importance of the safety functional requirements (SB-3.2)?	
	Safety Class electrical systems must be designed to preclude single point failure (SB-3.3)?	
	Process systems as identified in the preliminary design shall be designed to minimize waste production and mixing of radioactive and non-radioactive wastes (SB-3.4)?	
SI-4	The Integrated Safety Management Description has been prepared and incorporates preliminary design activities?	
	The requirements, methodology, and responsibility for ES&H activities are clearly identified and communicated? (SI-4.1)	
	The preliminary design incorporates an analysis of potential workplace hazards (industrial safety/hygiene) and establishes appropriate controls (SI-4.2)	
Quality Assurance		
QA-1	Design inputs are correctly translated into design documents in a timely manner?	
	Design inputs for interfacing organizations are specified in the design	

	documents or in supporting procedures? (QA-1.1)	
	The design incorporates applicable requirements and design bases (QA-1.2).	
	Design inputs are specified to the level of detail necessary to permit design activities to be correctly carried out and to provide a consistent basis for making design decisions, accomplishing design verification activities, and evaluating design changes (QA-1.3)	
	Design inputs are based upon contractual requirements and customer expectations and are technically correct and complete. (DOE G 414.1-2A) (QA-1.4)	
QA-2	Design methods used are appropriate	
	Responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. (NQA-1 300) (QA-2.1) This should include the integration function when multiple organizations, design efforts and systems are included in the total system design.	
	Design Analyses should be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. (NQA-1 400) (QA-2.2)	
	The design has been developed using sound engineering/scientific principles and appropriate standards. (QA-2.3)	
	Design assumptions, if necessary, are adequately described and reasonable (QA-2.4)	
	Design output compares reasonably to the design inputs (QA-2.4)	
QA-3	Organizational and physical design interfaces are identified and controlled	
	Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents related to an item or its processes, such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures (QA-3.1)	
	Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces (QA-3.2)	
QA-4	Suitable materials, parts, processes, and inspections and testing criteria are specified	
	The design provides for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of designed items. (DOE G 414.1-2A) (QA-4.1)	
QA-5	Changes to design are controlled in a manner commensurate with the original design (See CM, *Configuration Management*, for additional review criteria)	
	Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design (QA-5.1)	
QA-6	The design is independently verified to be adequate.	
	Design procedures identify the responsibilities of personnel verifying the design, the areas and features that require design verification, the pertinent	

	considerations to be verified, and the extent of documentation required to document verification (QA-6.1)	
	Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or tests) (QA-6.2)	
	The design has been verified or validated by individuals or groups other than those who performed the design work. (QA-6.3)	
	The design has been verified or validated before approval and implementation of the design. (QA-6.4)	
QA-7	Documentation and records are maintained in accordance with the QA program	
	Design documentation includes a list of approved and controlled computer codes. (DOE G 414.1-2A) (QA-7.1)	
	Design records include documentation such as design inputs, calculations, and analyses; engineering reports; design outputs; design changes; design verification activities; and other documents that provide evidence that the design process is adequately controlled in a timely manner. (DOE G 414.1-2A) (QA-7.2)	
	Procedures are established and described requiring documented verification of the dimensional accuracy and completeness of design drawings and specifications (QA-7.3)	
QA-8	Acquired software for safety-related calculations has been pre-verified or the results of the calculations performed verified for each application of the software to ensure it produces the correct solutions within the defined limits of its intended use.	
	Software acquired from a third party or from corporate inventories used in design calculations has been identified (QA-8.1).	
	Test cases that exercise the defined limits and physical problem being solved have been performed and the results verified to ensure acceptable results were generated from the software (QA-8.2).	
QA-9	Software used for classification, analysis and design of SSCs relied on for worker, public or environmental protection is controlled (QA-9.3).	
	Software, including spreadsheets, databases and their associated support tools (e.g., Excel, MS Access, Windows O/S) have been uniquely identified and the specific versions used in the design calculation noted (QA-9.4).	
	Software identified is stored in a location that is easily retrieval and access is restricted to authorized individuals (QA-9.5).	
	Updates to the software identified are created from this stored software (QA-9.6).	
QA-10	Spreadsheets and other software specifically created for use in the engineering design is developed using software quality and engineering practices appropriate for the impact on the engineering design.	
	Requirements for the spreadsheets and software are clearly described and documented in a manner that can be easily tested. The requirements are reviewed and approved (QA-10.1).	
	The structure, mathematical algorithms, control and logic flow, data structures applicable to the development of the spreadsheets and software is documented in enough detail for review by independent technical individual.	

	The independent review is documented (QA-10.2).	
	The spreadsheets and other software created for use in the engineering design are tested to ensure the documented requirements are met and produce the correct results for the problem being analyzed. The test results are documented and evaluated by a responsible authority to ensure the test requirements are met (QA-10.3).	
QA-11	Software configuration items are identified and controlled.	
	Products of the software development activities that need to be retained are identified and assigned a unique identifier. These products include the software requirements, software design, test cases and results, and records of reviews (QA-11.1).	
	The items identified are stored in a location that is easily retrieval and access is restricted to authorized individuals (QA-11.2).	
	Updates to the items identified are created from these stored versions (QA-11.3).	
Civil/Structural		
NPH-1	Structural design progress on the facility meets preliminary design expectations, as defined in site procedures, and satisfies performance categorization design requirements in accordance with DOE STD-1020, -1021, -1022, and -1023? (Note that this objective is in the process of being changed to meet DOE STD 1189 and ANSI/ANS 2.26-2004, Categorization of Nuclear Facility Structures, Systems and Components for Seismic Design; and ASCE/SEI 43-05, Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities. When adopted by DOE, this objective will be rewritten in terms of Limit States (LS) and Seismic Design Category (SDC).)	
	SSCs relied on to prevent significant onsite consequences are designated as Performance Category 3 for NPH hazard in accordance with DOE-STD-1021 (NPH-1.1)?	
	Appropriate codes and standards are selected and applied to the structural design (IBC, AISC, ACI) (NPH-1.2)?	
	Seismic loading is evaluated consistent with site-specific design response spectra (NPH1.3)?	
	The seismic design of systems and components accounts for adverse interactions from non-seismic structures, systems, and components (spatial interactions, spray interactions, and system interactions) (NPH-1.4)?	
NPH-2	Design calculations address major structures and SSCs and are complete and consistent with known conditions and facility layout at the preliminary design stage?	
	Calculations evaluate the capacity of connections between structural members (NPH-2.1)?	
	Calculations address all anticipated load cases (NPH-2.2)?	
	Calculations provide sufficient documentation of assumed inputs and outputs (NPH-2.3)?	
	Calculations consider structural behavior of the material to be used in construction? (NPH-2.4)	
Engineering Design - Process Design/Layout		
ED-1	The Facility Plans, Piping and Instrumentation Diagrams (P&ID), and preliminary	

	detail drawings have been coordinated with the Process Descriptions, Flow Diagrams, and Process Calculations and the facility layout supports the process requirements?	
	Facility and System drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-1.1)	
	System Design Descriptions (SDD) prepared for safety related systems and meet the requirements of DOE Order O 420.1B and DOE Standard DOE STD -3024-98, Content of System Design Descriptions? (ED-1.2)	
	SDDs describe the performance characteristics of the system which are important to safety and link the safety basis analysis to the selected controls? (ED-1.3)	
	The Structures, Systems and Components (SSC) of the safety related systems are properly characterized as to their safety pedigree in accordance with DOE O 420.1B and DOE-STD-3009? The necessary documents to support procurement and control of safety related SSCs have been developed? (ED-1.4)	
	The process equipment and system drawings meet the expectations of the Site procedure or contract specification for completeness and format? (ED-1.5)	
	The process equipment and system drawings in the submitted design package are accompanied by appropriate flow diagrams; calculations; and control parameters and setpoints? (ED-1.6)	
	Has a 3-D modeling system been applied to the design effort? The various engineering areas are being closely integrated into the layout? (i.e. electrical cable trays, HVAC ductwork, piping and instrument penetrations/runs) (ED-1.7)	
	Layout drawings and floor plans are coordinated with system drawings? The facility layout supports the process flow and facilitates movement of parts and tools to perform the facility mission? (ED-1.8)	
	The facility design includes adequate space for convenient access to major components (including piping, wiring, control tubing, etc.) during construction, testing, maintenance and inspection so that major disassembly is not required? (ED-1.9)	
	All engineering risks have been identified and addressed? If not, what risks remain? Are plans in place to resolve these issues prior to final design? (ED-1.10)	
	There is evidence that human factors principles are factored into the design (e.g., functional analysis, task analysis) (ED-1.11)	
	The Facility design addresses the good practices and guidance for layout, space allotment, hazards separation, and hazardous areas as identified in DOE-HDBK-1132-99. (ED 1.12)	
Engineering Design - Mechanical and Piping		
ED-2	The Mechanical and Piping drawings and supporting documentation are adequate to accomplish the design mission?	
	The process equipment and system drawings in the submitted design package meet the expectations of the Site procedure or contract specification for	

	completeness and format? (ED-2.1)	
	Piping and components meet the requirements of the designated Codes and Standards in the System Design Requirements document and materials are appropriate to the intended process? (ED-2.2)	
	The operating and design loads and load combinations are correctly specified for each system and equipment? Adequate calculations exist to support the selected design? (ED-2.3)	
	Vessels and piping systems are designed, sized, and qualified to the ASME Boiler and Pressure Vessel Code and ASME B31.3 code, including over-pressure protection? (ED-2.4)	
	Equipment and systems in high radiation areas are designed to minimize the need for repair or replacement? (ED-2.5)	
	Provisions are in place for periodic maintenance and inspection of systems and equipment to assure their continued integrity for the design life? (ED-2.6	
	The design for shop fabrication and field erection of systems and components (joining, welding, non-destructive examination, testing) is in accordance with the applicable codes and standards for each type of commodity? (ED-2.7)	
	The designs include the necessary strengthening, support, or restraints to meet the selected seismic performance criteria? (ED-2.8)	
	Adequate capacity exist in material transport systems to handle expected volumes of radioactive/hazardous materials during normal operating and accident conditions (ED-2.9)	
	Tanks and piping systems are of welded construction to the fullest extent possible (ED-2.10)	
	Tank and piping systems are designed to take advantage of gravity flow to reduce the potential for contamination associated with pumping and pressurization (ED-2.11)	
	All system components expected to be in contact with strong acids or caustics are corrosion resistant (ED-2.12)	
	Use of traps is avoided, and the piping is designed to minimize entrapment and buildup of solids in the system (ED-2.13)	
	The Facility design addresses the good practices and guidance for piping design and layout as identified in DOE-HDBK-1132-99. (ED 2.14)	
Engineering Design - Electrical, Instrumentation and Control		
ED-3	The electrical and instrument drawings and supporting documentation are adequate to accomplish the design mission?	
	The one-line diagrams and electrical distribution layout drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-3.1)	
	Where standard off-the-shelf electrical materials and equipment been selected, there are provisions for testing and labeling by a nationally recognized testing laboratory (international standards organization or recognized testing agency)? If not, evaluation and approval by the authority having jurisdiction (AHJ) has been performed? (ED-3.2)	
	Preliminary panel schedules and control diagrams are developed for the electrical systems? Load and fault calculations support the design	

	requirements? (ED-3.3)	
	The electrical portion of the design is sufficiently mature to define all major components (e.g., transformers, fuses and circuit breakers, and motors) as well as include adequate excess electrical capacity to provide for future expansion? (ED-3.4)	
	The basic cable tray layouts are sufficiently developed to identify layout interferences and material quantity needs? The cable tray designs have been integrated into a 3-D model? (ED-3.5)	
	When the facility includes a control room, the design considerations of DOE-HNDBK-1132-99, section 4.1, Control Centers/Control Rooms, have been taken into consideration? (ED-3.6)	
	The design incorporates provisions so that I&C system components can be tested periodically for operability and required functional performance (ED-3.7)?	
	Instrument channels and associated logic ensure that I&C components fail in a safe failure mode (ED-3.8)?	
Engineering Design - HVAC		
ED-4	The HVAC and Confinement System drawings and supporting documentation are adequate to meet DOE requirements and accomplish the design mission?	
	HVAC and Confinement System drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-4.1)	
	The design designations for seismic criteria of the safety related HVAC and Confinement Systems are consistent with the SDS and PDSR and are detailed enough to support procurement and cost decisions? (ED-4.2)	
	The HVAC Air Flow and Control drawings identify the seismic performance category of safety related SSCs and are adequate to support the performance requirements of the safety documentation? (ED-4.3)	
	The HVAC and Confinement System drawings comply with the requirements of DOE Order O 420.1B and meet the expectations of DOE-STD-1189-YR? (ED-4.4)	
	Confinement ventilation systems meet the performance criteria specified in DNFSB Recommendation 2004-2 Implementation Plan Document "Ventilation System Evaluation Guidance for Safety-Related and Non-Safety-Related Systems", Table 5-1, or later successor criteria? (ED-4.5)	
	The relationships between ventilation flows and pressures been evaluated to demonstrate that the flows and pressures can be maintained throughout normal, abnormal and accident conditions? Technical bases (i.e., calculations) developed to support performance requirements? (i.e., air flows, pressures, etc.) (ED-4.6)	
	The design of the secondary confinement system provides for continuous monitoring capability to detect loss of proper differential pressure with respect to the process area? (ED-4.7)	
	Operating areas are continuously monitored for hazardous release? Consideration is given to the use of redundant sensors and alarms? (ED-4.8)	
	The confinement systems address the design guidance in DOE-HDBK-1132-	

	99, Section 1.1 and any applicable guidance in Section 1.2? (ED-4.9)	
Configuration Management		
CM	Contractor has established a Configuration Management program which meets the requirements of DOE Order O 420.1B?	
	The contractor has developed local policies and procedures to implement an adequate Configuration Management Program? (CM-1.1)	
	Roles and responsibilities for configuration management and change control are clearly assigned and understood? (CM-1.2)	
	Design changes and field changes are being documented, reviewed and approved and effected documents are modified to reflect approved design changes? (CM-1.3)	
	Safety SSCs are identified that are subjected to the CM program (CM-1.4)	
	A design authority is clearly established for safety SSCs who is responsible for maintaining design control (i.e., establishing and maintaining design requirements, ensuring that design output documents accurately reflect the design basis, managing any changes to baseline documents) (CM-1.5)	

EM Environmental Management

safety ✣ performance ✣ cleanup ✣ closure

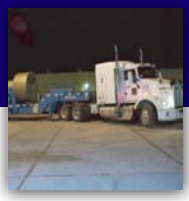
Standard Review Plan (SRP)

Final Design Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

FINAL DESIGN REVIEW MODULE

September 2008

[This Review Module was used to develop the Review Plan for 90% Design Review of SWPF. Lessons learned will be incorporated in the next revision of the Review Module.]

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

CD-(N)	Critical Decision – (numbered)
HVAC	Heating Ventilation and Air Conditioning
IPT	Integrated Project Team
MEL	Master Equipment List
DSA	Documented Safety Analysis
FDR	Final Design Report
PEP	Project Execution Plan
P&ID	Piping and Instrumentation Diagram
SDR	Safety Design Report
SDD	System Design Description
SDS	Safety Design Strategy
SRD	Systems Requirements Document
SSC	Structures, Systems and Components

I. INTRODUCTION

Design Reviews are an integral part of the contractor and federal project management process. As stated in DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets:*

> *Beginning at CD-1 and continuing through the life of the project, as appropriate, Design Reviews are performed by individuals external to the project. Design Reviews are performed to determine if a product (drawings, analysis, or specifications) is correct and will perform its intended functions and meet requirements. Design Reviews must be conducted for all projects and must involve a formalized, structured approach to ensure the reviews are comprehensive, objective, and documented.*

Final design is the last phase of development prior to construction. The purpose of the final design phase in a project is to prepare final drawings, technical specifications, and contract documents required to obtain bids and quotes for procurement and construction.

In preparation for CD-3 approval, the Federal Project Director must ensure that the contractor is ready to proceed with construction. This involves verification that the final design is complete, such that is provides an adequate basis upon which to construct the facility. The Final Design Review (FDR) supports this goal by evaluating the technical adequacy of the engineering design and ensuring that safety and quality assurance related activities/products are up to date.

II. PURPOSE

The Final Design Review (FDR) Module is a tool that assists DOE federal project review teams in evaluating the technical sufficiency of the final design prior to CD-3 approval. The FDR Module focuses on the engineering design, safety, and quality assurance to determine whether it meets overall design commitments, and technical/safety requirements. It also evaluates whether the design supports performance of the established facility functions. A FDR's principal focus is on the effectiveness of the design in meeting safety, health, and engineering standards, addressing technical risks, and ensuring successful constructability. Additionally, FDR's should concentrate, as appropriate on the design aspects associated with interfaces that rely on existing site infrastructure. FDRs may include project Quality Assurance program effectiveness in addressing a project's design and configuration management needs as well as effectively implementing requirements established in 10CFR830, Subpart A and DOE O 414.1C.

This module does not explicitly target other project areas such as cost and schedule, security, and environmental protection. Also, the safety basis review in the FDR is focused on the interface between safety basis development and design. Safety basis review guidance is established by DOE directives, including DOE-STD-1104. It is expected that the FDR will be performed in conjunction with other reviews for items such as security and environmental protection and that the federal project director will use

input from all of these reviews to determine if the project is ready to proceed to the next phase and begin construction.

DOE M 413.3-1 Section 6.4 states that the fundamental purpose of the design review is to ensure:

- Quality of the design
- Operational and functional objectives are met
- Maintenance of costs within the budget
- Design is biddable, constructible and cost-effective
- Interface compatibility
- Final contract documents comply with the design criteria
- A detailed, unbiased, analytical approach is given to all of the above identified items.

The performance objectives and criteria presented in this FDR are focused largely on the quality, the operability and the constructability of the design. Other elements of the final design review process are addressed in other EM standard review modules related to commissioning plans and readiness for construction. This has been done to provide a consistent and focused review process to evaluate the engineering and technical adequacy of the final design as presented for CD-3 approval.

III. ROLES AND RESPONSIBILITIES

A successful FDR depends on an experienced and qualified team. The team should be augmented with appropriate subject matter experts selected to complement the specific technical concerns of the project being reviewed (e.g., Structural, Seismic, Mechanical Engineering, Quality Assurance, etc.). The specific types of expertise needed will be dependent on the type of facility being reviewed, as well as other factors such as complexity and hazards/risks.

It is preferred that personnel selected to participate in a design review have design experience. This is particularly relevant for reviewers who evaluate engineering design elements against industry standards or other regulatory design requirements. It may not be practical or necessary for some other subject matter experts, such as various safety disciplines, to have this experience.

It is strongly recommended that the team leader should either be a project or systems engineer experienced in the management of a multi-disciplined review team (e.g. mechanical, electrical chemical, industrial, nuclear) that matches to the extent practicable the contractors design team. The review team should be augmented with subject matter experts as appropriate to review specialty matters such as structural analysis, seismic design criteria, criticality, and energetic reactions.

Management support is another necessary component to a successful FDR. Field element managers, as well as the Federal Project Director, must recognize the importance of the

FDR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the FDR process.

The roles and responsibilities for all involved in the FDR must be clear and consistent with various requirements of DOE O 413.3A. The table below provides a compilation of design review roles and responsibilities.

Table 1 – Design Review Roles and Responsibilities

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the design review.
	Facilitates the conduct of the design review. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Identifies the need for a FDR and determines the scope of the review effort.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the completion of corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the areas to be reviewed.
	Based on the areas selected for review, project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the design review pre-visit.
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of the data call and forwards to the Federal Project Director, a list of documents, briefings, interviews, and presentations needed to support the review.
	Forwards the final review plan to the Acquisition Executive for approval.

Position	Responsibility
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review and characterizes the findings.
	Coordinates incorporation of factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the Acquisition Executive for consideration in making the decision to authorize start of construction.
	Participates, as necessary in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for assigned area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares input to the review report.
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.

IV. REVIEW SCOPE AND CRITERIA

This FDR Module provides a set of review criteria that are organized into several technical/safety areas and engineering disciplines. These review areas are summarized below and include general requirements, radiation protection, criticality safety, fire protection, safety basis, integrated safety management, quality assurance (including software quality assurance), civil/structural, engineering design (process design/layout, mechanical and piping, electrical, instrumentation and control, HVAC), and configuration management. For each review area, Appendix A of this Module provides overall performance objectives and then a subset of review criteria that satisfy each performance objective. These performance objectives and review criteria will provide consistent guidance to project-specific design review teams to develop their Lines of Inquiry.

General Requirements

This area of the review is intended to ensure that the final design meets the operational and functional objectives of the project and that project documentation is adequate for approval of CD-3.

Radiation Protection

This area is focused on ensuring that the final design supports safety of operations and activities involving radiological material through engineered controls and barriers. A major emphasis of the review is concerned with 10 CFR 835 Subpart K – Design and Control elements and with physical design elements (e.g., confinement, shielding) rather than overall radiological control program requirements. Other aspects of 10 CFR 835, as well as DOE-STD-1098-99, *Radiological Control*, and the contractor's ALARA Program also require verification within the final design.

Criticality Safety

The intent of this review area is to ensure that the final design adequately considers the potential for criticality in planned activities and that the design implements the necessary and appropriate controls consistent with DOE O 420.1B and related ANSI/ANS Standards. The FDR is focused on the physical design elements rather than the overall criticality safety program

Fire Protection

The purpose of this review area is to ensure that the final design adequately considers fire safety in the planned activities and the design implements the necessary and appropriate controls consistent with DOE O 420.1B, DOE-STD-1066-99, NFPA standards, and other applicable regulatory requirements. The areas of review are derived from these requirements as related to physical design elements rather than the overall the fire protection program.

Safety Integration

Two primary aspects of safety integration are evaluated in the FDR. The first is on the overall management philosophy and approach to integrating safety into design. This review area establishes whether an Integrated Safety Management Description Document has been prepared and updated to address the final design activities. A major component of this review area is also to establish that workplace hazards have been identified and incorporated into the facility design.

The second aspect is related to the Safety Basis review area for Hazard Category 1, 2 or 3 nuclear facilities. This review areas is not intended to include or conflict with other ongoing reviews of the Safety Basis Documents, which are conducted in accordance with DOE-STD-1189. Rather, this review area is focused on verifying that controls derived

from the safety basis are adequately captured in the final design. This includes verification that appropriate safety classifications are assigned to SSCs within design documentation and that design commitments are consistent with DOE O 420.1B. The DOE review of the contractor's safety basis programs and activities is covered in DOE-STD-1104. This should include consideration of site characterization, including NPH elements (e.g., seismic, wind, flood), and appropriate performance criteria, integrated with the Civil/Structural elements below.

Quality Assurance

This review is primarily derived from the requirements of ASME NQA-1- 2000 or later edition and 10 CFR 830 Subpart A and focuses on the design elements rather than the overall QA program. The primary objectives are to ensure that (1) design inputs are correctly selected and translated into design documents in a timely manner; (2) design methods are appropriate; (3) organizational and physical interfaces are identified and controlled; (4) suitable materials, parts processes, and inspections and testing criteria have been specified; (5) changes to design are controlled in a manner commensurate with the original design; (6) the design is independently verified to be adequate; and (7) documentation and records of the design and design verification processes are maintained in accordance with the QA program. A software quality assurance (SQA) review should also be conducted as part of the overall QA review. This includes any software used to classify, design, or analyze structures, systems and components relied on to protect workers, the public and environment.

The requirements identified in 10 CFR830.122, Criterion 6 addresses QA for the design process and form the primary basis for the performance objectives. Also included are requirements from DOE Order O 414.1C, Quality Assurance, and the contractor's project specific Quality Assurance Plan.

Civil/Structural

The purpose of this review area is to ensure that the geotechnical/seismic studies, structural design and associated calculations, drawings and specifications are complete for the final design. Requirements from DOE O 420.1B and the DOE standard 1020 series related to NPH design form a major emphasis for the FDR. Validation associated with design calculations should be performed as part of the final design review process. Proper use of national standards, such as those promulgated by the American Concrete Institute (ACI), American Institute of Steel Construction (AISC), American Welding Society (AWS), etc. throughout project civil/structural specifications, will be confirmed.

Engineering Design

A major emphasis of the FDR is on the engineering functions that relate to facility systems necessary for confining hazardous and radioactive materials, either as a direct barrier or supporting a critical function of a safety system. The FDR Module addresses performance objectives and criteria according to process design/layout, mechanical and

piping, electrical, instrumentation and control, and HVAC. A number of DOE directives and industry standards provide good engineering principles, as well as functional design requirements, that form the basis for the FDR. Some examples are as follows:

- DOE Order O 420.1B, Facility Safety
- DOE-STD-3024-98, Content of System Design Descriptions (SDD)
- DOE-HDBK-1169-2003, Nuclear Air Cleaning Handbook
- DOE-STD-1189-2008, Integration of Safety into the Design Process
- DOE-HDBK-1132-99, Design Considerations
- DOE-HDBK-1092-2004, Handbook on Electrical Safety

Configuration management

Although Configuration Management is normally managed from within the Engineering Organization, its application to a construction project begins very early in the project planning and continues throughout the life of the project. For this reason, as well as for its importance in satisfying facility safety requirements it should be reviewed as a separate area. The review focuses on configuration management requirements found in DOE Order O 420.1B, *Facility Safety*; DOE STD-1073-2003, *Configuration Management Program*; and the Site/Contractor Configuration Management Program

V. REVIEW PLANS AND DOCUMENTATION

The results of a FDR will be used by the DOE Federal Project Director and ultimately the Acquisition Executive to help determine whether project funds may be authorized to authorize construction. It is important to clearly document the methods, assumptions and results of the FDR. Section 8 of the SRP provides guidelines for preparing a Review Plan and a final report.

The following activities should be conducted as part of the Review Plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents, assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this module.
- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provided for a unique identifier for each line of inquiry, arranged by subject area (e.g. Management-Personnel and Qualifications, Management-Processes and Systems, Technical-Civil, etc.) such that the results of each line of inquiry can be documented and tracked to closure.

- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. The method used the basis for closure/comment/finding and the result of the inquiry should all be documented and tracked.

The Review Plan should be broken down to provide coverage of the following topics.

Review Coverage

The physical areas of the facility operations that are subject to the PDR should be presented, along with subject areas that are being reviewed. Any areas that are excluded from the review should be discussed, along with the rationale for exclusion.

Design Assumptions

Design assumptions include any process decisions that frame the scope of the design effort and must be considered by reviewers when validating performance. This may include assumptions such as final product forms or performance characteristics related to operational steps or processes. Any explicit expectations imposed on the contractor by DOE, above and beyond those requirements and standards contained in the design contract, are also important assumptions that should be conveyed so that actions to modify the contract can be initiated to support document submittal/approval.

Performance Baseline Documents

The primary documents that form the project technical requirements and that are the basis for review criteria should be referenced in this section. At a minimum this should list the DOE contract that commissions the design, Facility and Design Description Documents, and DOE Order 420.1B and associated review guides/standards.

Design Documents

Design documents include facility documents expected to be provided to the Review Team. A detailed inventory list of all documentation is not necessary in this section. Rather, it should focus on document types expected. Where applicable, this includes the following types of documents: Facility and Design Description Documents; process flow diagrams; Preliminary Safety Design Report; structural drawings, calculations and specification; electrical drawings, calculations and specifications; instrumentation and controls drawings, calculations and specifications; mechanical drawings, calculations and specification; process system drawings, calculations, and specifications.

Performance Objectives and Criteria

The performance objectives and criteria that apply to the review process will be selected and presented in this section, or attached as an appendix to the Review Plan. These should be based on the EM Preliminary Design Review Module, Appendix A, as

applicable based on specific project characteristics. The rationale for selection should be presented.

VI. REFERENCE MATERIAL

REFERENCES

DOE Order DOE O 413.3A, Program and Project Management for the Acquisition of Capital Assets
DOE Manual DOE M 413.3-1, Project Management for the Acquisition of Capital Assets
DOE Standard DOE-STD-1189-YR Draft, Integration of Safety into the Design Process.
DOE Order DOE O 420.1B, Facility Safety
DOE Guide DOE G 420.1-1, Nonreactor Nuclear Safety Design Criteria and Explosives
DOE G 420.1-1, *Nonreactor Nuclear Safety Design Criteria and Explosives Safety Criteria Guide for use with DOE O 420.1, Facility Safety* DOE Order DOE O 430.1B, Real Property Asset Management
DOE Guide DOE G 430.1-1, Chapter 3, Stages of Project Development
DOE Standard DOE STD -3024-98, Content of System Design Descriptions
DOE Standard DOE-STD-3006-2003, Handbook for the Conduct of Operational Readiness Reviews
DOE Handbook DOE-HDBK-1132-99, Design Considerations
DOE O 414.1C, *Quality Assurance*
DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1C, Quality Assurance*

OTHER SOURCES CONSULTED

SPD-SWPF-217, Salt Waste Processing Facility Independent Technical Review
U-233 Material Downblending and Disposition Project 60% Design Review Report January 2008, Revision 0
NUREG-1718, Standard Review Plan for the Review of a Mixed Oxide (MOX) Fuel Fabrication Facility
DOE Order O 6430.1A, General Design Criteria

Appendix A - Performance Objectives and Criteria

Legend of Safety and Engineering Review Topics

Review Topical Area	Identifier
General Requirements	GR
Radiation Protection	RP
Criticality Safety	CS
Fire Protection	FP
Safety Integration	SB
Quality Assurance	QA
Civil/Structural	NPH
Engineering Design	ED
-Process Design/Layout	ED-1
-Mechanical and Piping	ED-2
-Electrical, Instrumentation and Control	ED-3
-HVAC	ED-4
Configuration Management	CM

Table A.1 – Performance Objectives and Criteria

ID #	Performance Objectives and Criteria	Met?
General Requirements		
GR-1	Management documents associated with the project sufficiently complete and contain enough detail to support proceeding to the construction phase?	
	The final design addresses safety and health standards, technical risks, and construction/operability requirements? (GR-1.1)	
	The project has satisfied requirements and commitments identified during the preliminary design phase? (GR-1.2)	
	Project Execution Plan schedule, milestones and completion date achievable and in agreement with the design submittals? (GR-1.3)	
GR-2	Design meets final design expectations, as defined in site procedures and meets Performance Requirements developed in the Design Requirements Document?	
	Design addresses safety and health standards, technical risks, construction and operability requirements? (GR-2.1)	
	Clear and complete system for tracking design assumptions, to assure their resolution prior to construction and operations? (GR-2.1)	
	Design incorporates adequate provisions for the safe removal, treatment, and disposition of secondary waste and other byproducts of the process? (GR-2.2)	
	Where process equipment will be exposed to demanding environmental conditions, is the equipment expected to survive the environment long enough to fulfill its mission? (GR-2.3)	
	Design incorporates construction and process materials suitable for the site and process environment? (GR-2.4)	
	Test results demonstrate the facility process effectiveness? (GR-2.5)	
	Any additional reasonable measures that could be implemented to facilitate the replacement of key pieces of equipment that are susceptible to degradation have been identified? (GR-2.6)	
	The project has identified all assumptions and requirements that are required to be carried forward to ensure that appropriate requirements for construction and administrative controls are developed? (GR-2.7)	
GR-3	System Description documentation properly integrates the Facility design with the Process design?	
	Structural design for the facility has been coordinated with the process design effort to ensure adequate space is available for installation and operation of all the equipment that is designated to be installed? (GR-3.1)	
	System Design Descriptions prepared for safety related systems and meet the requirements of DOE Order O 420.1B and DOE Standard DOE STD - 3024-98, Content of System Design Descriptions? (GR-3.4)	
GR-4	A process is in place to resolve any remaining technical uncertainties and to validate design assumptions?	
	All elements of the process demonstrated at full scale and production throughput verified by demonstration or calculation? (GR-4.1)	

ID #	Performance Objectives and Criteria	Met?
	Prototypes being acquired for any machine or process which has not previously been used in this application? Does the testing schedule provide confidence that the project schedule can be met? (GR-4.2)	
	Design assumptions are identified and there is a process in place to verify them with actual field measurement or modeling? (GR-4.3)	
	New fluid systems are being tested with mock-ups or with surrogate material to verify flow rates, hold up issues, or capacity? (GR-4.4)	
Radiation Protection		
RP-1	The facility design meets the requirements of 10 CFR 835 Subpart K – Design and Control?	
	The primary measures taken to maintain radiation exposure in controlled areas ALARA accomplished through physical design features (e.g., confinement, ventilation, remote handling, and shielding)? (RP-1.1)	
	Design features adequate to meet design objectives for controlling personnel exposure (concrete walls of sufficient thickness; penetrations and galleries adequately designed)? (RP-1.2)	
	Administrative controls employed only as supplemental method to control radiation exposure where use of physical design features is demonstrated to be impractical? (RP-1.3)	
	Optimization methods used to assure that occupational exposure is maintained ALARA in developing and justifying facility design and physical controls? (RP-1.4)	
	Design objectives for controlling personnel exposure from external sources of radiation in areas of continuous occupancy (2000 hours per year) to maintain exposure levels below an average of 0.5 mrem (5 microsieverts) per hour and as far below this average as is reasonably achievable? The design objectives for exposure rates for potential exposure to a radiological worker where occupancy differs from the above shall be ALARA and shall not exceed 20 percent of the applicable standards in Sec. 835.202. (RP-1.5)	
	Confinement and ventilation design features are relied on for control of airborne radioactive material, consistent with a design objective to avoid releases to the workplace atmosphere and in any situation, and then to control the inhalation of such material by workers? (RP-1.6)	
	Design or modification of a facility and the selection of materials include features that facilitate operations, maintenance, decontamination, and decommissioning? (RP-1.7)	
RP-2	The facility design meets the requirements of 10 CFR 835 Subpart E, Monitoring of Individuals and Areas?	
	Provides for : (1) Adequately documenting radiological conditions. (2) Detecting changes in radiological conditions. (3) Detecting gradual buildup of radiological material. (4) Verifying the effectiveness of engineering and process controls in containing radioactive materials and reducing radiation and/or	

ID #	Performance Objectives and Criteria	Met?
	radioactive material (5) Identifying and controlling potential sources of individual exposure to radiation and/or radioactive material (RP-2.1)?	
	Identifies instruments that are: (1) Appropriate for the type(s), levels, and energies of the radiation(s) encountered (2) Appropriate for existing environmental conditions. (RP-2.2)	
RP-3	The facility design is consistent with the requirements of 10 CFR 835 Subpart F – Entry Control Program?	
	Facility design provides for entry control commensurate with the existing and potential radiological hazards within the area including one or more of the following methods: a. Signs and barricades b. Control devices on entrances; c. Conspicuous visual and/or audible alarms; d. Locked entrance ways; or e. Administrative controls? (RP-3.1)	
	No control(s) are installed at any radiological area exit that would prevent rapid evacuation of personnel under emergency conditions? (RP-3.2)	
	Facility design provides for entry control for high and very high radiation areas? Such areas shall be monitored as necessary during access to determine the exposure rates to which the individuals are exposed (RP-3.3)	
	One or more of the following features are used for each entrance or access point to a high radiation area where radiation levels exist such that an individual could exceed a deep dose equivalent to the whole body of 1 rem (0.01 sievert) in any one hour at 30 centimeters from the source or from any surface that the radiation penetrates: f. A control device that prevents entry to the area when high radiation levels exist or upon entry causes the radiation level to be reduced below that level defining a high radiation area; g. A device that functions automatically to prevent use or operation of the radiation source or field while individuals are in the area; h. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; i. Entryways that are locked. During periods when access to the area is required, positive control over each entry is maintained; j. Continuous direct or electronic surveillance that is capable of preventing unauthorized entry; k. A control device that will automatically generate audible and visual alarm signals to alert personnel in the area before use or operation of the radiation source and in sufficient time to	

ID #	Performance Objectives and Criteria	Met?
	permit evacuation of the area or activation of a secondary control device that will prevent use or operation of the source. l. Very high radiation area physical controls. In addition to the above requirements, additional measures shall be implemented to ensure individuals are not able to gain unauthorized or inadvertent access to very high radiation areas. m. No control(s) shall be established in a high or very high radiation area that would prevent rapid evacuation of personnel. (RP-3.4)	
Criticality Safety		
CS-1	The final design ensures that operations with fissionable material remain subcritical under all normal and credible abnormal conditions?	
	The design satisfies the requirements of revisions to the consensus nuclear criticality safety standards of American National Standards Institute (ANSI)/American Nuclear Society (ANS) 8 in effect at the time of the approval of DOE O 420.1B? (CS-1.1)?	
	The final design is such that no single credible event or failure can result in a criticality (DOE O 420.1B)? (CS-1.2)	
	Criticality safety evaluations for fissionable materials operations have been performed in accordance with DOE-STD-3007-2007, *Guidelines for Preparing Criticality Safety Evaluations at Department of Energy Non-Reactor Nuclear Facilities***,** or they are approved by DOE (e.g,. parameters, limits and controls required to maintain sub-criticality for all normal and credible abnormal conditions)? (DOE O 420.1B) (CS-1.3)	
	The final design includes controls that are derived from the criticality safety evaluation in the preferred order of passive engineered controls, active engineered controls, or lastly administrative controls? (DOE 420.1B) (CS-1.4)	
	The final design implements the double contingency principle defined in ANSI/ANS 8.1, *Nuclear Criticality Safety in Operations with Fissionable Material outside Reactors*? (CS-1.5)	
	The final design provides an explanation whenever an ANSI/ANS standard or other DOE O 420.1B requirement is not planned to be implemented? (CS-1.6)	
CS-2	The final design ensures that nuclear criticality safety is controlled by one or more parameters of the system(s) within sub critical limits and by allowances for process contingencies?	
	The final design demonstrates controls through one or more of the following as appropriate***:*** ***a.*** Physical constraints ***b.*** Use of instrumentation ***c.*** Chemical means ***d.*** Reliance on natural or credible course of events ***e.*** Administrative procedures ***f.*** Other means? (CS-2.1)	

ID #	Performance Objectives and Criteria	Met?
	All controlled parameters and their limits are specified and the influence of variations of these parameters on the k_{eff} is understood and documented in the final design supporting documents? (CS-2.2)	
	The final design relies upon equipment design, where practicable, in which dimensions are limited rather than administrative controls? (CS-2.3)	
	The final design relies upon the use of neutron absorbers, if such reliance is consistent with the requirements of section 4.2.4 of ANSI/ANS 8.1, 8.5 (rashig rings) and 8.14 soluble neutron absorbers? (CS-2.4)	
	Subcritical limits derived from experiments or calculations are in accordance with the requirements of sections 4.2.5 and 4.3 of ANSI/ANS 8.1? (CS-2.5)	
CS-3	The design and use of a criticality alarm system(s) is in accordance with the requirements of ANSI/ANS 8.3?	
	The alarm system coverage meets the requirements of section 4.2 of ANSI/ANS 8.3? (CS-3.1)	
	The criticality alarm system design supports the requirements of section 4.3 of ANSI/ANS 8.3? (CS-3.2)	
	Dependability of the final design for a criticality alarm system is consistent with the requirements of ANSI/ANS 8.3 section 4.4? (CS-3.3)	
	The criticality alarm system(s) meet the criteria identified in ANSI/ANS 8.3 section 5? (CS-3.4)	
	The system supports testing and maintenance as identified in ANSI/ANS 8.3, Section 6? (CS-3.5)	
Fire Protection		
FP-1	The final design ensures that it provides a level of safety sufficient to meet DOE goals and objectives?	
	Fulfills requirement of highly protected risk (HPR) (DOE O 420.1B) (FP-1.1)?	
	Prevents loss of safety functions and safety systems as determined in the hazards analysis and provides defense in depth (DOE O 420.1B) (FP-1.2)?	
	Prevents fires and related effects that cause an unacceptable release of hazardous or radiological materials (FP-1.3)?	
	Prevents fires and related effects that cause vital DOE program to suffer an unacceptable interruption (FP-1.4)?	
	Prevents fires and related effects that result in the loss of critical process controls (FP-1.5)	
FP-2	The design meets or exceeds applicable fire protection and emergency response provisions of the governing local building code (the International Building Code if no local code applies), applicable regulations, DOE fire safety criteria, and industry standards, such as those promulgated by the NFPA?	
	The design identifies and reflects the full spectrum of applicable facility related fire protection and emergency response criteria as delineated by DOE and as adopted when the design criteria are / were approved. (FP-	

ID #	Performance Objectives and Criteria	Met?
	2.1)?	
	The design reflects and conforms to the provisions of the following chapters/sections of the local building code (International Building Code (IBC) if no local code applies): • Use and Occupancy Classification • Special Fire Safety Design Requirements for Unique Structures • Height and Area Limitations • Types of Construction • Fire-resistance Design Requirements • Combustibility of Interior Finishes • Fire Protection Systems • Means of Egress • Access for Emergency Vehicles • Fire resistance of Exterior Walls and Roofs • Protection of Structural Steel • Fire Protection and Emergency Services During Construction (FP-2.2)?	
	The design reflects and conforms to the provisions of the following chapters/ sections of the local fire code (International Fire Code if the IBC applies): • Fire Service Features • Building Services and Systems • Fire-resistance Rated Construction • Fire Protection Systems, Including Fire Water Supply • Means of Egress • Fire Exposures, including Wild Land Fire Risk • Flammable and Combustible Liquids and Gases • Hazardous Materials • Emergency Vehicle Accessibility to Facilities (FP-2.3)?	
	The design reflects and conforms to the facility specific provisions of Section 2 *Fire Protection* of Appendix A to 10 CFR Part 851 (FP-2.4)?	
	The design reflects and conforms to the following facility specific provisions of 29 CFR 1926, *Construction Industry Regulations*: • Subpart C, *General safety and Health Provisions* (Fire Safety and Emergency Services) • Subpart D, *Occupational Health and Environmental Controls* (Emergency Medical-related) • Subpart F, *Fire Protection and Prevention* • Subpart Z, *Toxic and Hazardous Substances* (FP-2.5)?	
	The design reflects and conforms to the facility specific provisions of Chapter II, *Fire Protection*; Section 3.c. *Fire Protection Design* of DOE	

ID #	Performance Objectives and Criteria	Met?
	O 420.1B, *Facility Safety*. (Specific review elements are delineated in P.O. 3.) (FP-2.6)?	
	The design reflects and conforms to the following facility specific provisions of DOE G 420.1-3, *Implementation Guide for DOE Fire protection and Emergency Services Programs:* • Section 4.2, *Highly Protected Risk Status* • Section 4.5, *Program Documentation* (construction-related) • Section 4.6, *Fire Hazards Analysis* • Section 4.9, *Baseline Needs Assessment* (emergency services) • Section 4.15, *Exemptions, Variances, Equivalencies* • Section 4.17, *Fire Protection Design* • Section 4.20, *Fire Suppression System Confinement or Containment* • Section 4.21, *Fire Protection System Classification* (FP-2.7)?	
	The design reflects and conforms to the following facility specific provisions of DOE-STD-1066-99, *Fire Protection Design Criteria*: • Chapter 5, *General Criteria* • Chapter 6, *Water Supply and Distribution System Criteria* • Chapter 7, *Automatic Sprinkler System Criteria* • Chapter 8, *Fire Alarm Systems* • Chapter 10, *Life Safety Criteria* • Chapter 11, *Electrical Equipment Criteria* • Chapter 12, *Protection Criteria for General Process Hazards* • Chapter 13, *Protection Criteria for Special Hazards* • Chapter 14, *Nuclear Filter Plenum Fire Protection* • Chapter 15, *Glovebox Fire Protection* (if included in scope) (FP-2.8)?	
	The design reflects and conforms to the following facility specific provisions of NFPA-801, *Standard for Fire Protection for Facilities Handling Radioactive Waste*: • Nuclear Safety Considerations • Identification of Hazards • General Plant Design • Life Safety Design Features • Fire Protection and Notification Systems • Equivalencies (FP-2.9)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1, *Uniform Fire Code* (Construction and Emergency Services Provisions) (FP-2.10)?	
	The design reflects and conforms to the facility specific provisions of NFPA-70, *National Electrical Code.* (FP-2.11)?	
	The design reflects and conforms to the facility specific provisions of NFPA-72, *National Fire Alarm Code* (FP-2.12)?	

ID #	Performance Objectives and Criteria	Met?
	The design reflects and conforms to the following facility specific provisions of NFPA-80, S*tandard for Fire Doors and Fire Windows* (FP-2.13)?	
	The design reflects and conforms to the facility specific provisions of NFPA-90A, *Standard for the Installation of air Conditioning and Ventilating Systems* (FP-2.14)?	
	The design reflects and conforms to the facility specific provisions of NFPA-101, *Life Safety Code* (FP-2.15)?	
	The design reflects and conforms to the facility specific provisions of NFPA-241, *Standard for Safeguarding Construction, Alteration and Demolition Operations* (FP-2.16)?	
	The design reflects and conforms to the facility specific provisions of NFPA-780, *Standard for the Installation of Lightning Protection Systems* (FP-2.17)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1144, *Standard for Protection of Life and Property from Wildfire* (FP-2.18)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1141, *Standard for Fire Protection in Planned Building Groups* (FP-2.19)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1221, S*tandard for the Installation, Maintenance and Use of Emergency Services Communications Systems* (FP-2.20)?	
	The design reflects and conforms to the facility specific provisions of NFPA-1710, *Standard for the Organization and Deployment of Fire Suppression Operations, Emergency Medical Operations, and Special Operations to the Public by Career Fire Departments* (FP-2.21)?	
FP-3	The final design for the facility and supporting systems meets or exceed the following overarching facility-specific fire protection design criteria:	
	A reliable and adequate supply of water for fire suppression. Documentation (text and / or drawings) must include a commitment to conform to applicable criteria, as delineated above, and should also include a design description that encompasses; fire water storage (quantity and duration), pumps, distribution piping, materials, and other available details (FP-3.1)?	
	Noncombustible construction material for facilities exceeding the size limits established by DOE (see DOE-STD-1066-99, *Fire Protection Design Criteria).* Documentation must include a commitment to conform to applicable criteria, as delineated above, and should also include the type(s) of construction that will be featured for each facility and reference to the listed structural assemblies that are intended to meet the construction classifications (FP3.2)?	
	Complete fire-rated construction and barriers, commensurate with the applicable codes and fire hazards, to isolate hazardous areas and minimize fire spread and loss potential consistent with limits as defined by DOE.	

ID #	Performance Objectives and Criteria	Met?
	Design documents should describe in general terms the subdivision of each facility into fire areas, as defined in DOE-STD-1066-99. The description should include a summary of how penetrations of fire area boundary construction will be protected. This description should address doorways, ventilation penetrations, cable and conduit penetrations and any anticipated unprotected openings in fire area walls and floor/ceiling assemblies (FP-3.3)***?***	
	Automatic fire extinguishing systems throughout all significant facilities and in all facilities and areas with potential loss of safety class systems (other than fire protection systems), significant life safety hazards, unacceptable program interruption, or fire loss potential in excess of limits defined by DOE. (FP-3.4)?	
	Redundant fire protection systems in areas where ***a.*** Safety class systems are vulnerable to fire damage, and no redundant safety capability exists outside of the fire area of interest, or ***b.*** The maximum possible fire loss (MPFL) exceeds limits established by DOE. An initial Maximum Possible Fire Loss (MPFL) calculation is provided to support the need for redundant systems. (FP-3.5)?	
	In new facilities, redundant safety class systems (other than fire protection systems) are located in separate areas and design documents identify those fire areas (such as a control room or automatic electric power transfer area) where redundant safety systems may be located. The description should include the nature and extent of redundant fire protection in these areas (FP-3.6)?	
	A means to notify emergency responders and building occupants of a fire (e.g., fire alarm or signaling system). The design should provide a description of a fire alarm / signaling system. (FP-3.7)?	
	Emergency egress and illumination for safe facility evacuation in the event of fire as required by applicable codes or fire standards. The design demonstrates that two remote exits are available from all occupied areas, except where permitted by the Life safety Code. Design documents provide an overview of the egress concept, including lighting and signage. Issues that might affect egress, such as security measures, should be identified without mentioning specific provisions (FP-3.8)?	
	Physical access and appropriate equipment that is accessible for effective fire department intervention (e.g., interior standpipe systems in multi-story or large, complex facilities). Design documents show access roads, location of fire hydrants, standpipe systems and fire department connections, entryways into facilities, and other design features (congested areas) that might adversely affect emergency services (FP-3.9)?	
	A means to prevent the accidental release of significant quantities of contaminated products of combustion and fire fighting water to the	

ID #	Performance Objectives and Criteria	Met?
	environment, such as ventilation control and filter systems and curbs and dikes. Such features would only be necessary if required by the FHA or safety analysis in conjunction with other facility or site environmental protection measures. (FP-3.10)?	
	A means to address fire and related hazards that are unique to DOE and not addressed by industry codes and standards. Mitigation features may consist of isolation, segregation or the use of special fire control systems (water mist, clean agent, or other special suppression systems) as determined by the FHA. The design identifies atypical fire hazards (such as chemicals or processes) and the fire protection means intended to mitigate their corresponding fire risk (FP-3.11)?	
	That the fire protection systems are designed such that their inadvertent operation, inactivation, or failure of structural stability will not result in the loss of vital safety functions or inoperability of safety class systems as determined by the safety analysis or DSA. A description of processes is provided that will be used to evaluate for such risk and the possible means (physical safeguards such as shielding or barriers) that would likely be used to minimize the threat from inadvertent operation, inactivation, or other failure. (FP-3.12)?	
FP-4	The design shall identify conditions for which literal compliance with the above-referenced criteria cannot be met in a cost-effect manner and where alternative (equivalent) fire safety and emergency response features will be proffered.	
	Design documentation (text) manifests a process for identifying conditions for which literal conformance is not feasible or cost-effective. This description should include a requirement for an engineering analysis by qualified fire protection engineers, review and approval by engineers, review and approval by appropriate contractor management, and a commitment to submit all such equivalency determinations to the DOE Authority Having Jurisdiction (AHJ). (FP-4.1)?	
	Design documentation (text) manifests a system for identifying, tracking, and record keeping of all pending decisions regarding fire safety and emergency services equivalencies (FP-4.2)?	
	Design documentation (text) manifests a commitment to implement a design that conforms to governing fire safety criteria when there is no agreement with the DOE AHJ regarding a pending equivalency. (Default decisions regarding design are to literal conformance.) (FP-4.3)?	
	Where required by Paragraph 3.b. (5) of DOE O 420.1B a (Preliminary) Fire Hazards Analysis (FHA) has been documented and updated from the preliminary design stage.	
	The PFHA has been completed under the supervision of a qualified (as defined by DOE) or (as defined in DOE STD-1066-99) fire protection engineer (FP-5.1)?	
	The scope and content of the PFHA are in conformance with the guidelines delineated in Section 4.6 of DOE G 420.1-3 (September 27, 2007 or current equivalent) (FP-5.2)?	

ID #	Performance Objectives and Criteria	Met?
	The conclusions of the PFHA are incorporated into PDSA and integrated into design basis and beyond design basis accident conditions (FP-5.3)?	
	Provisions exist for updating the PFHA over time as significant changes occur (FP-5.4)?	
Safety Integration		
SI-1	Safety Basis Documents are prepared and consistent with preliminary design documents?	
	A Preliminary Safety Design Report (PDSA) is prepared by the SDIT (SI-1.2)	
	The PDSA has been reviewed by DOE and verified to meet expectations of DOE-STD-1189-2008, or where deficient, explicit conditions of approval established. (SI-1.3)	
SI-2	The final design incorporates sufficient defense in depth consistent with preliminary safety analysis?	
	The design includes multiple layers of protection to prevent or mitigate the unintended release of radioactive materials to the environment (e.g., isolation, confinement, successive physical barriers, minimizing material at risk, etc)? (DOE O 420.1B) (SI-2.1)	
SI-3	The final design meets the requirements and objectives of DOE O 420.1B? This includes:	
	The final design ensures that safety SSCs are designed commensurate with the importance of the safety functional requirements (SB-3.2)?	
	Safety Class electrical systems must be designed to preclude single point failure (SB-3.3)?	
	Process systems as identified in the preliminary design shall be designed to minimize waste production and mixing of radioactive and non-radioactive wastes (SB-3.4)?	
SI-4	The Integrated Safety Management Description has been prepared and incorporates final design activities?	
	The requirements, methodology, and responsibility for ES&H activities are clearly identified and communicated? (SI-4.1)	
	The final design incorporates an analysis of potential workplace hazards (industrial safety/hygiene) and establishes appropriate controls (SI-4.2)	
Quality Assurance		
QA-1	Design inputs are correctly translated into design documents in a timely manner	
	Design inputs for interfacing organizations are specified in the design documents or in supporting procedures.	
	The design incorporates applicable requirements and design bases (QA-1.1).	
	Design inputs are specified to the level of detail necessary to permit design activities to be correctly carried out and to provide a consistent basis for making design decisions, accomplishing design verification activities, and evaluating design changes (QA-1.2)	

ID #	Performance Objectives and Criteria	Met?
	Design inputs are based upon contractual requirements and customer expectations and are technically correct and complete. (DOE G 414.1-2A) (QA-1.3)	
QA-2	Design methods used are appropriate	
	The design has been developed using sound engineering/scientific principles and appropriate standards. (QA-2.1)	
	Design assumptions, if necessary, are adequately described and reasonable (QA-2.1)	
	Design output compares reasonably to the design inputs (QA-2.2)	
QA-3	Organizational and physical design interfaces are identified and controlled	
	Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents related to an item or its processes, such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures (QA-3.1)	
	Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces (QA-3.2)	
QA-4	Suitable materials, parts, processes, and inspections and testing criteria are specified	
	The design provides for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of designed items. (DOE G 414.1-2A) (QA-4.1)	
QA-5	Changes to design are controlled in a manner commensurate with the original design	
	Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design (QA-5.1)	
	See CM, *Configuration Management*, for additional review criteria (QA-5.2)	
QA-6	The design is independently verified to be adequate.	
	Design procedures identify the responsibilities of personnel verifying the design, the areas and features that require design verification, the pertinent considerations to be verified, and the extent of documentation required to document verification (QA-6.1)	
	Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or tests) (QA-6.2)	
	The design has been verified or validated by individuals or groups other than those who performed the design work. (QA-6.3)	
	The design has been verified or validated before approval and implementation of the design. (QA-6.4)	
QA-7	Documentation and records are maintained in accordance with the QA program	

ID #	Performance Objectives and Criteria	Met?
	Design documentation includes a list of approved and controlled computer codes. (DOE G 414.1-2A) (QA-7.1)	
	Design records include documentation such as design inputs, calculations, and analyses; engineering reports; design outputs; design changes; design verification activities; and other documents that provide evidence that the design process is adequately controlled in a timely manner. (DOE G 414.1-2A) (QA-7.2)	
	Procedures are established and described requiring documented verification of the dimensional accuracy and completeness of design drawings and specifications (QA-7.3)	
QA-8	Acquired software for safety-related calculations has been pre-verified or the results of the calculations performed verified for each application of the software to ensure it produces the correct solutions within the defined limits of its intended use.	
	Software acquired from a third party or from corporate inventories used in design calculations has been identified (QA-8.1).	
	Test cases that exercise the defined limits and physical problem being solved have been performed and the results verified to ensure acceptable results were generated from the software (QA-8.2).	
QA-9	Software used to classification, analysis and design of SSCs relied on for worker, public or environmental protection is controlled (QA-9.3).	
	Software, including spreadsheets, databases and their associated support tools (e.g., Excel, MS Access, Windows O/S) have been uniquely identified and the specific versions used in the design calculation noted (QA-9.4).	
	Software identified is stored in a location that is easily retrieval and access is restricted to authorized individuals (QA-9.5).	
	Updates to the software identified are created from this stored software (QA-9.6).	
QA-10	Spreadsheets and other software specifically created for use in the engineering design is developed using software quality and engineering practices appropriate for the impact on the engineering design.	
	Requirements for the spreadsheets and software are clearly described and documented in a manner that can be easily tested. The requirements are reviewed and approved (QA-10.1).	
	The structure, mathematical algorithms, control and logic flow, data structures applicable to the development of the spreadsheets and software is documented in enough detail for review by independent technical individual. The independent review is documented (QA-10.2).	
	The spreadsheets and other software created for use in the engineering design are tested to ensure the documented requirements are met and produce the correct results for the problem being analyzed. The test results are documented and evaluated by a responsible authority to ensure the test requirements are met (QA-10.3).	
QA-11	Software configuration items are identified and controlled.	

ID #	Performance Objectives and Criteria	Met?
	Products of the software development activities that need to be retained are identified and assigned a unique identifier. These products include the software requirements, software design, test cases and results, and records of reviews (QA-11.1).	
	The items identified are stored in a location that is easily retrieval and access is restricted to authorized individuals (QA-11.2).	
	Updates to the items identified are created from these stored versions (QA-11.3).	
Civil/Structural		
NPH-1	Structural design meets design expectations/requirements, as defined in site procedures, and satisfies performance categorization design requirements in accordance with DOE STD-1020, -1021, -1022, and -1023? (Note that this objective is in the process of being changed to meet DOE STD 1189 and ANSI/ANS 2.26-2004, Categorization of Nuclear Facility Structures, Systems and Components for Seismic Design; and ASCE/SEI 43-05, Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities. When adopted by DOE, this objective will be rewritten in terms of Limit States (LS) and Seismic Design Category (SDC).)	
	SSCs relied on to prevent significant onsite consequences are designated as Performance Category 3 for NPH hazard in accordance with DOE-STD-1021 (NPH-1.1)?	
	Appropriate codes and standards are selected and applied to the structural design (IBC, AISC, ACI) (NPH-1.2)?	
	Seismic loading is evaluated consistent with site-specific design response spectra (NPH1.3)?	
	The seismic design of systems and components accounts for adverse interactions from non-seismic structures, systems, and components (spatial interactions, spray interactions, and system interactions) (NPH-1.4)?	
NPH-2	Design calculations address major structures and SSCs and are complete and consistent with known conditions and facility layout?	
	Calculations evaluate the capacity of connections between structural members (NPH-2.1)?	
	Calculations address all anticipated load cases (NPH-2.2)?	
	Calculations provide sufficient documentation of assumed inputs and outputs (NPH-2.3)?	
	Calculations consider structural behavior of the material to be used in construction? (NPH-2.4)	
Engineering Design - Process Design/Layout		
ED-1	The Facility Plans, Piping and Instrumentation Diagrams (P&ID), and detail drawings have been coordinated with the Process Descriptions, Flow Diagrams, and Process Calculations and the facility layout supports the process requirements?	
	Facility and System drawings in the submitted design package meet the expectations of the Site procedure or contract specification for	

ID #	Performance Objectives and Criteria	Met?
	completeness and format? (ED-1.1)	
	System Design Descriptions (SDD) prepared for safety related systems and meet the requirements of DOE Order O 420.1B and DOE Standard DOE STD -3024-98, Content of System Design Descriptions? (ED-1.2)	
	SDDs describe the performance characteristics of the system which are important to safety and link the safety basis analysis to the selected controls? (ED-1.3)	
	The Structures, Systems and Components (SSC) of the safety related systems are properly characterized as to their safety pedigree in accordance with DOE O 420.1B and DOE-STD-3009? The necessary documents to support procurement and control of safety related SSCs have been developed? (ED-1.4)	
	The process equipment and system drawings meet the expectations of the Site procedure or contract specification for completeness and format? (ED-1.5)	
	The process equipment and system drawings in the submitted design package are accompanied by appropriate flow diagrams; calculations; and control parameters and set points? (ED-1.6)	
	Has a 3-D modeling system been applied to the design effort? The various engineering areas are being closely integrated into the layout? (i.e. electrical cable trays, HVAC ductwork, piping and instrument penetrations/runs) (ED-1.7)	
	Layout drawings and floor plans are coordinated with system drawings? The facility layout supports the process flow and facilitates movement of parts and tools to perform the facility mission? (ED-1.8)	
	The facility design includes adequate space for convenient access to major components (including piping, wiring, control tubing, etc.) during construction, testing, maintenance and inspection so that major disassembly is not required? (ED-1.9)	
	All engineering risks have been identified and addressed? If not, what risks remain? Are plans in place to resolve these issues prior to final design? (ED-1.10)	
	There is evidence that human factors principles are factored into the design (e.g., functional analysis, task analysis) (ED-1.11)	
	The Facility design addresses the good practices and guidance for layout, space allotment, hazards separation, and hazardous areas as identified in DOE-HDBK-1132-99. (ED 1.12)	
Engineering Design - Mechanical and Piping		
ED-2	The Mechanical and Piping drawings and supporting documentation are adequate to accomplish the design mission?	
	The process equipment and system drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-2.1)	
	Piping and components meet the requirements of the designated Codes and Standards in the System Design Requirements document and	

ID #	Performance Objectives and Criteria	Met?
	materials are appropriate to the intended process? (ED-2.2)	
	The operating and design loads and load combinations are correctly specified for each system and equipment? Adequate calculations exist to support the selected design? (ED-2.3)	
	Vessels and piping systems are designed, sized, and qualified to the ASME Boiler and Pressure Vessel Code and ASME B31.3 code, including over-pressure protection? (ED-2.4)	
	Equipment and systems in high radiation areas are designed to minimize the need for repair or replacement? (ED-2.5)	
	Provisions are in place for periodic maintenance and inspection of systems and equipment to assure their continued integrity for the design life? (ED-2.6	
	The design for shop fabrication and field erection of systems and components (joining, welding, non-destructive examination, testing) is in accordance with the applicable codes and standards for each type of commodity? (ED-2.7)	
	The designs include the necessary strengthening, support, or restraints to meet the selected seismic performance criteria? (ED-2.8)	
	Adequate capacity exist in material transport systems to handle expected volumes of radioactive/hazardous materials during normal operating and accident conditions (ED-2.9)	
	Tanks and piping systems are of welded construction to the fullest extent possible (ED-2.10)	
	Tank and piping systems are designed to take advantage of gravity flow to reduce the potential for contamination associated with pumping and pressurization (ED-2.11)	
	All system components expected to be in contact with strong acids or caustics are corrosion resistant (ED-2.12)	
	Use of traps is avoided, and the piping is designed to minimize entrapment and buildup of solids in the system (ED-2.13)	
	The Facility design addresses the good practices and guidance for piping design and layout as identified in DOE-HDBK-1132-99. (ED 2.14)	
Engineering Design - Electrical, Instrumentation and Control		
ED-3	The electrical and instrument drawings and supporting documentation are adequate to accomplish the design mission?	
	The one-line diagrams and electrical distribution layout drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-3.1)	
	Where standard off-the-shelf electrical materials and equipment been selected, there are provisions for testing and labeling by a nationally recognized testing laboratory (international standards organization or recognized testing agency)? If not, evaluation and approval by the authority having jurisdiction (AHJ) has been performed? (ED-3.2)	
	Panel schedules and control diagrams are developed for the electrical systems? Load and fault calculations support the design requirements?	

ID #	Performance Objectives and Criteria	Met?
	(ED-3.3)	
	The electrical portion of the design defines all major components (e.g., transformers, fuses and circuit breakers, and motors) as well as includes adequate excess electrical capacity to provide for future expansion? (ED-3.4)	
	The basic cable tray layouts identify layout interferences and material quantity needs? The cable tray designs have been integrated into a 3-D model? (ED-3.5)	
	When the facility includes a control room, the design considerations of DOE-HNDBK-1132-99, section 4.1, Control Centers/Control Rooms, have been taken into consideration? (ED-3.6)	
	The design incorporates provisions so that I&C system components can be tested periodically for operability and required functional performance (ED-3.7)?	
	Instrument channels and associated logic ensure that I&C components fail in a safe failure mode (ED-3.8)?	
Engineering Design - HVAC		
ED-4	The HVAC and Confinement System drawings and supporting documentation are adequate to meet DOE requirements and accomplish the design mission?	
	HVAC and Confinement System drawings in the submitted design package meet the expectations of the Site procedure or contract specification for completeness and format? (ED-4.1)	
	The design designations for seismic criteria of the safety related HVAC and Confinement Systems are consistent with the SDS and PDSR and are adequate to support procurement and cost decisions? (ED-4.2)	
	The HVAC Air Flow and Control drawings identify the seismic performance category of safety related SSCs and are adequate to support the performance requirements of the safety documentation? (ED-4.3)	
	The HVAC and Confinement System drawings comply with the requirements of DOE Order O 420.1B and meet the expectations of DOE-STD-1189-YR? (ED-4.4)	
	Confinement ventilation systems meet the performance criteria specified in DNFSB Recommendation 2004-2 Implementation Plan Document "Ventilation System Evaluation Guidance for Safety-Related and Non-Safety- Related Systems", Table 5-1, or later successor criteria? (ED-4.5)	
	The relationships between ventilation flows and pressures been evaluated to demonstrate that the flows and pressures can be maintained throughout normal, abnormal and accident conditions? Technical bases (i.e., calculations) developed to support performance requirements? (i.e., air flows, pressures, etc.) (ED-4.6)	
	The design of the secondary confinement system provides for continuous monitoring capability to detect loss of proper differential pressure with respect to the process area? (ED-4.7)	
	Operating areas are continuously monitored for hazardous release? Consideration is given to the use of redundant sensors and alarms? (ED-	

ID #	Performance Objectives and Criteria	Met?
	4.8)	
	The confinement systems address the design guidance in DOE-HDBK-1132-99, Section 1.1 and any applicable guidance in Section 1.2? (ED-4.9)	
Configuration Management		
CM	Contractor has established a Configuration Management program which meets the requirements of DOE Order O 420.1B?	
	The contractor has developed local policies and procedures to implement an adequate Configuration Management Program? (CM-1.1)	
	Roles and responsibilities for configuration management and change control are clearly assigned and understood? (CM-1.2)	
	Design changes and field changes are being documented, reviewed and approved and effected documents are modified to reflect approved design changes? (CM-1.3)	
	A Master Equipment List (MEL) has been developed and identifies all safety related SSCs? The MEL specifies systems and equipment safety classification, performance category and required function during and following a design basis event? The MEL is being updated as design changes are implemented? (CM-1.4)	

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

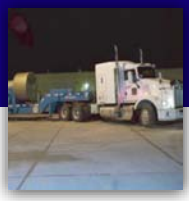
Standard Review Plan (SRP)

Construction Readiness Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

CONSTRUCTION READINESS REVIEW MODULE

September 2008

[This Review Module was used to develop the Review Plan for Salt Waste Processing Facility (SWPF) Construction Readiness Review (CRR). This Review Module contains the lessons learned from the SWPF Construction Readiness Review.]

TABLE OF CONTENTS

ACRONYMS

CAP	Corrective Action Plan
CD-(N)	Critical Decision (Number)
CEP	Construction Execution Plan
CRADS	Criteria Review and Approach Documents
CRR	Construction Readiness Review
EM	Office of Environmental Management
EIR	External Independent Review
EVMS	Earned Value Management System
FRAM	Functions, Responsibilities, and Authorities Manual
IPR	Independent Project Review
MS	Major System
OECM	Office of Engineering and Construction Management
PEP	Project Execution Plan
PSO	Program Secretarial Officer
QA	Quality Assurance
QC	Quality Control
STR	Subcontract Technical Representative (individual tasked to manage subcontractor activities)

I. INTRODUCTION

The authorization to proceed with construction of a new facility is given at the CD-3 phase of the project management cycle, after completion of the final design. Between CD-3 and CD-4 stages of the project, procurement and construction/assembly of facility structures, systems and equipment is conducted. These activities can present significant hazards to workers and involve a complex set of events that must be carefully planned and sequenced.

In preparation for the CD-3 approval, the Federal Project Director must ensure that the contractor is ready to proceed with construction. This involves verification that management systems are in place, adequate planning is conducted, procedures and training is completed, and construction hazards are adequately evaluated and controlled. These activities should be accomplished through a formal Construction Readiness Review (CRR) that supports the DOE O 413.3A process.

II. PURPOSE OF THE REVIEW MODULE

The objectives of this review module are to augment the stated objectives of the DOE Order O 413.3A for projects pending Critical Decision 3. Those being:

- "To assess the readiness for construction or execution and to confirm the completeness and accuracy of the Performance Baseline. The Scope of review for an EIR in support of CD-3 has several elements relative to construction readiness, but retains many of the elements contained in the Performance Baseline Review."
- Provide a review team with a set of topical areas and subject-specific considerations from which they may be able to develop specific construction and construction management oriented performance objectives and criteria in pursuit of a comprehensive assessment of the project's readiness to commence major procurement and construction activities.
- Provide DOE-EM with a standard template on which can be built construction assessments which will enhance the probability of success of major capital line-item projects which are commencing the most intense and vulnerable phase of execution (CD-3).
- Augment the DOE O 413.3A EIR/IPR/Program review process with construction-specific assessment perspectives typically not pursued in the reconfirmation of CD-2/Baseline related technical, budgetary and schedule assessments.

These guidelines are not intended to replace or conflict with the Construction/Execution Readiness Review conducted by the Office of Engineering and Construction Management for Major System Projects. Rather the EM guidelines are intended as a preliminary step to this process that focus on key management and technical aspects related to construction organizations, procedures and training. These guidelines may be utilized in the conduct of reviews of project construction/procurement readiness as deemed necessary by the acquisition authority or other EM authority requesting such a review.

III. ROLES AND RESPONSIBILITIES

A critical element of construction/procurement readiness reviews is the qualifications, training and most importantly the experience of the personnel selected to conduct the review. To the maximum extent possible, the personnel selected to participate in the reviews should have "on the ground", first hand experience (as opposed to an oversight role) in project or construction management or functional support of a successful line item engineering design and construction project executed under DOE O 413.3A.

The core review team personnel should include individuals possessing qualification and experience in the following areas:

- Project Management
- Construction Management
- Contracts and Procurement
- Safety Assurance (Facility and Construction)
- Quality Assurance
- Field Superintendents (Discipline-Specific Subcontract Technical Representatives-STRs)
- Project Controls
- Project Administrative Services
- Material Management

This core team should be augmented with technical personnel selected to complement the specific technical concerns of the project being reviewed. (e.g. Chemical, Structural, Seismic, Instrument, Process, Mechanical Engineering, etc.)

The structure and roles and responsibilities of the individual review team members and all others involved in the Construction Readiness Review (CRR) must be clear and consistent with the requirements of DOE O 413.3A and the DOE Functions Responsibilities and Authorities Manual (FRAM). The table below provides a compilation of construction readiness review roles and responsibilities.

Table 1 – Construction Readiness Review Roles and Responsibilities

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the CRR
	Facilitates the conduct of the CRR. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Coordinates with the Review Team Leader in the selection of technical areas for the review and in developing the review criteria.

Position	Responsibility
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the areas to be reviewed.
	Based on the project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the design review pre-visit.
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of and forwards to the Federal Project Director, the data call of documents, briefings, interviews, and presentations needed for the review.
	Forwards the final review plan to the Acquisition Executive for approval.
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review. Coordinates the characterization of the significance of the findings.
	Coordinates the review team handling of factual accuracy comments by Federal and Contractor personnel on the draft report.

Position	Responsibility
	Forwards the final review report to the Acquisition Executive for approval.
	Remains available as necessary to participate in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for the appropriate area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares the review report.
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.
	Concurs in the findings for his/her area of the review.

IV. REVIEW SCOPE AND CRITERIA

The scope of the review module is focused on key management and technical aspects of construction organizations, training and procedures. Since the review is focused on the readiness to proceed, it is not intended as an inspection guide for assessing implementation of construction practices or procurements during construction. The performance of these activities should be evaluated during routine oversight activities throughout the construction process.

This review module provides the review team with a "straw-man" template from which they may derive and pursue lines of inquiry that are applicable to the specific type of facility being constructed. The scope of the CRR is captured by review criteria that are presented in several broad categories. For each category, Appendix A of this Module provides overall performance objectives and then a subset of review criteria that satisfy each performance objective. These performance objectives and review criteria will provide consistent guidance to project-specific design review teams to develop their Lines of Inquiry.

Management Systems

This area of the review is focused on aspects the management systems, organization and staffing for the execution of the construction project. It is expected that key construction positions are established, related organizational roles and responsibilities are clear, and project staff are sufficiently staffed to oversee construction activities. Additionally, management systems should be in place to monitor performance against the project baseline.

Construction Procedures

This area of the review is focused on the contractor and key sub-contractor procedures used for the completion of the facility construction. It is expected that the procedures address the key elements and requirements to safely complete construction activities in accordance with applicable regulations and DOE requirements

Materials Management

This review area focuses on the materials management process for the construction activities, including the acquisition of materials, their delivery, packaging and waste management from materials receipt.

Safety Assurance

The construction contractor's capability to manage a safe project is verified in this review area. Key requirements related to integrated safety management systems, and specific plans and procedures related to industrial safety and industrial hygiene are evaluated. It is also verified that the contractor has completed a project safety and health plan as required by 10 CFR 851.

Project Controls

This review area focuses on the adequacy and health of project controls relied on to ensure adherence to the Performance Baseline and the systems/processes relied on for controlling any field changes to procedures or other project documents.

Construction Execution Plan

While the overall focus of the review module is on construction readiness, this particular review area is concerned with specific construction activities and practices, as well as the personnel and procedures in place to accomplish the work. Included are criteria related to general construction topics such as site preparation and work sequencing.

Training and Qualifications

This review area focuses on the training of qualifications of personnel responsible for construction activities. This review encompasses both the general training required for site access and the specific training and qualifications necessary for performing the planned construction activities.

Work Planning

This review area will assess the work planning to ensure that work processes are controlled by approved instructions, procedures, design documents, technical standards or hazard controls as appropriate for the task to be performed. This area also evaluates the organization of work and whether systems are in place and mature to support development of work packages/processes.

Constructability

This review area focuses on the project constructability. The key elements include the design specifications, drawings, site conditions and the construction schedule including the order of construction elements and potential impacts.

Field Engineering

The review area of field engineering is concerned with the readiness of activities explicit to construction of specific facility systems in accordance with their approved design, as well as ensuring feedback from field observations that may impact design. This area consists of mechanical, electrical, instrumentation, civil, and piping.

Welding

This review area focuses on the requirements, procedures and controls applicable to ensure that welding performed meets the design specifications/criteria and can be performed safely by the construction forces.

Rigging Operations

This review area focuses on the procedures and controls applicable to ensure that rigging operations are performed consistent with DOE requirements and can be performed safely by the construction forces.

Quality Assurance

This review area verifies that an approved Quality Assurance Plan is in place and is up to date to address quality assurance requirements pertinent to construction activities. This area also addresses QA during construction to ensure the final product meets the design and safety basis criteria.

Labor Management

This review area focuses on aspects of labor management necessary to ensure that the project can be successfully executed. The overall objective is to ensure the adequacy of the local craft labor force to support the project.

Construction Tools & Equipment

This area focuses on the availability and operability of the tools and equipment necessary to support the construction activities.

V. PREREQUISITES

Prior to initiating the review, the sponsor of the review should assure that the following activities and tasks have been completed and the results of such are documented and available to the review team;

- All designs completed and evidence of multi-discipline design reviews (with comments resolved).
- Constructability reviews completed (by construction STR equivalents) at 30% and 60% design completion with demonstrated comments incorporated.
- Construction Risks - properly recognized and addressed and mitigation strategies in place.
- Configuration Management processes in place and implemented.
- Change Control/Management processes and procedures in place and implemented.
- Construction and support staffing identified, qualified and in place or available.
- A Construction Execution Plan (CEP) or equivalent (satisfying the requirements of DOE) 413.3A "Construction Planning Documents" authored by the project construction manager and signed by the project manager, operations representative and all other members of the core and integrated contractor and federal project teams.

A. Core Documents Required

The project team should assemble necessary documents for review prior to the review team's arrival. These documents will include:

• Final Design Drawings and Specifications

• Results of and Responses to Site Final Design Review

• Project Execution Plan

• Construction Execution Plan

• Detailed Resource Loaded Schedule

• Detailed Cost Estimate

• System Functions and Requirements Document

• Risk Management Assessment

• Safety Documentation

• Acquisition Strategy

VI. REVIEW PLANS AND DOCUMENTATION

The Results of the Construction Readiness Review will be used by the DOE Federal Project Director and by the Acquisition Executive to determine whether the project can proceed to construction, implementation, procurement, or fabrication. As noted by DOE O 413.3A,

> *CD-3 provides authorization to complete all procurement and construction and/or implementation activities and initiate all acceptance and turnover activities. Approval of CD-3 authorizes the project to commit all resources necessary, within the funds provided, to execute the project.*

It is important to clearly document the methods, assumptions and results of the CRR. The following activities should be conducted as part of the review plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents listed in section 5 above, assignment of responsibilities for the development of specific performance objectives and criteria should be made.
- The review team members should develop specific performance objectives and criteria utilizing the topics and areas listed in the respective appendices of this module.
- The individual performance objectives and criteria should be compiled and submitted to the sponsor of the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provides for a unique identifier for each objective, arranged by subject area (e.g. Management-Personnel and Qualifications, Management-Processes and Systems, Technical-Civil, etc.) such that the results of each line of inquiry can be documented and tracked to closure.
- The performance objective and criteria evaluation can be accomplished via, document review, personnel interviews, or direct observation of an operation or any combination of these methods. The method used, the basis for closure/comment/finding, and the result of the inquiry should all be documented and tracked.

Section 8 of the SRP provides guidelines for preparing a Review Plan and a final report.

VII. REFERENCES

29 CFR 1926, Safety and Health Regulations for Construction
10 CFR 851, Worker Safety and Health Program
DOE Order DOE O 413.3A, Program and Project Management for the Acquisition of Capital Assets
DOE Manual DOE M 413.3-1, Project Management for the Acquisition of Capital Assets
DOE Standard DOE-STD-1189-YR Draft, Integration of Safety into the Design Process.

DOE Order DOE O 420.1B, Facility Safety
DOE Guide DOE G 420.1-1, Nonreactor Nuclear Safety Design Criteria and Explosives Safety Criteria Guide for use with DOE O 420.1(B) Facility Safety
DOE Order DOE O 425.1, Startup and Restart of Nuclear Facilities
DOE Order DOE O 430.1B, Real Property Asset Management
DOE Guide DOE G 430.1-1, Chapter 3, Stages of Project Development
DOE Standard DOE STD -3024-98, Content of System Design Descriptions
DOE Standard DOE-STD-3006-2003, Handbook for the Conduct of Operational Readiness Reviews
DOE Handbook DOE-HDBK-1132-99, Design Considerations

A. OTHER SOURCES CONSULTED

DOE Order O 6430.1A, General Design Criteria
Sodium-Bearing Waste Treatment Project (SBW) Integrated Waste Treatment Unit (IWTU)
EM-60 Construction Readiness Review, Review Report
24590-WTP-MAR-CON-07-0086, Rev. 0, WTP-HLW Restart Construction Readiness Assessment Report, Bechtel, Inc.
NUREG-1718, Standard Review Plan for the Review of a Mixed Oxide (MOX) Fuel Fabrication Facility

Appendix A - Performance Objectives and Criteria

Legend of Construction Readiness Review Topics

Review Topical Area	Identifier
Management Systems	MGT
Construction Procedures	CP
Materials Management	MMGT
Safety Assurance	SA
Project Controls	PC
Construction Execution Plan	CEP
Training and Qualifications	T&Q
Work Planning	WP
Constructability	CON
Welding	WEL
Rigging Operations	RIG
Field Engineering	FE
Quality Assurance	QA
Labor Management	LM
Construction Tools and Equipment	CTE

Table A.1 - Performance Objectives and Criteria

ID #	Performance Objectives and Criteria	Met?
Management Systems		
MGT-1	**The Contractor Project organization is properly organized and staffed to carry out the construction efforts?**	
	The Contractor has appointed a Project Manager responsible for the day to day management of the project and delivering the means, methods and resources to meet the contract end point requirements? (MGT-1.1)	
	Contractor personnel have been appointed to appropriate positions; e.g. Construction Management, Discipline Superintendents, Materials Managers, Subcontract Technical Representatives, and Field Representatives to properly supervise the fabrication and on-site construction efforts? (MGT-1.2)	
	Construction Oversight personnel have appropriate qualifications and have been trained to adequately oversee the construction activities? (MGT-1.3)	
	Roles and responsibilities of construction management and oversight personnel are properly established and understood by those involved in the project? (MGT-1.4)	
	The project oversight team contains adequate numbers of personnel and they have not been assigned conflicting responsibilities? (MGT-1.5)	
MGT-2	**A Performance Management System is in place, approved, and operating?**	
	The Contractor Performance Management System is **compliant with ANSI/EIA-748-A-1998 and** has been reviewed and validated by the Office of Engineering and Construction Management (OECM)? (MGT-2.1)	
	The critical parameters of the project are being tracked in the DOE Project Assessment and Reporting System? (MGT2.2)	

ID #	Performance Objectives and Criteria	Met?
	Cost and Schedule performance, milestone status, and financial status are being reported to DOE on a monthly basis? (MGT-2.3)	
	Quarterly Performance Reviews are being conducted and documented and results followed up? (MGT-2.4)	
	The Contractor has a system in place that tracks construction progress and status on a daily basis (MGT-2.5)?	
Construction Procedures		
CP-1	**Construction procedures are in place to govern the execution of construction activities?**	
	The construction organization has procedures to address the key elements of construction for the project? (CP-1.1)	
CP-2	**Construction procedures are controlled and implement the project baseline?**	
	Construction procedures are controlled by a procedure that addresses development, modification and approval of the procedures? (CP-2.1)	
	Construction procedures are based on and implement the current approved design documents? (CP-2.2)	
	Construction procedures are being maintained controlled in accordance with the governing procedure? (CP-2.3)	
CP-3	**Construction procedures address the associated hazards and identify controls to prevent or mitigate the identified hazards?**	
	Construction procedures are evaluated for hazards to the workers and controls are developed in accordance with the principles and requirements of the contractor document management system? (CP-3.1)	
	Construction procedures are periodically reviewed for accuracy and applicability? (CP-3.2)	
Materials Management		

ID #	Performance Objectives and Criteria	Met?
MMGT-1	**The Project Acquisition Strategy is complete for all phases of the project and has been updated based on Quarterly Performance Reviews?**	
	An Acquisition Plan is in place for all subcontracts and has been reviewed by the Integrated Project Team and concurred in by both the Federal Project Director and the DOE Contracting Officer? (MMGT-1.1)	
	The master acquisition schedule supports the project overall deadlines and is consistent with the Project Execution Plan and The Construction Execution Plan, if not integral to the PEP? (MMGT-1.2)	
	Acquisition of long lead time items is properly included in the project planning and is consistent with the CEP? (MMGT-1.3)	
MMGT-2	**Adequate space has been included in the site layout to accommodate additional equipment, materials, and any associated activities?**	
	Material laydown areas do not interfere with emergency response and access (MMGT-2.1)	
	Equipment and materials do not negatively impact traffic safety (MMGT-2.2).	
	Material/Equipment assembly activities do not interfere with emergency response, access, and/or traffic safety (MMGT-2.3)	
Safety Assurance		
SA-1	**The Integrated Safety Management Description has been updated to address construction activities?**	
	Safety plans for integrating safety management (including fire, occupational, radiological, IH, etc.) are completed and an integral part of the construction effort? (SA-1.1)	
	The requirements, methodology, and responsibility for ES&H activities are clearly identified and communicated? (SA-1.2)	
SA-2	**A project safety and health plan is prepared as required by DOE O 413.3A and 10 CFR 851 Appendix A?**	

ID #	Performance Objectives and Criteria	Met?
	Safety programs, documentation and controls are in place and adequate to ensure the safety of personnel during the execution of construction activities? (SA-2.1)	
	Programs and processes are adequate to address changes in the site and activity hazards during the construction process? (SA-2.2)	
	Worker construction hazards are evaluated and controls adequately established. Addresses (as applicable): construction activities such as excavation work, concrete work, steel erection; and addresses construction related hazards such as vehicle usage, heavy equipment, fall hazards (SA-2.3)?	
	Job Hazards Analyses reviewed, updated by appropriate discipline superintendents and/or other qualified personnel? (SA-2.4)?	
SA-3	**Safety programs/procedures adequately address applicable industrial hygiene and industrial safety elements?**	
	Hazcom: Emergency plans with contacts and numbers have been distributed and personnel trained in the proper use of these plans (SA-3.1)?	
	Industrial Hygiene: Sampling programs developed to ensure respiratory protection, etc are identified, defined and ready to implement Exposure assessment strategy and surveillance monitoring requirements implemented (SA-3.2)?	
	Industrial safety program addresses applicable hazards such fall protection, eye/hearing protection, flammable material storage, fire extinguishers, scaffolding, ladder safety, electrical safety, rigging and material movement (SA-3.3)?	
	Lock-out/Tag-out: The contractor LOTO program meets the requirements of the applicable CFRs and DOE? (SA-3.4)	
	A job hazards analysis process is implemented to evaluate the hazards associated with planned activities and to identify the appropriate controls? (SA-3.5)	
	The contractor has implemented a confined space program? (SA-3.6)	

ID #	Performance Objectives and Criteria	Met?
	A fall protection plan has been developed for the project with input from Civil Engineering and Safety Assurance personnel as appropriate? (SA-3.7)	
SA-4	**A contractor self-assessment process is in place and adequate for the construction project?**	
	A schedule is developed showing the self-assessments planned for the first 10 months of the construction project? (SA-4.1)	
SA-5	**Contractor medical facilities and staff are sufficient to support the project?**	
	Medical facilities and staff are sufficient for the daily needs of the project? (SA-5.1)	
	Medical facilities and staff are sufficient for medical placement exams, surveillance exams, and periodic exams as required by project personnel 10 CFR 851? (SA-5.2)	
SA-6	**The contractor has an adequate inventory and supply of safety related equipment the project?**	
	The contractor construction/baseline cost estimate considers the PPE needs such as fall arrest harnesses, lanyards, respirators, hard hats, etc.? (SA-6.1)	
	Adequate supplies of IH monitoring equipment and related supplies are available to support the project? (SA-6.2)	
SA-7	**Emergency response procedures list requirements for personal protective equipment, first aid, medical care, or emergency egress and are written and communicated to all employees?**	
	Procedures include provisions for emergency telephone numbers, exit routes, and training drills SA-7.1)?	
	Contractor and sub-contractor personnel, consultants, and any visitors in contractor controlled spaces know precisely what to do, and where to go in various cases of emergency (SA-7.2)?	
	Evacuation routes are known and clearly marked (SA-7.3)?	
SA-8	**Safety basis documents are complete and approved to support construction activities?**	
	A Preliminary Documented Safety Analysis is complete and approved by a DOE Safety Evaluation Report (SA-8.1)?	

ID #	Performance Objectives and Criteria	Met?
	No SER conditions of approval are affected by planned construction activities (SA-8.2)?	
Project Controls		
PC-1	**The PEP and CEP are controlled documents and changes to the project which may impact the Performance Baseline are controlled through a formal process of evaluation and documentation?**	
	The project is subject to a formal change control system which ensures that change requests to the project are documented, evaluated, and formally resolved. (PC-1.1)	
	The project change control system is documented in the PEP which also identifies the overall Performance Baseline, and the individual technical, schedule and cost baselines, against which changes are monitored and controlled? (PC-1.2)	
	Each organizational level (as appropriate and documented in the Project Execution Plan) manages a Change Control Board meeting the requirements of DOE M 413-1 for disposition of baseline change proposals within their level of authority/control. Board meetings and decisions are documented through meeting minutes and letters-of-decision? (PC-1.3)	
PC-2	**A functioning project control system is in place for managing project baselines using earned value techniques, variance analysis, contingency/reserve management and effective reporting in accordance with DOE orders and guidelines?**	
	If the project has a total cost of ≥ $20M the Earned Value Management System has been certified as compliant with ANSI/EIA-748? (PC-2.1)	
	Work tasks are defined and the tasks assigned to organizations responsible for performing the work? (PC-2.2)	
	Work packages are organized based on dependencies, interdependencies, constraints and other factors into a time-phased sequence that will fit within the boundaries established by mission dates and available budget? (PC-2.3)	

ID #	Performance Objectives and Criteria	Met?
	Is there adequate capability to provide for timely and accurate transfer of actual cost information from the accounting system into the earned value management system? (PC-2.4)	
	Is the project reporting and analyzing EVM information and is management acting on these analyses? (PC-2.5)	
	Is the control process for incorporation of formal changes adequate? (PC-2.6)	
	The contractor has established a Performance Measurement Baseline which is up to date and includes all elements of the project Work Breakdown Structure? (PC-2.7)	
PC-3	**The contractor has a functioning program for field project control – the program is focused on the successful management and execution of working level schedules that support the project baseline schedule?**	
	The contractor has work level schedules for the construction project and the first three months are in appropriate detail to support all necessary field activities? (PC-3.1)	
	The contractor program includes regularly scheduled meetings and progress reports to revise and update the working level schedule as the project is executed? (PC-3.2)	
	The contractor field project control program includes provisions to address schedule variances and recover schedule if and when execution delays occur? (PC-3.3)	
Construction Execution Plan		
CEP-1	**A Construction execution plan has been developed for the project?**	
	The CEP has been developed and approved by the appropriate personnel? (CEP-1.1)	
	The CEP is based on and supports the DOE approved project baseline schedule? (CEP-1.2)	
CEP-2	**The construction execution plan addresses the necessary key elements?**	

ID #	Performance Objectives and Criteria	Met?
	The CEP addresses and includes the following elements as appropriate for the project: • Work Breakdown structure • Principal work sequences and key logic links • Logistical issues affecting work efficiency such as access/egress, materials receipt and handing, waste management • Crane use strategy • Off site production and lead in • Detailed methodologies and sequences to address any non-routine construction activities? (CEP-2.1)	
	The Construction Execution Plan (CEP) contains comprehensive project-specific descriptions of the project, site plans, and schedules sufficient to facilitate understanding of the work required. (CEP-2.1)	
Training and Qualification		
T&Q-1	**The contractor training program ensures the work force is trained and qualified with the knowledge, skills, and abilities to effectively perform their work while protecting themselves, coworkers, the public and the environment?**	
	Has appropriate training and qualification been specified for personnel based on their assigned tasks and responsibilities? (T&Q-1.1)	
	Personnel assigned tasks are trained and qualified in accordance with federal or state laws, DOE directives and other applicable requirements? (T&Q-1.2)	
	Are equipment operators certified and/or qualified to operate assigned equipment? (T&Q-1.3)	
T&Q-2	**Personnel are trained and qualified to handle hazardous materials and waste as required by federal or state laws, DOE directives and other applicable requirements?**	

ID #	Performance Objectives and Criteria	Met?
	Employees receive introduction training with respect to hazardous materials in the general employee training? (T&Q-2.1)	
	Project specific training is provided as required to meet the requirements of 29 CFR 1910.120 or 29 CFR 1926? (T&Q-2.2)	`
T&Q-3	**Adequate training staff and resources are available for the required ES&H training related to construction?**	
	Required ES&H training is identified and tracked for newly hired workers (manual and non-manual) (T&Q-3.1)?	
	ES&H training resources account for all types of required training. Examples: Site Orientation, Fall Protection, Powered Industrial Truck (T&Q-3.2)?	
Work Planning		
WP-1	**Work processes are controlled by documents that are developed and approved in accordance with the applicable requirements?**	
	Work processes are controlled by approved instructions, procedures, design documents, technical standards, or other hazard controls appropriate to the specific tasks to be performed? (WP-1.1)	
	Work documents are maintained under a change control process? (WP-1.2)	
WP-2	**Work documents consider the hazards associated with the work (both from the task and the environment) and include the appropriate controls?**	
	Work documents identify hazards and controls in a clear manner that ensures that workers understand? (WP-2.1)	
	The work document process requires that hazards analyses and controls be updated when conditions or tasks have changed? (WP-2.2)	
	The work planning and management process includes a defined and implemented process for the control and incorporation of field changes both to drawings and work documents? (WP-2.3)	

ID #	Performance Objectives and Criteria	Met?
WP-3	**The contract preventative maintenance program is adequate for the permanent and temporary equipment to be used during construction?**	
	The PM frequencies for equipment are within the ranges specified by the equipment specifications? (WP-3.1)	
Constructability		
CON-1	**The Contractor has performed a thorough and comprehensive assessment of the project's readiness for construction?**	
	The Contractor has performed an adequate Design Authority review of the final project design and has resolved all significant findings? (CON-1.1)	
	The Contractor has reviewed all subcontractor submittals for completeness and for the flow down of design details to construction drawings? (CON-1.2)	
	There is evidence that the Contractor has evaluated DOE/industry applicable lessons learned that are commensurate with the type of construction being planned (CON-1.3)?	
CON-2	**Site Preparation Activities have are adequately planned to ensure that construction can proceed safely.**	
	Site Grading has been accomplished so as to provide for adequate surface drainage, preservation of the natural character of the terrain by minimum disturbance of existing ground forms. Site grading design has also ensured the safety and ease of personnel and vehicular access to the facility? (CON-2.1)	
	Onsite roadways and corridors are planned and laid out to minimize worker hazards (CON 2.2)?	
	Sidewalks and walk gradients provide for safe and convenient facility access and egress and inter-facility circulation. Widths of walks are based on anticipated traffic. Steps in walks and entrances are minimized to the extent possible? (CON-2.3)	

ID #	Performance Objectives and Criteria	Met?
	To the extent possible construction roads shall be established in locations and with profiles proposed for the final road system, and with shoulders and bases that can be surfaced after the construction period for use as the permanent roads. (CON-2.4)	
	Construction of road ditches and other work necessary to obtain adequate drainage and stabilization of soil for roads and construction areas has been completed as early as possible in the project construction phase? (CON-2.5)	
	Corps of Engineers or other appropriate design manuals have been utilized for technical guidance in the areas of hydrology and open-channel design for storm drainage. Open drainage ditches protected against erosion are used to the maximum extent practicable and are designed for not less than a 25-year frequency storm. Locally available materials are utilized for culverts and pipe systems, where economical? (CON-2.6)	
	Site support equipment and facilities such as personnel trailers, restrooms, telecommunications, and document processing equipment are in place, operational and adequate for the construction project? (CON-2.7)	
CON-3	**Construction plans give appropriate sequencing to work and installation of equipment?**	
	Installation of large or bulky equipment will not be impeded by obstructions or ongoing work (CON-3.1)?	
	Areas where electrical conduit and process piping will be installed are accessible (CON-3.2)?	
	Installation of piping or other systems is sequenced such that it doesn't impede performance of important safety systems (e.g., sprinkler heads not covered up) (CON-3.3)?	
Field Engineering		
FE-1	**Engineering design personnel are available to support construction activities**	

ID #	Performance Objectives and Criteria	Met?
	Design authorities are planned to be onsite and/or readily available to address technical issues that arise during construction (e.g., changing field conditions that affect designed components, modifications to design, etc) (FE-1.1)?	
FE-2	**The contractor has established adequate procedures, trained and qualified personnel, and equipment and materials related to civil/structural areas of concern**	
	Concrete plant equipment including trucks is adequate, properly maintained and at a level of cleanliness to support the concrete batch quality requirements. (FE-2.1)	
	Concrete plant procedures and records are adequate to maintain control of concrete batches and to document the quality of the mix. (FE-2.2)	
	Concrete Reinforcement plans include provisions for installation, preparation, preservation and support of reinforcing members in accordance with the design documentation? (FE-2.3)	
	Equipment inspection procedures, i.e. crane, lifts, government owned equipment etc. are defined, and documents are in place (FE-2.4)?	
	Concrete conveying equipment is available and ready to use. Tools supporting concrete placements (vibrators (appropriate diameters, large and small), surfacing equipment and cold weather protection as applicable) are in place. (FE-2.5)	
	Arrangements are in place for scheduling of concrete mixing, delivery, and placement to meet specified time requirements. (FE-2.6)	
	Plans for in situ testing, sampling, and laboratory analysis of concrete placement are in place and adequately documented to meet quality assurance requirements. (FE-2.7)	
	Has a project specific structural steel erection plan and schedule been developed? (FE-2.8)	
FE-3	**The contractor has established adequate procedures, trained and qualified personnel, and equipment and materials related to mechanical systems**	

ID #	Performance Objectives and Criteria	Met?
	A detailed installation and execution plan has been developed that addresses manpower and material delivery dates? (FE-3.1)	
	The construction team has determined the installation milestones to be used for monitoring and reporting the equipment installation progress? (FE-3.2)	
FE-4	**The contractor has established adequate procedures, trained and qualified personnel, and equipment and materials related to plant instrumentation**	
	A detailed instrumentation installation and execution plan has been developed that addresses manpower and material delivery dates? (FE-4.1)	
	The construction team has determined the instrumentation installation milestones to be used for monitoring and reporting the equipment installation progress? (FE-4.2)	
FE-5	**The contractor has established adequate procedures, trained and qualified personnel, and equipment and materials related to piping**	
	A detailed piping installation and execution plan has been developed that addresses manpower and material delivery dates? (FE-5.1)	
	The construction team has determined the piping installation milestones to be used for monitoring and reporting the equipment installation progress? (FE-5.2)	
FE-6	**The contractor has established adequate procedures, trained and qualified personnel, and equipment and materials related to electrical systems**	
	A detailed electrical systems installation and execution plan has been developed that addresses manpower and material delivery dates? (FE-6.1)	
	The construction team has determined the electrical systems installation milestones to be used for monitoring and reporting the equipment installation progress? (FE-6.2)	
Welding		

ID #	Performance Objectives and Criteria	Met?
WEL-1	**Welding activities are performed in accordance with the applicable standards and site procedures to ensure that the welds meet the criteria specified in the design and are performed safely?**	
	Welding is performed and inspected in accordance with the applicable standards and site procedures to ensure the welds meet the design specifications? (WEL-1.1)	
Rigging Operations		
RIG-1	**Hoisting and rigging operations for the construction activities are performed in accordance with chapter 15 of DOE-STD-1090-2007 and site procedures?**	
	Personnel operating mobile cranes are qualified in accordance with section 15.2.1 of the standard and applicable site procedures? (RIG-1.1)	
	Personnel operating forklift trucks are qualified in accordance with section 15.2.2 of the standard and applicable site procedures? (RIG-1.2)	
	Personnel performing rigging operations are qualified in accordance with section 15.2.3 of the standard and applicable site procedures? (RIG-1.3)	
	Persons-in-charge are qualified in accordance with section 15.2.4 of the standard and applicable site procedures? (RIG-1.4)	
	Designated leaders are qualified in accordance with section 15.2.5 of the standard and applicable site procedures? (RIG-1.5)	
	Inspectors are qualified in accordance with section 15.2.6 of the standard and applicable site procedures? (RIG-1.6)	
	Maintenance personnel are qualified in accordance with section 15.2.7 of the standard and applicable site procedures? (RIG-1.7)	
Quality Assurance		
QA-1	**The quality assurance plan is up to date and addresses construction activities and associated procurements?**	
	A quality assurance program is established, documented and updated to address construction related activities? (QAP-1.1)?	
	Quality assurance factors, including standards, specifications and limitations have been identified? (QAP-1.2)?	

ID #	Performance Objectives and Criteria	Met?
	A quality control and quality assurance oversight organization is in place and functional? (QAP-1.3)	
QA-2	Organization and construction related interfaces are identified and controlled?	
	Organizational responsibilities are described for preparing, reviewing, approving, and verifying construction and procurement documents (QA-2.1)?	
	Internal and external construction interface controls, procedures, and lines of communication among participating organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving construction interfaces (QA-2.2)?	
QA-3	**Procurement Documents are prepared with appropriate content and specificity?**	
	Technical requirements specifically reference drawings, specification, codes, etc., that describe the items or services being furnished (QA-3.1)?	
	Test, inspection, and acceptance criteria are identified (QA-3.2)?	
	QA program requirements are specified and commensurate with the importance and/or complexity of the item or service being provided (QA-3.3)?	
	Right of access to suppliers and sub-tier suppliers facilities and records is provided (QA-3.4)?	
	Requirements for the supplier's reporting of non-conformances is specified (QA-3.5)?	
	Contractor procedures require a documented review of the accuracy of procurement documents prior to award (QA-3.6)?	
QA-4	**Procurement of purchased items is controlled to ensure conformance with specified requirements?**	
	Supplier's capabilities are evaluated (i.e., history, records, facilities) and documented (QA-4.1)?	

ID #	Performance Objectives and Criteria	Met?
	Controls are in place to ensure submittal and evaluation of supplier-generated documents are accomplished in accordance with QA program requirements (QA-4.2)?	
	Acceptance methods and associated criteria such as certificates of conformance are established and documented (QA-4.3)?	
	Methods for control and disposition of supplier non-conformances that don't meet procurement QA requirements is specified (QA-4.4)?	
QA-5	**Controls are established that ensure that correct and accepted items are installed in the facility?**	
	Production related information is identified and evident on items to be installed (QA-5.1)?	
	Where physical identification is impractical, other identification methods are required such as physical separation or procedural control (QA-5.2)?	
	Any pertinent special requirements necessary for item identification are specified (e.g., items with limited life, specific identification or traceability to code requirements) (QA-5.3)?	
QA-6	**Special processes that are necessary to ensure quality of construction (such as those supporting welding, heat treating, and NDA) are required to be performed by qualified individuals in accordance with established procedures?**	
	Activities and qualifications (personnel, equipment) are appropriately addressed in Instructions and procedures (QA-6.1)?	
	Acceptance criteria and requirements of applicable codes and standards are specified in procedures (QA-6.2)?	
	Records are maintained for qualification of personnel, processes and equipment (QA-6.3)?	
QA-7	**Inspections and tests required to verify conformance of items to QA requirements are planned and specified?**	
	Inspection requirements and acceptance criteria are consistent with the design requirements or other technical documents (QA-7.1)?	

ID #	Performance Objectives and Criteria	Met?
	Inspection hold points are identified where necessary (QA-7.2)?	
	Planned inspections of items under construction is specified (QA-7.3)?	
	Any required testing that is necessary to verify conformance of items is specified, as well as the requirement to document the results of any tests (QA-7.4)?	
Labor Management		
LM-1	**Labor management is adequately addressed in the construction execution plan and the other appropriate project control and baseline documents?**	
	There is a labor plan included as part of the construction execution plan and includes a craft manpower curve presented by trade? (LM-1.1)	
	A local labor survey has been conducted to determine the craft/labor availability? (LM-1.2)	
	Local labor craft skills and productivity have been assessed and are adequate to support the project? (LM-1.3)	
	The current and local employment has been evaluated? (LM-1.4)	
	Local critical craft shortages have been evaluated? (LM-1.5)	
	The contractor has a process in place for craft recruiting and requisitioning? (LM-1.6)	
LM-2	**Craft resources required and the necessary training are identified and managed by the contractor during the construction project?**	
	Craft training programs are in place and adequate? (LM-2.1)	
	Craft manpower requirements are preplanned and properly requisitioned using the contract program? (LM-2.2)	
	Craft manpower curves are being maintained and used to manage the project? (LM-2.3)	
Construction Tools and Equipment		

ID #	Performance Objectives and Criteria	Met?
CTE-1	**Construction tools and equipment needs are evaluated and identified in the construction execution plan or other project baseline documents.**	
	The equipment schedule matches the manpower staffing and equipment forecasts, (e.g. welders to welding machines)? (CTE-1.1)	
	Are maintenance requirements including spare parts requirements and equipment standardization considered during the equipment selection process? (CTE-1.2)	
	Does a contractor process exist to evaluate equipment utilization? (CTE-1.3)	
CTE-2	**Construction tools and equipment are maintained as required to ensure their safe operation during for the project.**	
	Lube and oil change requirements are established for each piece of equipment? (CTE-2.1)	
	Required preventive maintenance is performed? (CTE-2.2)	
	The contractor has established an equipment maintenance program as appropriate for the project (CTE-2.3)	
	Equipment repair records are maintained? (CTE-2.4)	
	Do equipment maintenance schedules show scheduled routine, periodic and preventative maintenance and inspections? (CTE-2.5)	

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

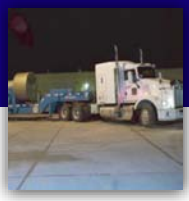
Standard Review Plan (SRP)

Commissioning Plan Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

Commissioning Plan Review Module

September 2008

[This Review Module will be piloted by the DUF_6 Project early in 2009.]

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I. INTRODUCTION

Development of a Commissioning Plan is a required element of the contractor and federal project management process. As stated in DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets:*

> *When the project nears completion and has progressed into formal transition and commissioning, which generally includes final testing, inspection, and documentation, the project is prepared for operation, long-term care, or closeout. The nature of the transition and its timing depends on the type of project and the requirements that were identified subsequent to the mission need.*

DOE Order 413.3A further states:

> *"…All projects must have a project transition/closeout plan that clearly defines the basis for attaining initial or full operating capability or meeting performance criteria as required for project closeout, as applicable.*

Table 2 of DOE Order 413.3A requires a "Checkout, Testing, and Commissioning Plan", and a "Project Transition to Operations Plan" as part of the CD-4 requirements. For this review module the term Commissioning Plan will encompass the elements of the "Checkout, Testing, and Commissioning Plan" and the "Project Transition to Operations Plan." These two documents are essential to the successful transition of the project from the design and construction phase to the operations phase.

For the purposes of this module commissioning is the systematic process of assuring by verification and documentation, from the design phase to a minimum of one year after construction, that all facility systems perform interactively in accordance with the design documentation and intent, and in accordance with operational needs, including preparation of operation personnel. While the Commissioning Plan is a required element for CD-4, the commissioning and transition process must be initiated early in the project process for the transition to operations to occur efficiently. As a minimum, the commissioning plan and related activities should be initiated in the construction phase of the project.

II. PURPOSE

The Commissioning Plan Review (CPR) Module is a tool that assists DOE federal project review teams in evaluating the sufficiency of the Commissioning Plan and its implementation. The CPR can be used by the DOE federal project teams both to evaluate the adequacy of the Commissioning Plan documentation/programs and the execution of programs by the contractor. The CPR Module addresses all of the key aspects of commissioning and transition activities including; systems and equipment testing and acceptance, quality assurance, selection and training of personnel, procedure development and implementation, maintenance procedures and equipment, safety basis

implementation, safety management program implementation, and emergency preparedness.

Completion of commissioning and transition activities is the immediate precursor to achieving and declaring readiness for operations. Therefore, successful completion by the construction and operations contractors of the Commissioning Plan elements identified in this document will provide a supporting basis for the contractor declaration of readiness. It is suggested that the this document be used with the elements of DOE O 425.1C, *Startup and Restart of Nuclear Facilities*, to ensure that the key elements for readiness are integrated into the project and addressed early in the project.

III. ROLES AND RESPONSIBILITIES

A successful CPR depends on an experienced and qualified team. The team should be augmented with appropriate subject matter experts selected to complement the specific elements of the Commissioning Plan being reviewed. The specific types of expertise needed will be dependent on the type of facility being reviewed, as well as other factors such as complexity and hazards/risks.

To the maximum extent possible, personnel selected to participate in a Commissioning Plan review should have design, construction, commissioning or operating experience within the DOE complex or related programs. First hand experience (as opposed to that of an oversight role) in a successful engineering design and construction project, including transition activities, executed under DOE O 413.3A, is preferred.

Management support is another necessary component to a successful CPR. Field element managers, as well as the Federal Project Director, must recognize the importance of the CPR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the CPR process.

The roles and responsibilities for all involved in the CPR must be clear and consistent with the various requirements of DOE O 413.3A. The table below provides a compilation of design review roles and responsibilities.

Table 1 - Design Review Roles and Responsibilities

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the CP review.
	Facilitates the conduct of the review. Allocates office space, computer equipment, and support personnel to the team as necessary to accomplish the review within the scheduled time frame
Federal Project Director	Coordinates with the Review Team Leader in the selection of subject areas for the review and in developing the review criteria.
	In conjunction with the Contractor Project Manager, develops the

Position	Responsibility
	briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the subject areas to be reviewed.
	Based on the project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications, technical knowledge, process knowledge, facility specific information, and independence of the Team Members.
	Leads the CP review pre-visit.
	Leads the review team in completing the Review Criteria for the various subject areas to be reviewed.
	Coordinates the development of and forwards to the Federal Project Director, the data call of documents, briefings, interviews, and presentations needed for the review.
	Forwards the final review plan to the Acquisition Executive for approval.
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review. Coordinates the characterization of the severity of the findings.
	Coordinates the review team response to factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the Acquisition Executive for approval.
	Remains available as necessary to participate in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for the appropriate area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre-visit document review.
	Participates in the on-site review activities. Conducts interviews,

Position	Responsibility
	document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her subject areas. Prepares the review report.
	Makes recommendations to the Review Team Leader for the characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her subject area of review.

IV. REVIEW SCOPE AND CRITERIA

The primary objective of the Commissioning Plan is to provide a detailed plan for the testing and acceptance of facility systems and equipment and to clearly define the basis for attaining initial operating capability, full operating capability and project closeout. The CPR review is expected to be the final project review involving DOE personnel prior to the completion of operational readiness review activities. The scope of a CPR is influenced by factors such as the types and magnitude of hazards, the complexity of the facility or process, and the project mission. These influences are considered when the Commissioning Plan Review Team is commissioned, and they are reflected in the final review criteria selected by the review team. Once selected, the review criteria define the planned scope of the CPR.

This Module provides a set of review criteria that are organized into each of the key commissioning/transition areas. These review areas are summarized below and include: system turnover process, plant testing, quality assurance, plant staffing, training and qualification, procedures, emergency preparedness, maintenance, safety basis implementation, and safety management programs. For each review area, Appendix A of this Module provides overall performance objectives and then a subset of review criteria that satisfy each performance objective. These performance objectives and review criteria will provide consistent guidance to project-specific review teams to develop their Lines of Inquiry.

General Requirements/Overview

This area of the review is intended to address the overall commissioning process including the commissioning authority identification and responsibilities, budget, commissioning plan format and content and commissioning schedules. Some of these elements will be considered in greater detail in other review areas, however the goal of this area is to ensure that integration of these elements into a successful commissioning plan (document) and process.

System Turnover Process

This area of the review is intended to capture the elements required to evaluate the adequacy of the formal process to transfer responsibility for equipment and systems from the construction forces to the facility operating staff. This area of review includes assessing the process to ensure that requirements of DOE Orders and industry standards are incorporated into a consistent, cost effective and rigorous process for placing new, modified or restarted SSCs into service. This review will also evaluate the adequacy of acceptance and systems tests to ensure that the equipment/systems meet the design criteria and project objectives.

Quality Assurance

This review area verifies that Quality Assurance requirements are identified and implemented for the commissioning process. This area also addresses QA during testing and acceptance to ensure the final product meets the design and safety basis criteria.

Plant Staffing

This review area focuses on the overall plant staffing and hiring plan. A detailed plan is necessary for the project to ensure that the correct mix of qualified personnel is hired for the various project phases. This review area is limited to the selection and hiring of personnel and does not address the training or/qualification of personnel to the site and project procedures.

Training and Qualification

The purpose of this review area is to ensure that the personnel hired per the plant staffing plan are trained and qualified to perform their assigned duties prior to commencing those duties. This review area also addresses the adequacy of the overall training and qualification process for the transition and initial operations phases.

Procedure development

This review area focuses on the adequacy of procedures for operation and maintenance of the facility both during the transition phase and in the operations mode. Procedures are required for normal, off-normal and emergency operations.

Emergency Preparedness

This review area focuses on the adequacy of the emergency preparedness program and procedures to ensure the safety of the workers, public and the environment during an off-normal event. The EP review is limited to the transition program – the operational readiness review will ensure that the program is sufficient for facility operations.

Maintenance Implementation

This review area addresses the adequacy of the project maintenance program and procedures necessary to maintain the facility operational once full operations are achieved. This includes the calibration program, surveillance program, preventative maintenance program, and the associated work control and recall processes necessary to effectively implement and perform maintenance activities.

Safety Basis Implementation

The purpose of this review area is to ensure that the approved safety basis and associated controls have been adequately implemented for the operations. Successful implementation of the safety basis documents and controls will encompass many other areas addressed in this process. The associated areas include the implementation of controls in operating procedures and training of personnel to the safety basis and controls.

Safety Management Programs

As the project transitions from construction to operations, the safety management programs will also transition from those of construction related and focused programs to SMPs identified and committed to in the safety basis documents. This review area will ensure the adequacy of the SMPs as implemented.

V. REVIEW PLANS AND DOCUMENTATION

The results of a CPR will be used by the DOE Federal Project Director and ultimately the Acquisition Executive to help determine that the facility may begin operations. It is important to clearly document the methods, assumptions and results of the CPR. Section 8 of the SRP provides guidelines for preparing a Review Plan and a final report.

The following activities should be conducted as part of the Review Plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents, assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and subject areas listed in the respective appendices of this module.
- The individual lines of inquiry should be compiled and submitted to the sponsor of the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme such that the results of each line of inquiry can be documented and tracked to closure.

- The lines of inquiry should be satisfied via document reviews and personnel interviews. The method used as the basis for closure/comment/finding and the results of the inquiry should be documented and tracked.

VI. REFERENCE MATERIAL

www.wbdg.org – Whole Building Design Guide Website, *Plan the Commissioning Process* by the WBDG Project Management Committee, 6/5/2008

Commissioning Plan for the DUF_6 Conversion Project at Paducah, Kentucky and Portsmouth, Ohio, Rev 0, August 2007

Appendix A - Performance Objectives and Criteria

Legend of Safety and Engineering Review Topics

Review Topical Area	Identifier
General Requirements/Overview	GR
System Turnover Process	ST
Quality Assurance	QA
Plant Staffing	PS
Training & Qualifications	T&Q
Procedure Development	PD
Emergency Preparedness	EP
Maintenance Implementation	MI
Safety Basis Implementation	SB
Safety Management Programs	SMP

Table A.1 – Performance Objectives and Criteria

ID #	Performance Objectives and Criteria	Met?
General Requirements/Overview		
GR-1	Has the project clearly identified an appropriate commissioning authority?	
	Is the commissioning authority impartial? (GR-1.1)	
	Does the commissioning authority have the necessary education and experience to perform the task for the project? (GR-1.2)	
GR-2	Does the project have a formal documented commissioning plan?	
	Does the commissioning plan include the following items as appropriate? • General Project Information • Overview and Scope of Project Commissioning • Commissioning Protocols and Communications • Commissioning Process, including team responsibilities • Commissioning schedule • Commissioning documentation • Appendices o Testing and Inspection Plans o Pre-Functional and Test Procedures o Construction Checklists o Issues logs? (GR-2.1)	
	Has the commissioning plan been approved by the commissioning authority? (GR-2.2)	
	Is the commissioning plan maintained under a configuration control process and updated as appropriate? (GR-2.3)	
GR-3	Does the project budget include a specified budget item for commissioning activities?	
	Is the identified commissioning budget sufficient? (Generally 2 to 4 percent of the construction cost for systems being commissioned). (GR-3.1)	
	Does the commissioning budget consider the following items as appropriate? • Commissioning process start • Number and complexity of systems being commissioned • Complexity of the overall project • The necessary level of detail in the commissioning process • Deliverables required	

ID #	Performance Objectives and Criteria	Met?
	• Allocation costs such as increased design fees, contractor bids, training, etc. • The type of project? (GR-3.2)	
GR-4	Does the project have adequate commissioning schedules?	
	Were the schedules developed by the commissioning team and construction personnel? (GR-4.1)	
	Are the schedules sufficiently detailed to ensure their effective implementation and execution? (GR-4.2)	
	Do the schedules address all of the systems that require commissioning? (GR-4.3)	
	Are the schedules integrated with the construction schedules for effective implementation? (GR-4.4)	
	Are the schedules maintained and changes to the schedules controlled under an appropriate process? (GR-4.5)	
System Turnover Process		
ST-1	Does the project have a formal and documented process for commissioning/the transfer of equipment from the construction staff to the operating staff?	
	Does the process include all of the key systems, equipment and facilities that are encompassed in the project? (ST-1.1)	
	Does the process include specific schedules that are incorporated in the project baseline? (ST-1.2)	
	Does the system turnover process address systems testing and acceptance, and system documentation for maintenance and operations? (ST-1.3)	
	Are roles and responsibilities for systems turnover clearly defined and well understood by the appropriate personnel? (ST-1.4)	
	Is the commissioning/transition process identified in the design process or earlier? (ST-1.5)	
ST-2	Does the project have a formal and documented process for plant testing of equipment and systems?	
	Is the plant testing process adequately identified in project/facility procedures? (ST-2.1)	
	Does the plant testing process procedures include specific roles and responsibilities appropriate for the facility systems and equipment to be tested and transitioned using the program? (ST-2.2)	
ST-3	Does the plant testing program include an acceptance testing program for initial testing and acceptance of equipment?	
	Does the plant testing process include acceptance testing for systems and equipment in accordance with	

ID #	Performance Objectives and Criteria	Met?
	the manufacture's specifications? (ST-3.1)	
	Are acceptance tests for key equipment witnessed by QA or engineering personnel? (ST-3.2)	
	Are acceptance of testing results reviewed and approved by engineering and QA personnel? (ST-3.3)	
	Is there a formal process to document deficiencies identified during acceptance testing and track them to resolution? (ST-3.4)	
ST-4	Does the plant testing program includes a process for system testing by the receiving organization?	
	Are system test plans developed by process engineers? (ST-4.1)	
	Doe process and operations engineers serve as the test engineers? (ST-4.2)	
	Do operators assist in the manipulation of equipment during the tests? (ST-4.3)	
	Is there a formal process to document deficiencies identified during the system testing and track them to resolution? (ST-4.4)	
	Does the systems testing process evaluate the ability of the components in the system to work together to achieve the design objective? (ST-4.5)	
ST-5	Does the project have a formal documented process for the turnover of systems from construction/testing to operations?	
	Does the systems turnover process include a method to track deficiencies to completion? (ST-5.1)	
	Is acceptance of the system by operations formally documented? (ST-5.2)	
	Does the process include the development, verification and implementation of startup procedures? (ST-5.3)	
ST-6	Has the project acquired the services of a qualified commissioning agent?	
	Has the commissioning agent been involved in the project since the design stage?(ST-6.1)	
	In the design stage, has the commissioning agent completed review of the project requirements and the basis of design? (ST-6.2)	
	Has the commissioning agent been involved in design reviews including the preliminary and final design documents? (ST-6.3)	
	Does the commissioning agent ensure that the Commissioning Plan is updated throughout the project including after each phase of the design review? (ST-6.4)	
Quality Assurance		

ID #	Performance Objectives and Criteria	Met?
QA-1	Are controls established that ensure that correct and accepted items are installed in the facility?	
	Is production related information identified and evident on items to be installed (QA-1.1)?	
	Where physical identification is impractical, are other identification methods required such as physical separation or procedural control (QA-1.2)?	
	Are any pertinent special requirements necessary for item identification so specified (e.g., items with limited life, specific identification or traceability to code requirements) (QA-3.3)?	
QA-2	Are quality assurance requirements identified in the commissioning plan?	
	Are quality assurance requirements for testing and acceptance clearly identified in the commissioning plan? (QA-2.1)	
	Are quality assurance personnel involved in the testing and acceptance process to verify that equipment and systems are built and installed in accordance with the design requirements and applicable design codes? (QA-2.2)	
Plant Staffing		
PS-1	Does the commissioning plan include a plan for the staffing of the facility for transition to and final operations?	
	Does the staffing plan for commissioning include sufficient details to identify the specific numbers and qualifications of personnel that are required for each phase of the transition to final operations? (TS-1.1)?	
	Are sufficient resources identified at the site/surrounding area to support the staffing plan? (PS-1.2)	
PS-2	Does the plant staffing plan identify the numbers and qualifications for personnel required to complete commissioning activities including testing activities?	
	Are testing and acceptance personnel identified in the commissioning plan? (PS-2.1)	
	Are the qualifications of personnel identified for testing and acceptance developed based on the systems and processes that they will be involved with? (PS-2.2)	
Training and Qualifications		
T&Q-1	Does the contractor training program ensure that the work force is trained and qualified with the knowledge, skills, and abilities to effectively perform their work while protecting themselves, co-workers, the public and the environment?	
	Has appropriate training and qualification been	

ID #	Performance Objectives and Criteria	Met?
	specified for personnel based on their assigned tasks and responsibilities? (T&Q-1.1)	
	Are personnel assigned tasks trained and qualified in accordance with federal or state laws, DOE directives and other applicable requirements? (T&Q-1.2)	
	Are equipment operators certified and/or qualified to operate assigned equipment? (T&Q-1.3)	
T&Q-2	Are personnel trained and qualified to handle hazardous materials and waste as required by federal or state laws, DOE directives and other applicable requirements?	
	Do employees receive introductory training with respect to hazardous materials in the general employee training? (T&Q-2.1)	
T&Q-3	Are adequate training staff and resources available for the required ES&H and other training?	
	Is required ES&H training identified and tracked for newly hired workers? (T&Q-3.1)	
	Do training resources account for all types of required training? (T&Q-3.2)	
	Are training personnel adequately trained? (T&Q-3.3)	
T&Q-4	Does the commissioning plan have a clearly defined process for training operating personnel?	
	Are operating personnel trained on the systems they will be operating as part of the commissioning/transition process? (T&Q-4.1)	
	Does training specifically address: • Step-by step procedures for normal operations • Adjustment instructions including information for maintaining operational parameters • Troubleshooting procedures • Maintenance and inspection procedures • Repair instructions including disassembly, component removal, replacement and reassembly, and • Upkeep of maintenance documentation and logs? (T&Q-4.2)	
Procedure Development		
PD-1	Does the commissioning plan include a documented process for development of the operating procedures for new/modified equipment and systems?	
	Are operating procedures developed by process and operations engineering personnel and are approved in accordance with site procedures and programs. (PD-1.1)?	

ID #	Performance Objectives and Criteria	Met?
	Are procedures developed for normal, off-normal and emergency operations (PD-1.2)?	
	Are procedures uniform in format and follow DOE requirements and guidance for content and format (PD-1.3)?	
	Do procedures include the appropriate limits and requirements from the safety basis document and or TSRs?(P-1.4)	
	Are startup procedures developed for the initial startup and operation of systems? (P-1.5)	
PD-2	Are procedures developed for maintenance and repair activities?	
	Are maintenance and inspection procedures developed as part of the commissioning/transition process? (PD-2.1)	
	Are troubleshooting procedures developed as part of the commissioning/transition process? (PD-2.2)	
	Are repair procedures developed as part of the commissioning/transition process? (PD-2.3)	
Emergency Preparedness		
EP-1	Does the commissioning plan include an emergency preparedness program that meets the requirements of the DOE Orders and associated guidance?	
	Is the emergency preparedness program for transition activities formal and documented in accordance with applicable DOE Orders? (EP-1.1)	
	Are facility personnel trained and qualified including the appropriate emergency procedures and processes? (EP-1.2)	
EP-2	Does the emergency preparedness program address the facility equipment, conditions and activities for the commissioning/transition phase?	
	Do emergency preparedness hazards analyses consider the planned commissioning/transition activities? (EP-2.1)	
	Do emergency preparedness hazards analyses consider initial operations? (EP-2.2)	
	Are emergency preparedness responses based on equipment and systems that are fully operational and do not rely upon systems in testing and transition? (EP-2.3)	
	As systems are transitioned to operations, are the appropriate emergency procedures updated or transferred? (EP-2.4)	
Maintenance Implementation		

ID #	Performance Objectives and Criteria	Met?
MI-1	Does the commissioning plan include a formal document process for maintenance implementation as systems and equipment complete the testing process and are transferred to operations?	
	Are maintenance requirements derived from the equipment manufactures and their recommendations (MI-1.1)?	
	Does the MI program include a formal process for the recall of components and equipment for calibration and maintenance activities? (MI-1.2)?	
	Does the MI program include surveillance activities for equipment and parameters in accordance with manufacture recommendations and safety basis commitments and requirements? (MI-1.3)	
	Does the MI program include a work development and control process that allows for the effective and timely development of work to support maintenance and surveillance activities? (MI-1.4)	
Safety Basis Implementation		
SB-1	Does the commissioning plan include a formal documented process for the implementation of the approved safety basis document and controls?	
	Does the SB implementation plan include a review of operating and transition procedures to ensure the implementation of safety basis commitments and controls? (SB-1.1)	
	Does the SB implementation plan include a review of facility equipment and conditions to ensure that they are consistent with the facility as described in the approved SB documents? (SB-1.2)	
	Does the SB implementation plan include a process to review all outstanding work documents to ensure that they are consistent with the SB requirements? (SB-1.3)	
	As required by DOE orders and guidance, are the safety basis documents incorporated into an Authorization Agreement for the transition and operation of the facility? (SB-1.4)	
SB-2	Are facility personnel trained and qualified on the SB documents?	
	Has training been developed and provided for personnel to ensure that they are knowledgeable about the SB document, its commitments and requirements? (SB-2.1)	
	Have personnel in positions requiring qualifications been qualified in accordance with the training program?	

ID #	Performance Objectives and Criteria	Met?
	(SB-2.2)	
SB-3	Does the commissioning plan include a facility safety equipment list?	
	Has the facility equipment list been revised to reflect the new/modified and the equipment as they are transitioned? (SB-3.1)	
	Does the commissioning plan include a process to ensure the facility safety equipment list is consistent with the safety basis documents? (SB-3.2)	
SB-4	Does the commissioning plan include the USQ process for configuration management during transition activities?	
	Have facility/project USQ procedures been revised to include the new SB documents? (SB-4.1)	
	Have outstanding facility modification packages been reviewed (USQ'd) against the SB documents being implemented with no deficiencies identified? (SB-4.2)	
Safety Management Programs		
SM-1	Have the SMPs identified in the SB documents been effectively implemented?	
	Have SMP commitments in the SB documents been identified and verified as implemented? (SM-1.1)	
	Does the project safety management program include a process for routine self-assessment and identification of appropriate corrective actions? (SM-1.2)	
SM-2	Does the Safety management program identified in the commissioning plan include the appropriate SMPs?	
	Does the safety management program effectively implement the ISMS process (SM-2.1)?	
	Does the safety management program address required security programs to ensure the security of the operations? (SM-2.2)	
	Does the safety management program address the following programs as appropriate? • Waste management • Transportation • Environmental management • Nuclear materials control? (SM-2.3)	

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

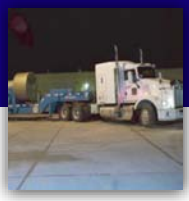
Standard Review Plan (SRP)

Management Self-Assessment Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

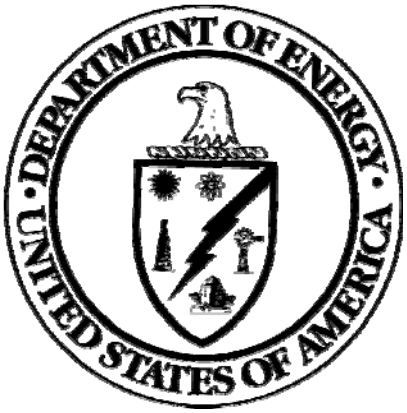
Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

OFFICE OF ENVIRONMENTAL MANAGEMENT

MANAGEMENT SELF ASSESSMENT REVIEW MODULE



September 2008

[This Review Module will be piloted by the DUF_6 Project early in 2009.]

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I. INTRODUCTION

The U.S. Department of Energy (DOE) is committed to conducting work efficiently and in a manner that protects workers, the public, and the environment. As stated in DOE P 450.4,

> *It is Department policy that safety management systems described herein shall be used to systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment.*

Safety Management Systems provide a formal, systematic process through which organizations plan, perform, assess, and improve the safe conduct of work. The Safety Management System has been institutionalized through DOE Directives and contracts to establish the Department-wide safety management objectives, guiding principles, and functions.

The Management Self Assessment (MSA) is conducted prior to preparations for the DOE Operational Readiness Review (ORR) or for the Readiness Assessment, as appropriate. Operational Readiness Reviews and Readiness Assessments are important parts of the federal project management process. DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets* outlines Critical Decisions (CDs) as the five major milestones in the approval by DOE at various stages of acquisition. Relevant to facility startup or restart, Operational Readiness Reviews or Readiness Assessments are conducted prior to approving the CD-4.

II. PURPOSE

This Management Self Assessment Review Module is a tool that assists DOE federal project review teams in evaluating contractor line management's effort to bring a project or facility into a condition where it is sufficiently prepared to initiate formal DOE readiness review activities for the final authorization to start or resume operations prior to CD-4 approval. The MSA review plan as presented here addresses the requirements of 48 CFR 970.5223-1, DOE Order 425.1C, *Startup and Restart of Nuclear Facilities*, DOE-STD-3006-2000, *Planning and Conduct of Operational Readiness Reviews (ORR),* and DOE-HDBK-3027-99, *Integrated Safety Management Systems (ISMS) Verification Team Leader's Handbook.*

As defined in 48 CFR 970.5223-1(c), DOE contractors shall manage and perform work in accordance with a documented Safety Management System that establishes how the contractor will accomplish the following core functions:

- Define the scope of work,
- Identify and analyze hazards associated with the work,
- Develop and implement hazard controls,
- Perform work within controls; and
- Provide feedback on the adequacy of controls and continue to improve safety management.

In addition, DOE P 450.4 and 48 CFR 5223-1(b) identify the guiding principles for integrated safety management:

As defined in 48 CFR 970.5223-1(c), and DOE P 450.4, *Safety Management System Policy,* DOE contractors shall manage and perform work in accordance with a documented Safety Management System that conforms with the following Guiding Principles (GP):

- GP-1, Line Management Responsibility. Line management responsibility for protection of employees, the public, and the environment. Line management includes contractor and subcontractor employees managing or supervising employees performing work.
- GP-2, Clear Roles and Responsibilities. Clear and unambiguous lines of authority and responsibility for ensuring (ES&H) are established and maintained at all organizational levels.
- GP-3, Competence per Responsibilities. Personnel possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.
- GP-4, Balanced Priorities. Resources are effectively allocated to address ES&H, programmatic, and operational considerations. Protecting employees, the public, and the environment is a priority whenever activities are planned and performed.
- GP-5, Identification of Safety Standards. Before work is performed, the associated hazards are evaluated and an agreed-upon set of ES&H standards and requirements are established which, if properly implemented, provide adequate assurance that employees, the public, and the environment are protected from adverse consequences.
- GP-6, Tailor Hazard Controls to Work. Administrative and engineering controls to prevent and mitigate hazards are tailored to the work being performed and associated hazards. Emphasis should be on designing the work and/or controls to reduce or eliminate the hazards and to prevent accidents and unplanned releases and exposures.
- GP-7, Operations Authorization. The conditions and requirements to be satisfied for operations to be initiated and conducted are established and agreed-upon by DOE and the contractor. These agreed-upon conditions and requirements are requirements of the contract and binding upon the contractor. The extent of documentation and level of authority for agreement shall be tailored to the complexity and hazards associated with the work and shall be established in a Safety Management System.

These guiding principles are also the guiding principles identified in DOE O 425.1C, Attachment 1. Therefore the review scope and criteria for the Management Assessment Review (MSAR) provides a list of assessment criteria designed to ensure that the completed contractor readiness activities have been adequately performed to demonstrate that the guiding principles have been met and that the actions identified are completed to the degree necessary to allow the DOE readiness review activities.

III. ROLES AND RESPONSIBILITIES

A successful MSAR depends on an experienced and qualified team. The team should be augmented with appropriate subject matter experts selected to complement the specific elements

of the safety management programs being assessed. The specific types of expertise needed will be dependent on the type of facility being reviewed, as well as other factors such as complexity and the hazards and risks expected during operations.

To the maximum extent possible, personnel selected to participate in a MSAR should have facility operations experience within the DOE complex or related programs. Personnel should be familiar with the requirements of DOE O 425.1C. Knowledge of DOE nuclear safety requirements is also important since contractor implementation of these requirements is being reviewed.

Management support is another necessary component to a successful MSAR. Field element managers, as well as the Federal Project Director, must recognize the importance of the MSAR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the MSAR process.

The roles and responsibilities for all involved in the MSAR must be clear and consistent with the various requirements of DOE O 413.3A and and DOE O 425.1C. The table below provides a compilation of design review roles and responsibilities.

Table 1. Design Review Roles and Responsibilities

Position	Responsibility
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the review.
	Facilitates the conduct of the review. Allocates office space, computer equipment, and support personnel to the team as necessary to accomplish the review within the scheduled time frame
Federal Project Director	Coordinates with the Review Team Leader in the selection of subject areas for the review and in developing the review criteria.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director and the Acquisition Executive, selects the subject areas to be reviewed.
	Based on the project complexity and hazards involved, selects the members of the review team.

Position	Responsibility
	Verifies the qualifications, technical knowledge, process knowledge, facility specific information, and independence of the Team Members.
	Leads the MSAR pre-visit.
	Leads the review team in completing the Review Criteria for the various subject areas to be reviewed.
	Coordinates the development of and forwards to the Federal Project Director, the data call of documents, briefings, interviews, and presentations needed for the review.
	Forwards the final review plan to the Acquisition Executive for approval.
	Leads the on-site portion of the review.
	Ensures the review team members complete and document their portions of the review. Coordinates the characterization of the severity of the findings.
	Coordinates the review team response to factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the Acquisition Executive for approval.
	Remains available as necessary to participate in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for the appropriate area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre-visit document review.
	Participates in the on-site review activities. Conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her subject areas. Prepares the review report.
	Makes recommendations to the Review Team Leader for the characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her subject area of review.

IV. REVIEW SCOPE AND CRITERIA

The primary objective of the management self assessment review guide is to provide a detailed approach for DOE federal project review teams to use in evaluating contractor's line

management effort to bring a project or facility into a condition of readiness to start or resume operations prior to CD-4 approval. This Guide provides a set of review criteria that are organized into three key areas:

- Prerequisites for DOE Readiness Review
- Completion of Contractor Readiness Review
- Closure of Action Items from Contractor Readiness Review.

For each review area, Appendix A of this guide provides overall performance objectives and an associated set of acceptance criteria to satisfy each performance objective. These performance objectives and criteria will provide consistent guidance to assist project-specific review teams in developing their Lines of Inquiry.

Prerequisites for DOE Readiness Review
This area of review is intended to evaluate the completion of prerequisites for initiation of the DOE readiness review. DOE Order 425.1C specifically identifies a number of items that must be completed prior to execution of DOE readiness review activities. The specified items include both items that must be completed by the contractor and then verified by DOE and items that must be performed by DOE.

Completion of Contractor Readiness Review
This area of review is intended to ensure that the contractor readiness review has been performed in accordance with the approved plan of action, has been documented in the final report, corrective actions have been identified for readiness review items and lessons learned have been documented. The depth and breadth of the readiness review activities performed by the contractor will be graded based on the hazards and complexity of the planned startup or restart activity and may be addressed in either an ORR or RA.

Closure of Action Items from Contractor Readiness Review
This area of review is intended to ensure that any deficiencies identified in the contractor readiness review process are either closed or are on a manageable DOE approved prestart list prior to DOE initiating their readiness review activities. For items to remain open on a DOE approved prestart list, they must have a well-defined schedule for closure.

V. REVIEW PLANS AND DOCUMENTATION

The results of an MSA will be used by the DOE Federal Project Director and ultimately the Acquisition Executive to help determine that the facility may begin operations. It is important to clearly document the methods, assumptions and results of the MSA. Section 8 of the SRP provides guidelines for preparing a Review Plan and a final report.

The following activities should be conducted as part of the Review Plan development and documentation/closure of the review:

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents, assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and subject areas listed in the respective appendices of this module.
- The individual lines of inquiry should be compiled and submitted to the sponsor of the review for concurrence prior to starting the review.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document reviews and personnel interviews. The method used as the basis for closure/comment/finding and the results of the inquiry should be documented and tracked.

REFERENCES

DOE-HDBK-3027-99, *Integrated Safety Management Systems (ISMS) Verification Team Leader's Handbook*

DOE P 450.4, *Safety Management System Policy*, 10/15/96.

DOE 450.4, *Line Environment, Safety and Health Oversight*, 06/26/97.

DOE P 450.6, *Secretarial, Policy Statement, Environment, Safety and Health.*

DOE G 450.4-1B, *Integrated Safety Management System Guide for use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); The Functions, Responsibilities, and Authorities Manual; and The Department of Energy Acquisition Regulation*, Vols. 1 and 2, 03/01/01.

DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, 7/28/06.

DOE Order 151.1C, *Comprehensive Emergency Management System*, 11/02/2005

DOE Order 425.1C, *Startup and Restart of Nuclear Facilities*, 3/13/03.

DOE West Valley Demonstration Project Interim End State Contract management Plan, December 2007

EM-62, SOPP #47, Rev. 0, *Environmental Management Headquarters Operational readiness Assistance Program.*

48 CFR 970.5223-1(c), (e), *Integration of Environment, Safety, and Health into Work Planning and Execution.*

Appendix A – Performance Objectives and Criteria

Legend of review topics:

Review Topic Area	Identifier
1. Prerequisites for DOE Readiness Review	PR
2. Completion of Contractor Readiness Review	CRR
3. Closure of Action Items from Contractor Readiness Review	COA

Table A.1. Performance Objectives and Requirements to be Considered When Conducting Management Self Assessments

ID#	Performance Objectives and Requirements	Met?
PR, Prerequisites for DOE Readiness Review		
PR-1	The contractor and DOE plans of action have been approved by the authorization authority.	
	The contractor plan of action addresses each of the minimum core requirements as identified in paragraph 4d of DOE Order 425.1C that is applicable to the project startup. (PR-1.1)	
	The DOE plan of action specifies additional prerequisites such as certification of readiness to oversee facility operations by operations office and headquarters management. (PR-1.2)	
PR-2	DOE has received correspondence from the responsible contractor certifying that the facility is ready for startup.	
PR-3	The contractor has successfully completed practice and demonstrations of all procedures and activities in the order in which they are to be performed.	
PR-4	DOE line management has certified that it meets the DOE plan of action.	
	A DOE facility representative is assigned to the facility and qualified per DOE startup plan and requirements. (PR-4.1)	
	DOE project management and other support staff is prepared to support oversight of operations. (PR-4.2)	
PR-5	The Documented Safety Analysis (DSA) and Technical Safety Requirements (TSRs) are approved and implemented for the facility.	
CRR, Completion of Contactor Readiness Review		
CRR-1	The contractor's Readiness Review is complete and a final report has been issued.	
	The final report makes a conclusion as to whether operations can proceed safely. (CRR-1.1)	
	The final report states whether the facility has established: • An agreed-upon set of requirements to govern safe operations • The set of requirements has been formalized with DOE • These requirements have been appropriately implemented • In the opinion of the review team adequate protection of the public, the worker and the environment has been maintained. (CRR1.2)	
CRR-2	The readiness review satisfies all of the pre-requisites and items identified in the plan of action	
COA, Closure of Action Items from Contractor Readiness Review		
COA-1	The resolution of all findings from the Readiness Review has been documented and is maintained with the plan of action and final report.	
	Any remaining open pre-start findings are on a manageable list approved by DOE. (COA-1.1)	

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

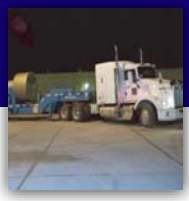
Standard Review Plan (SRP)

Safety Analysis Reports for Packaging and Transportation Review Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

LAWRENCE
LIVERMORE
NATIONAL
LABORATORY

UCID-21218 Rev. 3

Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings

Revision 3

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February 2008

DISCLAIMER

UCID-21218 Rev. 3

Packaging Review Guide
for Reviewing
Safety Analysis Reports for Packagings

Revision 3

February 2008

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ABSTRACT

This Packaging Review Guide (PRG) provides guidance for Department of Energy (DOE) review and approval of packagings to transport fissile and Type B quantities of radioactive material. It fulfills, in part, the requirements of DOE Order 460.1B for the Headquarters Certifying Official to establish standards and to provide guidance for the preparation of Safety Analysis Reports for Packagings (SARPs).

This PRG is intended for use by the Headquarters Certifying Official and his or her review staff, DOE Secretarial offices, operations/field offices, and applicants for DOE packaging approval.

This PRG is generally organized at the section level in a format similar to that recommended in Regulatory Guide 7.9 (RG 7.9). One notable exception is the addition of Section 9 (Quality Assurance), which is not included as a separate chapter in RG 7.9. Within each section, this PRG addresses the technical and regulatory bases for the review, the manner in which the review is accomplished, and findings that are generally applicable for a package that meets the approval standards.

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APPENDICES

FIGURES

TABLES

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ACKNOWLEDGMENTS

This work was funded by the Packaging Certification Program, Office of Safety Management and Operations, Environmental Management, U. S. Department of Energy. The authors would like to thank Dr. James Shuler, EM-60, for his overall direction and support.

Revision 3 is a complete update of the 1999 edition of this document, whose authors deserve acknowledgment for the initial foundation from which this work was developed: M. K. Sheaffer, B. L. Anderson, L. E. Fischer, R. S. Hafner, J. Hovingh, S. C. Keeton, G. C. Mok, M. E. Mount, E. W. Russell, C. K. Syn, and M. C. Witte.

As noted in the Introduction, this document incorporates substantial guidance from various reports published by the U.S. Nuclear Regulatory Commission (NRC), including NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Material*, and NUREG-1617, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*. The authors would like to thank the NRC staff, with whom we have worked for almost two decades, for their support and assistance.

Appreciation should also be acknowledged to the packaging review staff at Argonne National Laboratory, and at Eagle Research Group, Inc., for their comments and suggestions on the draft of this document.

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ABBREVIATIONS AND ACRONYMS

ANL	Argonne National Laboratory
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
AWS	American Welding Society
B&PV	Boiler and Pressure Vessel (ASME Code)
Bq	Becquerel
cc	cubic centimeter
CFR	Code of Federal Regulations
cg	center of gravity
Ci	curie
cm	centimeter
CoC	certificate of compliance
CSI	Criticality Safety Index
DOE	U.S. Department of Energy
DOE O	U.S. Department of Energy Order (used in designation of new-series orders)
DOT	U.S. Department of Transportation
ft	foot
g	acceleration due to gravity
h	hour
HAC	Hypothetical Accident Conditions
in.	inch
k_{eff}	effective multiplication factor
kPa	kilopascal
IAEA	International Atomic Energy Agency
ISG	Interim Staff Guidance
LLNL	Lawrence Livermore National Laboratory

m	meter
MNOP	Maximum Normal Operating Pressure
MPa	megapascal
mrem	millirem
mSv	millisievert
NCT	Normal Conditions of Transport
NRC	U.S. Nuclear Regulatory Commission
PBq	petabecquerel (10^{15} Bq)
PRG	Packaging Review Guide (this document)
psi	pounds (force) per square inch
QA	quality assurance
ref	reference
RG	Regulatory Guide
s	second
SARP	Safety Analysis Report for Packaging(s)*
SCO	surface contaminated object
SRNL	Savannah River National Laboratory
SSCs	structures, systems, and components (important to safety)
SER	Safety Evaluation Report
Sv	sievert
TBq	terabecquerel (10^{12} Bq)
TI	transport index
TRR	Technical Review Report

* The term "SARP" is commonly used by DOE and its contractors to denote the document that describes and evaluates the proposed package. NRC licensees typically use the term "Safety Analysis Report (SAR)." In addition to the SARP, the "application" typically includes a transmittal letter and other supplemental information docketed during the review process.

INTRODUCTION

Background

Department of Energy Order 460.1B (i.e., DOE O 460.1B)[1] establishes requirements for the proper packaging and transportation of hazardous material by DOE and its contractors.* Unless otherwise authorized or excluded by this order, DOE transportation of fissile and Type B quantities of radioactive material must be in packagings approved by the Headquarters Certifying Official under conditions specified in the DOE Certificate of Compliance (CoC).

The authority for DOE to certify packagings is established by 49 CFR 173.7(d),[2] which states that packagings made by or under the direction of DOE may be used for the transportation of radioactive materials when evaluated, approved, and certified by DOE against standards equivalent to those specified in 10 CFR 71.[3] DOE O 460.1B explicitly states that such packages must comply with the standards of 10 CFR 71, and with any other requirements deemed applicable by the Headquarters Certifying Official.

Purpose

This Packaging Review Guide (PRG) provides guidance for DOE review and approval of packagings to transport fissile and Type B quantities of radioactive material. It fulfills, in part, the requirements of DOE O 460.1B for the Headquarters Certifying Official to establish standards and to provide guidance for the preparation of Safety Analysis Reports for Packagings (SARPs).

This PRG is intended for use by the Headquarters Certifying Official and his review staff, DOE Secretarial offices, operations/field offices, and applicants for DOE packaging approval. The primary objectives of this PRG are to:

- Summarize the regulatory requirements for package approval
- Describe the technical review procedures by which DOE determines that these requirements have been satisfied
- Establish and maintain the quality and uniformity of reviews
- Define the base from which to evaluate proposed changes in scope and requirements of reviews
- Provide the above information to DOE organizations, contractors, other government agencies, and interested members of the general public.

* Similar requirements were previously established by DOE Orders 1540.2 and 5480.3, which may still be applicable depending on specific contractual relationships.

This PRG was originally published in September 1987. Revision 1, issued in October 1988, added new review sections on quality assurance and penetrations through the containment boundary, along with a few other items. Revision 2 was published October 1999. Revision 3 of this PRG is a complete update, and supersedes Revision 2 in its entirety.

Related Documents

DOE's authority to certify packages is based on the premise that the DOE evaluation and approval process will provide an assurance of safety equivalent to that required by the NRC. Such assurance can be provided by:

- Requiring that DOE package designs meet the standards of 10 CFR 71 or their equivalent
- Ensuring that the evaluation methods used to demonstrate compliance with these standards are equivalent to those used by the Nuclear Regulatory Commission.

Consequently, the evaluation process described in this PRG relies substantially on 10 CFR 71 and the following other NRC documents:

- NUREG-1609, *Standard Review Plan for Transportation Packages for Radioactive Material*[4]
- NUREG-1617, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*[5]
- Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material*[6, 7]
- Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material*[8, 9]
- Other regulatory guides such as the Interim Staff Guidance (ISG) and NUREG reports that provide guidance on criteria for evaluating transportation packages.

Scope

Because of the large variety of packages and the many different approaches that can be taken to evaluate these packaging designs, no single guide can address in detail every situation that might be applicable to a review. This PRG is intended to provide a general description of the principles and procedures for evaluating packaging applications. DOE may therefore need to modify or expand the guidance in this PRG to adapt to specific packaging designs. This PRG does not relieve any DOE element or contractor from the requirements of DOE O 460.1B or other pertinent regulations, or imply that SARPs reviewed in accordance with this guide will necessarily be approved.

This PRG addresses shipment of fissile or Type B quantities of radioactive material in DOE certified packagings under the provision of DOE O 460.1B and 10 CFR 71. The following areas of DOE O 460.1B and 10 CFR 71 *are not* currently within the scope of this PRG:

- Shipment of hazardous material other than fissile and Type B radioactive material
- Shipment of DOE radioactive material in packages approved by Department of Transportation (DOT), NRC, or International Atomic Energy Agency (IAEA)
- Shipment of plutonium by air
- Qualification and shipment of low specific activity material and surface contaminated objects
- Qualification and shipment of special form radioactive material
- Notifications, violations, and penalties
- Exemptions and exceptions
- Requirements incorporated into DOE O 460.1B or 10 CFR 71 by reference to other regulations (e.g., DOE, NRC, DOT, or U.S. Postal Service).

Organization of PRG

The main body of this PRG is organized into nine sections in a format similar to that recommended in Regulatory Guide 7.9 (RG 7.9) for the SARP.[*] One notable exception is the addition of Section 9 (Quality Assurance), which is not included as a separate chapter in RG 7.9. Within each section, this PRG addresses the technical and regulatory bases for the review, the manner in which the review is accomplished, and general findings applicable to a package that meets the approval standards. Each section follows the format below.

Introduction

The introduction succinctly states the objective of the review for each section, provides summary information as appropriate, and relates the review to information provided in other chapters of the SARP.

No chapter of a SARP can be reviewed independently from information presented in other chapters. For example, the Containment review depends in part on (1) the packaging and contents description presented in the General Information chapter and (2) the condition of the package under the normal and hypothetical accident condition tests in the Structural and Thermal Evaluation chapters. Likewise, the results of the Containment review may result in the need to implement specific Package Operations, Acceptance Tests, or other Quality Assurance procedures. The introduction to each section of this PRG presents a schematic representation of these interfaces. These representations are intended only as examples and should not be considered as a complete list of all information to be reviewed. In addition, specific interfaces may vary with the details of a particular package design or with the specific format of the SARP.

[*] For clarification, the major divisions of RG 7.9 (and a SARP) are referred to as "chapters." The major divisions of this PRG are considered "sections."

Subsection 1. Areas of Review

This subsection identifies the principal areas that are reviewed to demonstrate that the packaging design complies with regulatory requirements. In general, the Areas of Review correspond to the major subsections of RG 7.9, although in some cases they have been modified for clarity and completeness.

Subsection 2. Regulatory Requirements

This subsection summarizes the applicable regulatory requirements of 10 CFR 71. In many instances, the wording from the regulation is shortened, and two or more related requirements are sometimes combined for brevity. This modification in wording is not intended to change or interpret the regulations. Furthermore, the reader is cautioned that the categorization of regulatory requirements by SARP section (or PRG chapter) is a subjective judgment, which may depend on the package design as well as the specific format in which the SARP is organized. Regulatory requirements are generally listed in the order that they are addressed in the Review Procedures.

Subsection 3. Review Procedures

This subsection provides guidance for the review of a package. The Review Procedures are organized in parallel with the Areas of Review identified in Subsection 2 above. Because of the large number of different package designs, DOE may need to expand or modify these procedures to adapt to a specific package or to address the method of evaluation presented in the SARP.

The review of the evaluation presented in the SARP will often necessitate confirmatory analyses by the reviewers. The effort and level of detail of such analyses will depend on many factors, including the issues evaluated, the method of evaluation (e.g., test or analysis), the complexity of the evaluation, the experience of the reviewer, similarity to other approved packages, the margin between evaluated performance and regulatory requirements, importance to safety, and many other factors.

Subsection 4. Evaluation Findings

This subsection presents an example of the major findings of the review. The review staff will modify the wording as appropriate to address specific details of the SARP and methods of review. In addition, this subsection identifies typical limiting assumptions or conditions applicable to the evaluation that might not be specified in the General Information chapter of the SARP but that should be included as conditions of approval in the CoC.

Subsection 5. References

This subsection identifies references cited in the section. DOE orders are specified in this PRG by order number (e.g., DOE O 460.1B or DOE O 414.1C). Revision designations (e.g., A, B, C) are those in effect at the time of publication of this PRG.

Appendices of PRG

This PRG contains four appendices. Appendix A provides definitions of common package-related terms, many of which are also defined in 10 CFR 71 or 49 CFR Part 173. Appendix B presents a summary listing of 10 CFR 71 requirements and the SARP chapters to which they are generally applicable. The 2004 revision of 10 CFR 71 resulted in several changes and additional requirements, which are highlighted in Appendix C. A summary of issues relevant to materials and fabrication, which are typically addressed in several SARP chapters, is included in Appendix D.

Requirements and Guidance

Throughout this PRG, the word *must* is intended to imply a requirement imposed by CFR or DOE order. Other conditions generally considered necessary for package approval are specified by the word *should*. Because these conditions are not specifically imposed by regulation or order, the SARP may, if appropriate, justify that they are not applicable or that other conditions are more pertinent to the proposed package.

Technical Review Report

The technical review of DOE SARPs is conducted by Lawrence Livermore National Laboratory (LLNL), Argonne National Laboratory (ANL), Savannah River National Laboratory (SRNL) or a combination of these laboratories. The results of these reviews are documented in a Technical Review Report (TRR), which summarizes:

- Applicable regulatory requirements
- Methods by which the SARP demonstrated that these requirements were met
- A description of the technical review of the evaluation presented in the SARP, including confirmatory analysis and other bases for accepting the SARP evaluation
- Summary findings of the technical review.

The TRR provides the justification for the technical information included in the Safety Evaluation Report (SER), a report issued by the Headquarters Certifying Official to document DOE's review of the package for compliance with DOE O 460.1B and 10 CFR 71.

References

[1] U.S. Department of Energy, *Packaging and Transportation Safety*, DOE Order 460.1B, April 4, 2003.

[2] Department of Transportation, Research and Special Programs Administration, *49 CFR Parts 171, 172, et al., Hazardous Materials Regulations; Compatibility with the Regulations of the International Atomic Energy Agency; Final Rule*, 69 F.R. 3632, January 26, 2004, as amended.

[3] Nuclear Regulatory Commission, 10 CFR Part 71, *Compatibility with IAEA Transportation Standards (TS-R-1) and Other Transportation Safety Amendments; Final Rule*, 69 F.R. 3698, January 26, 2004, as amended.

[4] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Radioactive Material*, NUREG-1609, May 1999.

[5] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*, NUREG-1617, March 2000.

[6] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Proposed Revision 2 to Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material*, May 1986.

[7] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material*, Regulatory Guide 7.9, Revision 2, March 2005.

[8] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Revision 1, June 1986.

[9] U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, *Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material*, Regulatory Guide 7.10, Revision 2, March 2005.

1.0 GENERAL INFORMATION REVIEW

This review verifies that the package design has been described in sufficient detail to provide an adequate basis for its evaluation.

The General Information chapter of the Safety Analysis Report for Packaging (SARP) is reviewed by all members of the review team. During the review, the team leader (or the team leader's designee) coordinates input from team members and prepares questions or requests for additional information from the applicant as appropriate. At the completion of the review, the individual responsible for questions on the General Information chapter also prepares the corresponding section of the Technical Review Report (TRR).

The results of the General Information review are considered in the review of all other chapters of the SARP. An example of this information flow for this review is shown in Figure 1.1.

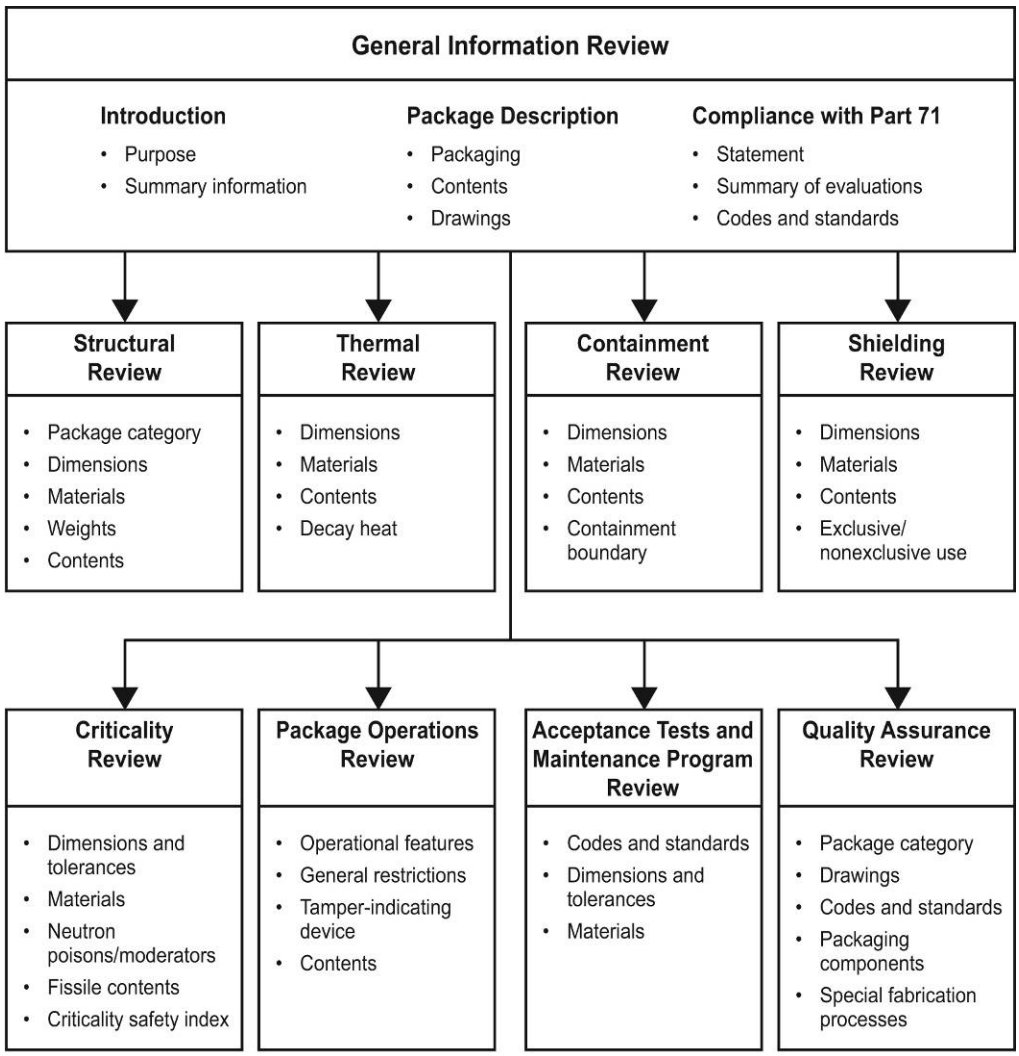

Figure 1.1 Example of Information Flow for the General Information Review

1.1 Areas of Review

The package description and engineering drawings should be reviewed. The review should include:

1.1.1 Introduction

- Purpose of Application
- Summary Information
- Statement of Compliance
- Summary of Evaluation

1.1.2 Package Description

- Packaging
- Contents
- Special Requirements for Plutonium
- Operational Features

1.1.3 Appendices

- Drawings
- Other Information

1.2 Regulatory Requirements

The requirements of 10 CFR 71 applicable to the General Information review include:

- An application for package approval must be submitted in accordance with Subpart D of 10 CFR 71. [§71.0(d)(2)]
- An application for modification of a previously approved package is subject to the provisions of §71.19 and §71.31(b). All changes in the conditions of package approval must be approved. [§71.19, §71.31(b), §71.107(c)]
- The application must include a description of the packaging design in sufficient detail to provide an adequate basis for its evaluation. [§71.31(a)(1), §71.33(a)]
- The application must include a description of the contents in sufficient detail to provide an adequate basis for evaluation of the packaging design. [§71.31(a)(1), §71.33(b)]
- The application must reference or describe the quality assurance program applicable to the package. [§71.31(a)(3), §71.37]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31I]

- An application for renewal of a previously approved package must be submitted no later than 30 days prior to the expiration date of the approval to assure continued use. [§71.38]
- The smallest overall dimension of the package must not be less than 10 cm (4 in.). [§71.43(a)]
- The outside of the package must incorporate a feature that, while intact, would be evidence that the package has not been opened by unauthorized persons. [§71.43(b)]
- A package with a transport index greater than 10, a Criticality Safety Index greater than 50, or an accessible external surface temperature greater than 50°C (122°F) must be transported by exclusive-use shipment. [§71.43(g), §71.47(a), §71.47(b), §71.59(c)]
- The maximum activity of radionuclides in a Type A package must not exceed the A_1 or A_2 values listed in 10 CFR 71, Appendix A, Table A-1. For a mixture of radionuclides, the provisions of Appendix A, paragraph IV apply, except that for krypton-85, an effective A_2 equal to 10 A_2 may be used. [Appendix A, §71.51(b)]
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- A fissile material package must be assigned a Criticality Safety Index for nuclear criticality control to limit the number of packages in a single shipment. [§71.59, §71.35(b)]
- Plutonium in excess of 0.74 TBq (20 Ci) must be shipped as a solid. [§71.63]
- The package must be conspicuously and durably marked with its model number, serial number, gross weight, and package identification number. [§71.19, §71.85(c)]

1.3 Review Procedures

The following procedures are generally applicable to the review of the General Information chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 1.1 of this Packaging Review Guide (PRG).

1.3.1 Introduction

1.3.1.1 Purpose of Application

Verify that the purpose of the application is clearly stated. The application may be for approval of a new design, for modification of an approved design, or for renewal of an existing approval (e.g., Certificate of Compliance [CoC]). The purpose may be identified in the SARP itself, or in an accompanying transmittal letter for the application.

Applications for approval of a new design should be complete and should contain the information identified in Subpart D (Application for Package Approval) of 10 CFR 71.

Applications for modification of an approved design should clearly identify the changes being requested. Modifications may include design changes, changes in authorized contents, or changes in the conditions of the approval (including changes in the designation of the package identification number). Design changes should be clearly identified on revised engineering drawings. The application should include an assessment of the requested changes and

justification that these changes do not affect the ability of the package to meet the requirements of 10 CFR 71. Applications for modifications are subject to the provisions of §71.19 and §71.31(b), as applicable. Changes in the package identification number to designate compliance with revised regulations (e.g., the addition of "-96") are subject to §71.19(e). A summary of regulatory changes affecting the "-96" designation is provided in Appendix C of this PRG.

Applications for renewal of an existing approval should be made within 30 days of expiration of the approval to assure continued use. Expiration of approvals and applications for renewal are subject to the provisions of §71.38.

1.3.1.2 Summary Information

Confirm that the package type and model number are designated. A new Type B package design should be designated B(U)-96 unless it has a maximum normal operating pressure greater than 700 kPa (100 psi) gauge or a pressure relief device that would allow the release of radioactive material under the tests specified in §71.73 (hypothetical accident conditions). In those cases, the package should be designated B(M)-96.

Review the maximum activity and radionuclides of the contents. Ensure they are consistent with the designated package type. For a mixture of radionuclides, the maximum activity allowed in a Type A package must be determined in accordance with 10 CFR 71 Appendix A and §71.51(b). Packages for transporting fissile radionuclides should also be designated as fissile material packages (e.g., AF-96, B(U)F-96) unless the exemptions of §71.15 are applicable.

Ensure that any restrictions regarding the type of conveyance for shipment of the package are designated. Note that special requirements apply to the air shipment of plutonium, e.g., §71.64, §71.74, and §71.88. Review of packagings for plutonium air shipments is not addressed in this PRG.

For Type B packages, verify that the designated package category is properly justified. Definitions of package categories are summarized in Table 1.1. Detailed justification, including calculation of an effective A_2 from the maximum activity of the contents, might be presented in the appendices to the General Information chapter or in another chapter of the SARP (e.g., Containment).

Table 1.1 Category Designations for Type B Packages[1-1]

Contents Form	Category I	Category II	Category III
Normal Form*	Greater than 3,000 A_2 or greater than 1.11 PBq (30,000 Ci)	Between 3,000 A_2 and 30 A_2, and not greater than 1.11 PBq (30,000 Ci)	Less than 30 A_2 and less than 1.11 PBq (30,000 Ci)

*Similar requirements apply to special form radioactive material, which is not explicitly addressed in this PRG.

The package category will determine which code[1-2] or other criteria[1-3, 1-4] are appropriate for components that affect the structural integrity of containment, criticality, or shielding systems. Although the designation of these codes or standards should be indicated on the engineering drawings and applicable fabrication specifications indicated in this chapter (see Section 1.3.3.1), a more detailed discussion and justification may be deferred to the Structural Evaluation chapter of the SARP. Similarly, details of other codes and standards for the package may be presented in the General Information chapter or may be discussed in the applicable chapter of the SARP. Review designated codes and standards as appropriate.

Confirm that the SARP identifies the applicant's quality assurance (QA) program applicable to the package. Details of QA program requirements should be presented in the QA chapter of the SARP.

For fissile material packages, confirm that a Criticality Safety Index (CSI), based on nuclear criticality safety, is designated for each content. This index will generally be designated in the CoC as the *minimum criticality safety index*. Note that the CSI, used in shipment, depends on criticality safety and the Transport Index (TI) is based on external radiation levels. Unlike the CSI based on criticality, the TI based on radiation is determined by radiation levels of the package as loaded for shipment and is not specified in the CoC. Ensure that the maximum number of packages that may be shipped in a single conveyance and any restrictions for exclusive-use shipment, if applicable, are consistent with the CSI based on criticality safety.

Determine if the shipment of the package is limited to exclusive use because of other regulatory requirements (e.g., external radiation levels or CSI value, or package surface temperatures). Additional information should be included in the Package Operations chapter of the SARP.

1.3.1.3 Statement of Compliance

Confirm that SARP contains an unequivocal statement that the package complies with 10 CFR 71.

1.3.1.4 Summary of Evaluation

In addition to a statement that the package complies with 10 CFR 71, the General Information chapter of the SARP should include a summary of the package evaluations presented in subsequent SARP chapters, with a specific reference to the chapters in which compliance is demonstrated. The summary information should address:

- Criticality requirements, §71.15, §71.22, §71.55, §71.59
- General requirements for all packages, §71.43
- Structural requirements for lifting and tie-down devices and for shipments containing more than 10^5 A_2, §71.45 and §71.61
- External radiation requirements for all packages, §71.47
- Requirements for Type B packages, §71.51
- Special requirements for plutonium packages, §71.63

- Structural and thermal performance of the package under the tests for normal conditions of transport and hypothetical accident conditions, §71.71 and §71.73, respectively
- Requirements for operating controls and procedures, Subpart G
- Requirements for quality assurance, Subpart H.

The review of each SARP chapter should confirm that this summary information is consistent with the detailed evaluation and with the requirements of 10 CFR 71.

1.3.2 Package Description

1.3.2.1 Packaging

Review the text description of the packaging. Sketches, figures, or other schematic diagrams should be provided as appropriate. Ensure that the description of the packaging presented in the text and figures is consistent with that depicted on the engineering drawings (see Section 1.3.3.1).

Verify that the following information, as applicable, is adequately discussed:

- General packaging description, including overall dimensions, maximum weight, and minimum weight, if appropriate
- Containment features, including a clear identification of the containment boundary
- Shielding features, including personnel barriers
- Criticality control features, including neutron poisons, moderators, and spacers
- Heat-transfer features, including gaps and coolants, that affect transfer and dissipation of heat
- Structural features, including supporting structures, lifting and tie-down devices, and impact limiters.

Proprietary information, if applicable, should be clearly identified. Justification for withholding this information from public disclosure should be presented in a format comparable to that specified in 10 CFR 2.390.

Verify that the SARP defines the exact boundary of the containment system. This may include the containment vessel, welds, drain or fill ports, valves, pressure relief devices, seals, test ports, lids, cover plates, and other closure devices. If multiple seals are used for a single closure, the seal, defined as the containment-system seal, should be clearly identified. A sketch of the containment system should be provided, and all components should be shown on the engineering drawings in the appendices. Additional information regarding the review of the containment boundary and special containment requirements for plutonium and for damaged reactor fuel are addressed in Section 4 of this PRG.

Based on the package description and engineering drawings, confirm that the package meets the following requirements of §71.43(a) and §71.43(b):

- The smallest overall dimension of the package is not less than 10 cm (4 in.)
- The outside of a package must incorporate a feature, such as a seal, that is not readily breakable and that, while intact, would be evidence that the package has not been opened by unauthorized persons.

1.3.2.2 Contents

Confirm that the contents are described in the same detail as that intended for the CoC. The description should include, as a minimum, the following information:

- Identification and maximum quantity (radioactivity or mass) of the radioactive material
- Identification and maximum quantity of fissile material
- Chemical and physical form, including density and moisture content, and the presence of other moderating constituents
- Location and configuration of contents within the packaging, including secondary containers, wrapping, shoring, and other material not defined as part of the packaging
- Identification and quantity of nonfissile materials used as reflectors, neutron absorbers, or moderators
- Any material subject to chemical, galvanic, or other reaction, including the generation of combustible and reactive gases
- Maximum normal operating pressure
- Maximum weight (including shoring, canisters, secondary containers, etc.) and minimum weight if appropriate
- Maximum decay heat.

If the contents include reactor fuel rods or assemblies, the following additional information should be specified as appropriate:

- Type of fuel, maximum enrichment and density of fissile material prior to irradiation (including specifications of non-uniform enrichment, if applicable). If the reactivity (activity) of irradiated fuel is larger than fresh fuel, the isotopic composition of the irradiated fuel should also be presented.
- Burnup, minimum initial enrichment, specific power, cooling time, and heat load
- Fuel assembly specifications, including dimensional data for the fuel pellets, cladding, fuel-cladding gap, rods, guide tubes, and other assembly structures considered in the evaluation
- Control assemblies or other contents (e.g., startup sources) present

- Number of assemblies or rods
- For damaged fuel, the extent of damage, description of containerization, or any other applicable limits
- Other information necessary to evaluate compliance with 10 CFR 71, as applicable.

1.3.2.3 Special Requirements for Plutonium

If the contents include plutonium in excess of 0.74 TBq (20 Ci), verify that the contents are in solid form.

1.3.2.4 Operational Features

Verify that appropriate operational features are discussed. A schematic diagram of any special operational feature should be included if applicable. Additional information on operational features may be presented in the Package Operations chapter of the SARP.

1.3.3 Appendices

1.3.3.1 Drawings

Verify that information on the engineering drawings is sufficiently detailed and consistent with the package description. The appendices should not include a full set of drawings for large, complex packages, nor should they include detailed construction drawings for packages of any type. A detailed discussion of information to be included on drawings is presented in NUREG/CR-5502.[1-5]

Department of Energy (DOE) orders (e.g., DOE O 460.1B and 1540.2) authorize transportation of Type B or fissile radioactive material by DOE and DOE contractors in packages approved by the Headquarters Certifying Official under conditions specified in the CoC. The purpose of the engineering drawings in the SARP is to define the package design, approved by DOE, and compliance with these drawings is typically included in the certificate as a condition of package approval. Packages that do not conform to the drawings in the SARP are not authorized for use.

Confirm that each drawing has a title block that identifies the preparing organization, drawing number, sheet number, title, date, and signature or initials indicating approval of the drawing. Revised drawings should identify the revision number, date, and description of the change in each revision. Proprietary information, if applicable, should be clearly identified. The drawings should include:

- General arrangement of packaging and contents, including dimensions
- Design features that affect the package evaluation (see Section 1.3.2.1 above)
- Packaging markings, including model number, serial number, gross weight, and package identification number
- Maximum allowable weight of the package
- Maximum allowable weight of the contents and secondary packaging
- Minimum weights, if appropriate.

Information on design features should include, as appropriate:

- Identification of the design feature and its components
- Materials of construction, including applicable material specifications
- Codes, standards, or other similar specification documents for fabrication, assembly, and testing (including welding symbols), and inspection. As appropriate, such information may be included on a separate fabrication specification that can be referenced as a condition of approval in the certificate. Compliance with this specification should generally be noted on the drawings as applicable.
- Location, with respect to other package features
- Dimensions with appropriate tolerances
- Operational specifications (e.g., bolt torque, specifications of pressure-relief devices, etc.).

1.3.3.2 Other Information

Confirm that the appendices include a list of references and a copy of any applicable references not generally available to the reviewer, as appropriate. The appendices may also provide supporting information on special fabrication procedures (as noted on the drawings), determination of the package category, and other appropriate supplemental information deemed necessary by the applicant or reviewer.

1.4 Evaluation Findings

1.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 1.2 above are satisfied. Because confirmation of some information presented in the General Information chapter of the SARP depends on a detailed review of subsequent chapters, preparation of the findings for this section may be deferred until the review of later chapters is completed.

The TRR should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the package design has been adequately described to meet the requirements of 10 CFR 71.

1.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in Section 5 of the CoC. In addition to a summary package description and specifications of authorized contents, the conditions of approval applicable to the General Information chapter of the SARP typically include:

- Type of conveyance
- Minimum criticality safety index

- Restriction to exclusive-use shipment, if applicable
- Drawings that define the package design, and additional fabrication specifications as applicable
- Requirement to add serial numbers to previously approved packages, as applicable.

1.5 References

[1-1] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)*, Regulatory Guide 7.11., June 1991.

[1-2] American Society of Mechanical Engineers, *ASME Boiler and Pressure Vessel Code*, 2004, New York.

[1-3] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Shipping Containers for Radioactive Materials*, NUREG/CR-3019 (UCRL-53044), March 1984.

[1-4] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854 (UCRL-53544), March 1985.

[1-5] U.S. Nuclear Regulatory Commission, *Engineering Drawings for 10 CFR Part 71 Package Approvals*, NUREG/CR-5502 (UCRL-ID-130438), May 1998.

2.0 STRUCTURAL REVIEW

This review verifies that the structural performance of the package design has been adequately evaluated for the tests specified under normal conditions of transport and hypothetical accident conditions and that the package design meets the structural requirements of 10 CFR 71.

The Structural review is based in part on the descriptions and evaluations presented in the General Information and the Thermal Evaluation chapters of the Safety Analysis Report for Packaging (SARP). Similarly, results of the Structural review are considered in the review of subsequent chapters of the SARP. An example of this information flow for the Structural review is shown in Figure 2.1.

Although 10 CFR 71 specifies only a few explicit structural requirements for packages (e.g., lifting and tie-down requirements), the structural performance of the package under normal conditions of transport and hypothetical accident conditions significantly affects its ability to meet the containment, shielding, and subcriticality requirements of the regulation. Consequently, the Structural review focuses on confirming the SARP evaluation of the effects of these tests and on coordinating these effects with the review of the Thermal, Containment, Shielding, and Criticality Evaluation chapters.

2.1 Areas of Review

The structural design of the package should be reviewed. The Structural review should include the following:

2.1.1 Description of Structural Design

- Design Features
- Codes and Standards

2.1.2 Materials of Construction

- Material Specifications and Properties
- Prevention of Chemical, Galvanic, or Other Reactions
- Effects of Radiation on Materials

2.1.3 Fabrication, Assembly, and Examination

- Fabrication and Assembly
- Examination

2.1.4 General Considerations for Structural Evaluations

- Evaluation by Test
- Evaluation by Analysis

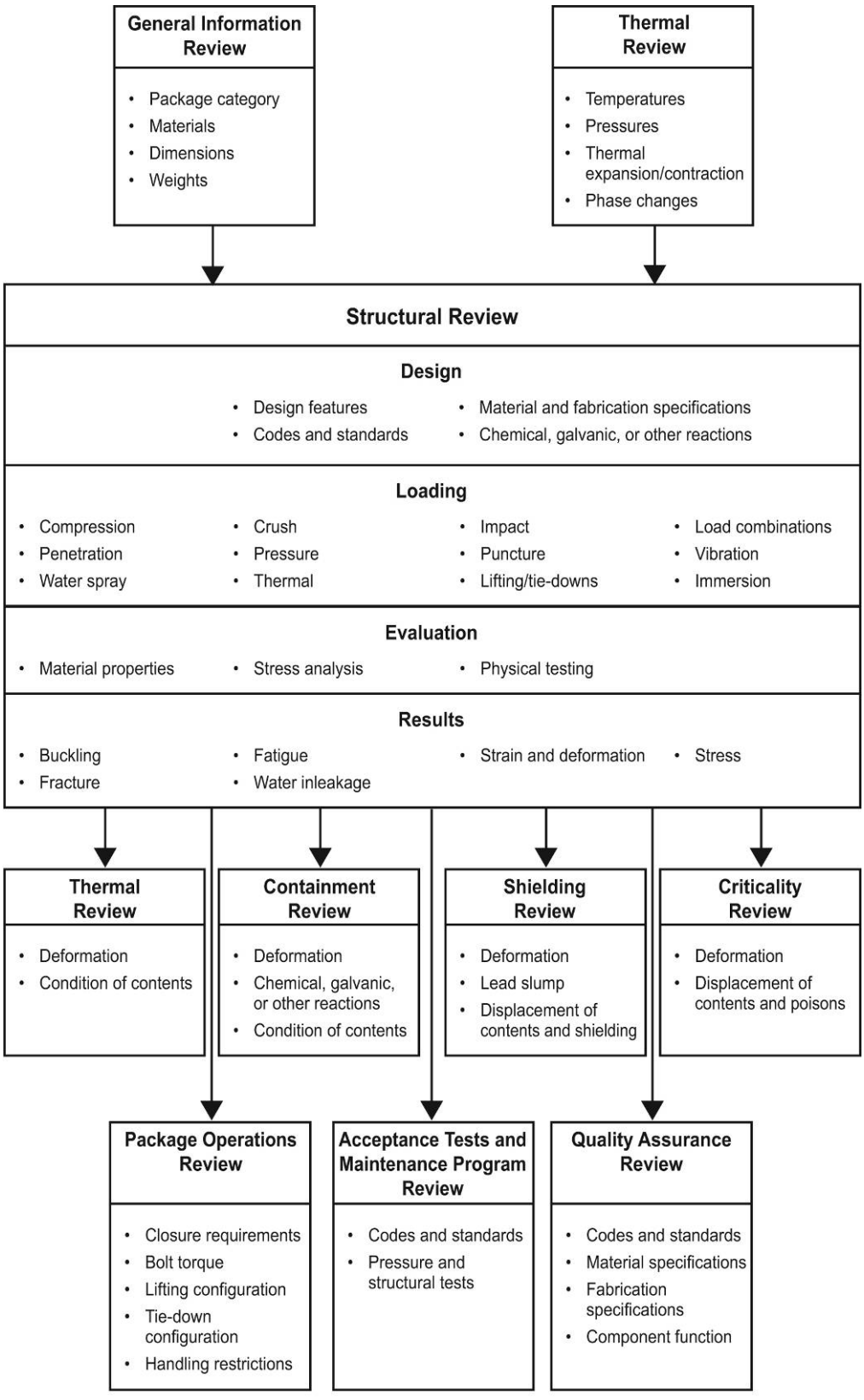

Figure 2.1 Example of Information Flow for the Structural Review

2.1.5 Structural Evaluation of Lifting and Tie-Down Devices

- Lifting Devices
- Tie-Down Devices

2.1.6 Structural Evaluation for Normal Conditions of Transport

- Heat
- Cold
- Reduced External Pressure
- Increased External Pressure
- Vibration
- Water Spray
- Free Drop
- Corner Drop
- Compression
- Penetration
- Structural Requirements for Fissile Material Packages

2.1.7 Structural Evaluation for Hypothetical Accident Conditions

- Free Drop
- Crush
- Puncture
- Thermal
- Immersion–Fissile material
- Immersion–All packages

2.1.8 Structural Evaluation for Special Pressure Conditions

- Special Requirement for Packages $>10^5 A_2$
- Analysis of Pressure Test

2.1.9 Appendices

2.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Structural review are as follows:

- The package must be described and evaluated to demonstrate that it meets the structural requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]

- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must be made of materials of construction that assure there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or between the packaging components and the package contents. The effects of radiation on the materials of construction must be considered. [§71.43(d)]
- The package design must meet the lifting and tie-down requirements of §71.45.
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- A Type B package, containing more than $10^5 A_2$, must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than one hour without collapse, buckling, or inleakage of water. [§71.61]
- The performance of the package must be evaluated under the tests specified in §71.71 for normal conditions of transport. [§71.41(a)]
- The package must be designed, constructed, and prepared for shipment so there would be no loss or dispersal of contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]
- A package for fissile material must be so designed and constructed and its contents so limited to meet the structural requirements of §71.55(d)(2) through §71.55(d)(4) under the tests specified in §71.71 for normal conditions of transport.
- The performance of the package must be evaluated under the tests specified in §71.73 for hypothetical accident conditions. [§71.41(a)]
- The package design must have adequate structural integrity to meet the internal pressure test requirement specified in §71.85(b).

2.3 Review Procedures

The following procedures are generally applicable to the review of the Structural Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 2.1 of this PRG.

2.3.1 Description of Structural Design

2.3.1.1 Design Features

Review the structural design features presented in the General Information and Structural Evaluation chapters of the SARP. Design features important to the structural evaluation include:

- Components that provide structural integrity for heat transfer, containment, shielding, and subcriticality design features (e.g., impact limiters, containment vessels, neutron-absorber plates)
- Components that affect, or are affected by, the performance of structural components (e.g., lead shielding, lifting and tie-down devices)
- Components that provide structural integrity to the contents (e.g., internal supporting structures).

Information on structural design features should include, as appropriate:

- Location, dimensions, and tolerances
- Materials of construction and their specifications (See Section 2.3.2.1)
- Fabrication methods (See Section 2.3.3.1)
- Weights and centers of gravity of packaging and major subassemblies
- Maximum weight of contents (minimum weight, if appropriate)
- Maximum normal operating pressure
- Description of closure systems
- Description of handling requirements.

Verify that the text and sketches describing the structural design features are consistent with the engineering drawings.

2.3.1.2 Codes and Standards

Confirm that the SARP identifies established codes and standards applicable to the structural evaluation. The codes and standards should be appropriate for the intended purpose and be properly applied. The reviewer should verify that the code or standard:

- Was developed for structures of similar design and material, if not specifically for shipping packages
- Was developed for structures with similar loading conditions
- Was developed for structures that have similar consequences of failure
- Adequately addresses potential failure modes
- Adequately addresses margins of safety.

Several regulatory guides, NUREGs, codes, and standards documents provide guidance for package design. RG 7.8[2-1] identifies the load combinations to be used in package evaluations, and RG 7.6[2-2] provides design criteria for containment systems. The criteria of RG 7.6 are based on the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code,[2-3] Section III, Division 1, Subsection NB. In addition, ASME has recently published a new code section (Section III, Division 3), which is specifically intended for transportation

packages. Although both RG 7.6 and ASME Section III, Division 3, specifically address the containment systems of spent-fuel (and high-level-waste packages), their guidance may also be applied to the containment systems of other Category I packages. NUREG/CR-4554, Vol. 6[2-4] and NUREG/CR-6322[2-5] discuss the buckling evaluation of containment vessels and baskets, respectively. In addition, ANSI N14.6[2-6] and NUREG-0612[2-7] have been used for the design of packaging trunnions.

Other NUREGs provide guidance on fabricating package components. NUREG/CR-3854[2-8] provides a list of industrial codes and standards for fabrication, and NUREG/CR-3019[2-9] presents criteria specifically for welding. These NUREGs also provide useful guidance for package design because the code or standard for fabrication should be the same as that for design, operation, and maintenance unless justified otherwise.

Table 2.1 summarizes those sections of the ASME B&PV Code that are generally acceptable for Type B packagings, based on the package category designations described in Table 1.1. Because the ASME Code (except for Section III, Division 3) was not developed for transportation packages, various articles may not be applicable and some Code requirements (e.g., pressure relief devices) may not be consistent with 10 CFR 71 requirements. The review should ensure that the SARP clearly identifies the provisions of the Code applicable to materials, fabrication, examination, and testing of the packaging and that excluded provisions are appropriately justified. Specifications of Section III, Subsection NB, should be generally reviewed against those in Section III, Division 3, Subsections WA and WB.

Table 2.1 Sections of ASME B&PV Code Applicable to Type B Packages

Component Function	Category I	Category II	Category III
Containment	Section III, Division 1, Subsection NB or Section III, Division 3	Section III, Division 1, Subsection ND*	Section VIII, Division 1§
Criticality (structural support)	Section III, Division 1, Subsection NG (NF for Buckling)		
Shielding and Other Safety Features	Section VIII, Division 1 or Section III, Division 1, Subsection NF		

* Category I criteria are also acceptable.

§ Category I and II criteria are also acceptable.

2.3.2 Materials of Construction

Summary guidance for review of materials is presented in Appendix D of this PRG.

2.3.2.1 Material Specifications and Properties

As discussed in Section 1.3.3.1, an appropriate specification should be identified on the engineering drawings for the control of each material. Materials and their properties should be

consistent with the design code or standard selected. In the ASME B&PV Code, material specifications are generally addressed in Section II.

Review the properties of the materials of construction. Verify that the materials of construction have been examined as required by the design code or selected standard. If no code or standard is available, the SARP should provide adequately documented material properties along with references and, as appropriate, justify the quality assurance methods used to ensure that these properties are achieved. Coordinate with the Quality Assurance review as appropriate.

Verify that the material properties are appropriate for the load conditions (e.g., static, cyclic, or dynamic impact loading, hot or cold temperatures, wet or dry conditions, and any combination of them). Confirm that appropriate temperatures at which allowable stress limits are defined are consistent with minimum and maximum service temperatures. Verify that the force-deformation properties for impact limiters are based on appropriate test conditions (e.g., strain rate and temperature). Ensure that materials are thermally stable for long-term exposure at elevated temperatures, as appropriate.

Verify that the materials of structural components have sufficient fracture toughness to preclude brittle fracture under normal conditions of transport and hypothetical accident conditions. RG 7.11[2-10] and RG 7.12[2-11] provide criteria for fracture toughness of ferritic steels. Brittle fracture is usually not a concern for austenitic steels unless fabrication processes increase their susceptibility to embrittlement. If the contents include or produce hydrogen gas, ensure that hydrogen embrittlement has been appropriately addressed.

Additional guidance on materials review is given in the NRC Interim Staff Guidance document on materials evaluation.[2-12]

2.3.2.2 Prevention of Chemical, Galvanic, or Other Reactions

Review the materials and coatings of the package to verify that they will not produce a significant chemical, galvanic, or other reaction among packaging components, among packaging contents, or between the packaging components and the package contents. The review should consider reactions resulting from inleakage of water, including wet loading of spent fuel or other contents. Evaluate the possible generation of hydrogen and other flammable or corrosive gases. NRC Information Notice 96-34[2-13] discusses hydrogen generation that resulted from the reaction between acidic borated water and a zinc coating applied to the internal surfaces of a spent fuel storage cask.

Galvanic interactions and the formation of eutectics should be considered for metallic components that may come into physical contact with one another. Such interactions could occur with depleted uranium, plutonium, lead, or aluminum in contact with steel.

2.3.2.3 Effects of Radiation on Materials

Verify that the effects of radiation on the packaging materials have been appropriately considered. These effects include degradation of seals, sealing materials, coatings, adhesives, and structural materials.

Review of radiolysis, and of the associated production of hydrogen and other gases by radiation is discussed in Sections 3 and 4 of this PRG.

2.3.3 Fabrication, Assembly, and Examination

Summary guidance for review of fabrication, assembly, and examination is presented in Appendix D of this PRG.

2.3.3.1 Fabrication and Assembly

Paragraphs 71.31(c) and 71.37(a)of 10 CFR 71 specify that the application should provide information on codes, standards, and the quality assurance program for fabrication and assembly. In terms of the B&PV Code, these processes are referred to as fabrication and installation, and are generally addressed in the 2000- and 4000-series articles of Section III, with welding qualifications specified in Section IX. In SARP reviews, the term "fabrication" is often used to mean both fabrication and assembly (e.g., welding). As noted above, guidance on appropriate codes and standards is provided in NUREG/CR-3854 and NUREG/CR-3019.

If fabrication and assembly specifications are prescribed by an appropriate code or standard (e.g., ASME, American Welding Society [AWS]), the code or standard should be identified on the engineering drawings. Unless the SARP justifies otherwise, specifications of the same code or standard used for design should also be used for fabrication and assembly. For components for which no code or standard is applicable, the SARP should identify the specifications on which the evaluation depends and describe the method of control to assure that these specifications are achieved. This description may reference a quality assurance or other appropriate specifications document. Such specifications should be included on the engineering drawings and separate fabrication specifications as appropriate. As noted in Section 1.3.3.1 of this PRG, the engineering drawings are generally specified as conditions of approval in the Certificate of Compliance (CoC).

2.3.3.2 Examination

Although the term "examination" is not specifically mentioned in 10 CFR 71, it is generally considered as part of the fabrication and assembly processes, or simply as part of fabrication. In the B&PV Code, examination is addressed in the 5000-series articles of Section III, with additional details on nondestructive-evaluation methods specified in Section V.

Examination addresses the methods and criteria by which the fabrication is determined to be acceptable. Unless the SARP justifies otherwise, specifications of the same code or standard used for fabrication should also be used for examination. For components for which no fabrication code or standard is applicable, the SARP should summarize the examination methods and acceptance criteria in the Acceptance Tests and Maintenance Program chapter. As noted in Section 8 of this PRG, acceptance tests are generally included as conditions of approval in the CoC. Examination specifications should also be provided on the engineering drawings and fabrication specifications as appropriate.

2.3.4 General Considerations for Structural Evaluations

Structural evaluations of the package design may be performed by analysis, test, or a combination of both methods. The evaluations should demonstrate that the structural

performance of the package meets the criteria discussed in Section 2.3.6 below for normal conditions of transport and in Section 2.3.7 for hypothetical accident conditions. Additional conditions for evaluation of the structural design are described in Sections 2.3.5 and 2.3.8. The review of these evaluations should verify that:

- The most unfavorable initial loading and environmental conditions have been addressed. See RG 7.8 for guidance on selection of initial conditions.
- The most unfavorable drop or loading orientations for the entire sequence of tests have been considered. The most unfavorable orientations for one component may not be the most unfavorable for another component.
- The evaluation methods are appropriate for the loading conditions considered and follow accepted practices and precepts.
- The results are interpreted correctly.

2.3.4.1 Evaluation by Test

If the package is evaluated by test, the review should include the following:

- Verify that the test procedures and equipment are adequate. Confirm that the methods and instruments are sufficient for describing the structural response or damage. Both interior and exterior damage should be considered. UCRL-ID-121673[2-14] provides guidance for drop testing, including the use of reduced-scale models.
- Review the description of the target surface (e.g., material, mass, dimensions) used for the drop, crush, and puncture tests. Confirm that it represents an essentially unyielding surface. An example of such a surface is described in International Atomic Energy Agency (IAEA) TS.G-1.1(ST-2),[2-15] but the determination that a surface is essentially unyielding depends on package-specific details.
- Review the description of the steel plate (e.g., material, mass, dimensions, orientation) used for the crush test, if applicable. Confirm that it meets the specifications of §71.73(c)(2).
- Review the description of the steel bar (e.g., material, dimensions, orientation, method of mounting) used for the puncture test. Confirm that it is securely attached to an essentially unyielding surface, has sufficient length to cause maximum damage to the package, and meets the other specifications of §71.73(c)(3).
- Verify that the test specimen has been fabricated using the same materials, methods, and quality assurance as specified in the package design. Any differences should be identified and the effects evaluated in the SARP. The test specimen should include all components and design features (e.g., gap between containment and internals) that are expected to have significant effects on the test results. Substitutes for the contents and other simulated components should have the same weight, structural properties, and interaction with the packaging as the actual contents and components. If applicable, verify that the scale-model specimen is properly scaled, fabricated, and instrumented. Confirm that the

SARP justifies that size effects are not significant (e.g., material properties are not affected by size).

- Verify that the tests consider the orientations for which the most unfavorable damage is expected, and that the selection is justified. The SARP should address drops that (1) produce the highest g-loads on package components and (2) challenge the most vulnerable orientations and components of the package (e.g., bolts, closure rings, seals, valves, and ports). The first group of drops includes those with the package center of gravity (cg) located directly above the center of the impact area, such as end drops, side drops, and cg-over-corner drops. It also includes slap-downs, in which the cg is not directly over the impact area, as slap-down drops of a long package can produce a high g-load in the second impact. Drops in the second group will depend on the vulnerable package components and their failure modes. Components vulnerable to impact loads should generally be protected by special design features such as recessed construction, protective cover plates, and impact limiters. Ensure that the evaluation of most unfavorable damage considers the thermal (fire) test and water immersion test (if applicable), which follow the drop, crush (if applicable), and puncture tests.
- Verify that the test addresses movement or damage of the contents as appropriate. For example, movement or damage of fuel rods or assemblies may impact the criticality evaluation.
- Verify that all test results are evaluated and their implications interpreted, including interior and exterior damage of the test article. Unexpected or unexplainable test results indicating possible testing problems or non-reproducible specimen behavior should be discussed and evaluated.
- Verify that the interpretation of the test results addresses differences between test conditions and regulatory conditions. For example, ambient temperature and decay heat may result in package temperatures and stresses during transportation that differ from those of the tested specimen.
- Review the video and photos of the tests as appropriate.
- Verify that the test results are reliable and repeatable. Test results should convincingly show that any package fabricated in accordance with the approved design will meet regulatory requirements.
- Review the criteria for evaluating pass/fail for the test conditions. Compare the test results with these criteria. If acceptance tests are performed after the structural testing, the acceptance tests should be performed according to appropriate codes and standards.

2.3.4.2 Evaluation by Analysis

If the package is evaluated by analysis, the review should include the following:

- Verify that the SARP clearly describes the analysis methods, models, and results, including all assumptions and input data. (See RG 7.6 for guidance on design criteria for analysis.)

- Verify that the models and material properties are appropriate for the load combinations considered. Ensure that the material properties (e.g., elastic, plastic) are consistent with the analysis methods. The SARP should justify the strain rate at which the properties were determined. Confirm that the analysis considers true stress-strain or engineering stress-strain, as applicable.
- Verify that the applied boundary conditions in the analysis model are appropriate. For free-drop impact analyses, impact loads for package components are usually derived from the dynamic analyses of the package and used in a quasi-static stress analysis of the component. Confirm that a dynamic amplification factor has been appropriately applied to account for vibration and other dynamic effects. A summary of quasi-static and dynamic analysis methods for impact analysis is provided in NUREG/CR-3966.[2-16]
- Verify that the analysis evaluates the most unfavorable orientations, and that the selection is justified. Ensure that the evaluation of most unfavorable damage considers the entire sequence of tests.
- Verify that the analysis evaluates the effect of the test conditions on the contents as appropriate. (See Section 2.3.4.1.)
- Verify that the computer codes, if applicable, are properly used, benchmarked, and maintained under an appropriate quality assurance program. At least one representative input and output file (or key section of the file) should generally be included in the SARP.
- Verify that the response of the package to loads, in terms of stress and strain to components and structural members, is shown and that the structural stability of individual members, as applicable, is evaluated.
- Verify that the results are correctly interpreted and demonstrate adequate margin of safety. The maximum stresses or strains should be compared to corresponding design-code allowables.

2.3.5 Lifting and Tie-Down Standards for All Packages

2.3.5.1 Lifting Devices

Review the design and evaluation of lifting devices that are a structural part of the package, their connection to the package body, and the package body in the local area around the lifting devices. Verify that the evaluation demonstrates these devices comply with the requirements of §71.45(a), including failure under excessive load.

2.3.5.2 Tie-Down Devices

Review the design and evaluation of tie-down devices that are a structural part of the package, their connection to the package body, and the package body in the local area around the tie-down devices. Verify that the evaluation demonstrates that these devices comply with the requirements of §71.45(b), including failure under excessive load.

2.3.6 Structural Evaluation for Normal Conditions of Transport

The evaluation of the package under the normal conditions of transport is based on the effects of the tests and conditions specified in §71.71. These tests must not result in a significant decrease in package effectiveness. For example, these tests should result in:

- No significant decrease in the effectiveness of packaging components that provide heat transfer or insulation. Coordinate with the Thermal review.
- No significant decrease in the effectiveness of packaging components that provide containment, including no loss or dispersal of contents or release of radioactive material exceeding the requirements of §71.51(a)(1), as applicable. Coordinate with the Containment review.
- No significant decrease in the effectiveness of packaging components that provide shielding, including no increase in radiation levels exceeding the requirements of §71.47 or §71.51(a)(1). Coordinate with the Shielding review.
- No significant decrease in the effectiveness of packaging components that provide criticality control, including no change exceeding the requirements of §71.55(d). (See Section 2.3.6.11.) Coordinate with the Criticality review.
- No change to the contents that significantly affects heat transfer, containment, shielding, or criticality.
- No change to the packaging or contents that affects their performance under the tests for hypothetical accident conditions discussed in the next section.

The ambient air temperature before and after the tests must remain constant at that value between -29°C (-20°F) and +38°C (100°F) which is most unfavorable for the feature under consideration. The initial internal pressure in the containment vessel must be considered to be the maximum normal operating pressure, unless a lower internal pressure consistent with the selected ambient temperature is less favorable.

2.3.6.1 Heat

Verify that the evaluation for the heat condition is adequate. Confirm that the maximum temperatures used for this evaluation are consistent with the Thermal Evaluation chapter of the SARP. The evaluations should consider the maximum normal operating pressure in combination with the maximum internal heat load and any residual fabrication stresses.

Verify that any differential thermal expansions and possible geometric interferences have been considered.

Verify that the stresses are within the limits for normal condition loads.

2.3.6.2 Cold

Verify that the evaluation for the cold condition is adequate. Confirm that the temperatures used for this evaluation are consistent with the Thermal Evaluation chapter of the SARP. The evaluations should consider the minimum internal pressure with the minimum internal heat load

and any residual fabrication stresses. The minimum decay heat should be zero unless the SARP provides a minimum heat load as a condition of package approval.

Verify that differential thermal expansions which could result in possible geometric interferences have been considered. Confirm that possible freezing of liquids and brittle fracture of materials have been considered.

Verify that the stresses are within the limits for normal condition loads.

2.3.6.3 Reduced External Pressure

Ensure that the SARP adequately evaluates the package design for the effects of reduced external pressure equal to 25 kPa (3.5 psi) absolute. Verify that the SARP considers the greatest possible pressure difference between the inside and outside of the package as well as between the inside and outside of the containment system.

2.3.6.4 Increased External Pressure

Determine that the SARP adequately evaluates the package design for the effects of increased external pressure equal to 140 kPa (20 psi) absolute. Verify that the SARP considers this loading condition in combination with minimum internal pressure. Confirm that the SARP considers the greatest possible pressure difference between the inside and outside of the package as well as between the inside and outside of the containment system. Ensure that the SARP has considered the possibility of buckling (see NUREG/CR-4554, Vol. 6).

2.3.6.5 Vibration

Determine that the SARP adequately evaluates the package design for the effects of vibration incident to transport. A fatigue analysis should be provided for highly stressed systems, considering the combined stresses due to vibration, temperature changes, and pressure loads. If closure bolts are reused, verify that the bolt preload is included in the fatigue evaluation. NUREG/CR-6007[2-17] provides guidance on bolt evaluation. Verify that a resonant vibration condition, which can cause rapid fatigue damage, is not present in any packaging component. The effect on package internals should be considered. Additional guidance for vibration evaluation is provided in NUREG/CR-2146[2-18] and NUREG/CR-0128.[2-19]

2.3.6.6 Water Spray

Review the package design for the effects of the water spray test. Verify that this test has no significant effect on material properties.

2.3.6.7 Free Drop

Review the package design for the effects of the free drop test.

Review the evaluation of the closure lid bolt design for the combined effects of free drop impact force, internal pressures, thermal stress, O-ring compression force, and bolt preload. Bolt evaluation methods are presented in NUREG/CR-6007.

Review the evaluation of other package components, such as port covers, port cover plates, and shield enclosures, for the combined effects of package drop impact force, internal pressures, and thermal stress.

2.3.6.8 Corner Drop

Review the package design for the effects of the corner drop test, if applicable.

2.3.6.9 Compression

Review the package design for the effects of the compression test, if applicable.

2.3.6.10 Penetration

Review the evaluation of the package for the penetration test. Verify that the SARP considers the most vulnerable package location.

2.3.6.11 Structural Requirements for Fissile Material Packages

The SARP should demonstrate that there will be no reduction in effectiveness of the packaging, including:

- The geometric form of the contents is not substantially altered.
- The containment system precludes inleakage of water, unless such inleakage has been assumed in the criticality analysis of arrays under normal conditions of transport as specified in §71.59(a)(1).
- The total effective packaging volume on which nuclear criticality safety is assessed is not reduced by more than 5%.
- The effective spacing between fissile contents and the outer surface of the packaging is not reduced by more than 5%.
- No occurrence of an aperture in the outer surface of the packaging is large enough to permit the entry of a 10-cm (4-in.) cube.

Coordinate with the Criticality review as appropriate.

2.3.7 Structural Evaluation for Hypothetical Accident Conditions

The evaluation under hypothetical accident conditions must be based on sequential application of the tests specified in §71.73, in the order indicated, to determine their cumulative effect on a package. The evaluation of the ability of a package to withstand any one test must consider the damage resulting from the preceding tests. In addition, as stated in Section 2.3.6, the tests under normal conditions of transport must not affect the package's ability to withstand the hypothetical accident condition tests.

Verify that the SARP has properly determined the effects of the hypothetical accident condition tests on both the packaging and its contents. The most unfavorable effects of these tests should be identified for evaluation in the Thermal, Containment, Shielding, and Criticality Evaluation chapters of the SARP. Ensure that the SARP has addressed the effects of the tests on the:

- Components required for heat transfer or insulation
- Components of the containment system (plastic deformation of the containment closure system is generally unacceptable)
- Shielding components
- Components required for subcriticality
- Displacement, deformation, and geometry of the contents.

Coordinate with the Thermal, Containment, Shielding, and Criticality reviews as appropriate.

With respect to the initial conditions for the tests (except for the water immersion tests), the ambient air temperature before and after the tests must remain constant at that value between -29°C (-20°F) and +38°C (100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system must be the maximum normal operating pressure unless a lower internal pressure consistent with the selected ambient temperature is less favorable.

2.3.7.1 Free Drop

Review the evaluation of the free drop test. Verify that structural evaluation has addressed the most unfavorable drop orientation, including cg-over-corner, oblique orientation with secondary impact (slap down), side drop, and drop onto the closure systems. Determination of the most unfavorable orientation must consider the entire sequence of tests, and the most unfavorable orientation might not be the same for all components. If a feature such as a tie-down component is a structural part of the package, it should be addressed in the evaluation.

For a package with lead shielding, the effects of lead slump should be evaluated. The lead slump determined should be consistent with that used in the shielding evaluation. Lead slump is discussed in NUREG/CR-4554, Vol. 3.

2.3.7.2 Crush

Review the evaluation of the package for the dynamic crush test, if applicable. Verify that the choice of the most unfavorable orientation has been justified.

2.3.7.3 Puncture

Review the evaluation of the package for the puncture test. Verify that the most unfavorable orientation has been identified and justified. Any damage resulting from the free drop and crush tests must be included in the evaluation. Ensure that punctures at oblique angles, near a support, at a valve, and at a penetration or protrusion have been considered, as appropriate. Confirm that the puncture test does not result in peripheral damage that could jeopardize the package during the subsequent thermal and water-immersion tests (e.g., loss of package lid which could result in melting of seals).

Although analytical methods are available for predicting puncture, empirical formulas derived from puncture test results of laminated panels are usually used for design of packages. The Nelm's formula, developed specifically for package design, provides the minimum thickness needed for preventing the puncture of the steel surface layer of a typical steel-lead-steel laminated cask wall. A description of methods for puncture evaluation is provided in NUREG/CR-4554, Vol. 7. Additional considerations for puncture testing are identified in Nuclear Regulatory Commission (NRC) Bulletin 97-02.[2-20]

2.3.7.4 Thermal

Coordinate with the Thermal review to verify that the structural design is evaluated for the effects of a fully engulfing fire, as specified in §71.73(c)(4). Any damage resulting from the free drop, crush, and puncture conditions must be incorporated into the initial condition of the package for the fire test. Determination of the maximum pressure in the package during or after the test must consider the temperatures resulting from the fire and any increase in gas inventory caused by combustion or decomposition processes. Verify that the maximum thermal stresses, which can occur either during or after the fire, are properly evaluated and are consistent with the Thermal Evaluation chapter of the SARP.

2.3.7.5 Immersion—Fissile Material

If the contents include fissile material subject to the requirements of §71.55, and if water inleakage has not been assumed for the criticality analysis, review the evaluation of the test of a damaged specimen immersed under a head of water of at least 0.9 m (3 ft.) in the attitude for which maximum leakage is expected.

2.3.7.6 Immersion—All Packages

Review the evaluation of a separate, undamaged specimen subjected to water pressure equivalent to immersion under a head of water of at least 15 m (50 ft.). For test purposes, an external pressure of water of 150 kPa (21.7 psi) gauge is considered to meet these conditions.

2.3.8 Structural Evaluation of Special Pressure Conditions

2.3.8.1 Special Requirement for Type B Packages Containing More Than 10^5A_2

Verify that Type B packages containing more than 10^5A_2 with an activity greater than 10^5A_2 are appropriately evaluated to demonstrate that their containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of at least one hour without collapse, buckling, or inleakage of water. This pressure should be applied directly to the containment system, and no

structural support from other package components should be considered.[2-21] Ensure that the stresses in the vicinity of the closure regions do not result in permanent deformation.

2.3.8.2 Analysis of Pressure Test

As required by §71.85(b), prior to first use of each packaging with a maximum normal operating pressure exceeding 35 kPa (5 psi) gauge, the containment system must be pressure tested at 150% of its maximum normal operating pressure. A similar test (125% of the design pressure) is prescribed by Section III of the B&PV Code. If such tests are applicable, confirm that analysis in the SARP demonstrates that they can be performed safely.

2.3.9 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, computer code descriptions, input and output files, test results, and other appropriate supplemental information.

2.4 Evaluation Findings

2.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 2.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the structural design has been adequately described and evaluated and that the package design meets the structural requirements of 10 CFR 71.

2.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. In addition to specifications of authorized contents and information specified on the engineering drawings, conditions of approval typically applicable to the Structural Evaluation chapter of the SARP include:

- Maximum weight of the package (if not indicated on drawings); minimum weight, if applicable.
- Maximum weight of the contents, including shoring, packing materials, and other components not defined as part of the packaging (if not indicated on drawings); minimum weight, if applicable.

2.5 References

[2-1] U.S. Nuclear Regulatory Commission, *Load Combinations for the Structural Analysis of Shipping Casks for Radioactive Material*, Regulatory Guide 7.8, Revision 1, March 1989.

[2-2] U.S. Nuclear Regulatory Commission, *Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels,* Regulatory Guide 7.6, Revision 1 March 1978.

[2-3] American Society of Mechanical Engineers, ASME Boiler and Pressure Vessel Code, 2004.

[2-4] U.S. Nuclear Regulatory Commission, *SCANS (Shipping Cask Analysis System): A Microcomputer Based Analysis System for Shipping Cask Design Review*, NUREG/CR-4554 (UCID-20674), February 1990.

[2-5] U.S. Nuclear Regulatory Commission, *Buckling Analysis of Spent Fuel Basket*, NUREG/CR-6322 (UCRL-ID-119697), May 1995.

[2-6] Institute for Nuclear Materials Management, *American National Standard for Radioactive Materials—Special Lifting Devices for Shipping Containers Weighing 10,000 Pounds (4500 kg) or More*, ANSI N14.6, 1993.

[2-7] U.S. Nuclear Regulatory Commission, *Control of Heavy Loads at Power Plants*, NUREG-0612, June 1982.

[2-8] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854 (UCRL-53544), March 1985.

[2-9] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Shipping Containers for Radioactive Materials*, NUREG/CR-3019 (UCRL-53044), March 1985.

[2-10] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)*, Regulatory Guide 7.11, June 1991.

[2-11] U.S. Nuclear Regulatory Commission, *Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Wall Thickness Greater than 4 Inches (0.1 m),* Regulatory Guide 7.12, June 1991.

[2-12] U.S. Nuclear Regulatory Commission, *Materials Evaluation*, ISG-15, Spent Fuel Projects Office, January 10, 2001.

[2-13] U.S. Nuclear Regulatory Commission, *Hydrogen Gas Ignition during Closure Welding of a VSC-24 Multi-Assembly Sealed Basket*, NRC Information Notice 96-34, May 31, 1996.

[2-14] G. C. Mok, et al., *Guidelines for Conducting Impact Tests of Shipping Containers for Radioactive Material*, UCRL-ID-121673, Lawrence Livermore National Laboratory, September 1995.

[2-15] Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, TS-G-1.1 (ST-2), International Atomic Energy Agency, Vienna, 2002.

[2-16] U.S. Nuclear Regulatory Commission, *Methods for Impact Analysis of Shipping Containers*, NUREG/CR-3966 (UCID-20639), November 1987.

[2-17] U.S. Nuclear Regulatory Commission, *Stress Analysis of Closure Bolts for Shipping Casks*, NUREG/CR-6007 (UCRL-ID-110637), January 1993.

[2-18] U.S. Nuclear Regulatory Commission, *Dynamic Analysis to Establish Normal Shock and Vibration of Radioactive Material Shipping Packages, Volume 3: Final Summary Report,* NUREG/CR-2146, Vol. 3, October 1983.

[2-19] U.S. Nuclear Regulatory Commission, *Shock and Vibration Environments for a Large Shipping Container During Truck Transport (Part II)*, NUREG/CR-0128, August 1978.

[2-20] U.S. Nuclear Regulatory Commission Bulletin 97-02, *Puncture Testing of Shipping Packages under 10 CFR Part 71*, September 23, 1997.

[2-21] U.S. Nuclear Regulatory Commission, *Compatibility with the International Atomic Energy Agency*, Federal Register, Volume 60, No. 188, September 28, 1995, p. 50257.

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3.0 THERMAL REVIEW

This review verifies that the thermal performance of the package design has been adequately evaluated for the tests specified under normal conditions of transport and hypothetical accident conditions and that the package design meets the thermal requirements of 10 CFR 71.

The Thermal review is based in part on the descriptions and evaluations presented in the General Information and Structural Evaluation chapters of the Safety Analysis Review for Packaging (SARP). Similarly, results of the Thermal review are considered in the Structural review and in the review of subsequent chapters of the SARP. An example of information flow for the Thermal review is shown in Figure 3.1.

Although 10 CFR 71 specifies only a few explicit thermal requirements for packages (e.g., maximum allowable surface temperature), the thermal performance of the package under normal conditions of transport and hypothetical accident conditions must be addressed in the structural evaluation, and the combined structural/thermal performance of the package affects its ability to meet the containment, shielding, and subcriticality requirements of the regulation. Consequently, the Thermal review focuses on confirming the SARP evaluation of the effects of these tests and on coordinating these effects with the review of the Structural Evaluation, Containment, Shielding Evaluation, and Criticality Evaluation chapters.

3.1 Areas of Review

The description and evaluation of the package thermal design should be reviewed. The Thermal review should include the following:

3.1.1 Description of Thermal Design

- Design Features
- Decay Heat of Contents
- Codes and Standards
- Summary Tables of Temperatures
- Summary Table of Maximum Pressures

3.1.2 Material Properties, Thermal Limits, and Component Specifications

- Material Properties
- Temperature Limits
- Component Specifications

3.1.3 General Considerations for Thermal Evaluations

- Evaluation by Test
- Evaluation by Analysis

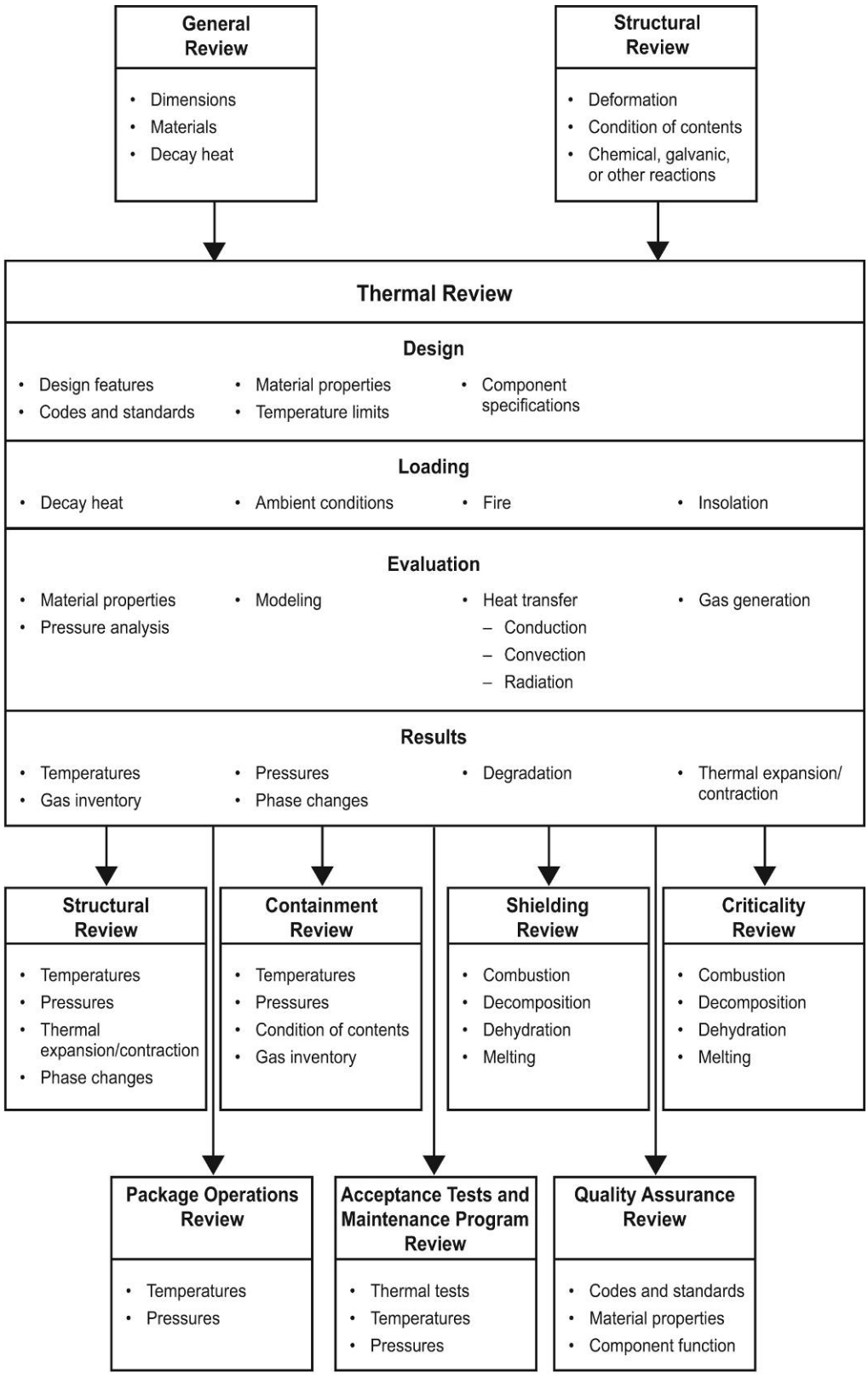

Figure 3.1 Example of Information Flow for the Thermal Review

3.1.4 Thermal Evaluation under Normal Conditions of Transport

- Initial Conditions
- Effects of Tests
- Maximum and Minimum Temperatures
- Maximum Normal Operating Pressure
- Maximum Thermal Stresses

3.1.5 Thermal Evaluation under Hypothetical Accident Conditions

- Initial Conditions
- Effects of Thermal Tests
- Maximum Temperatures and Pressures
- Maximum Thermal Stresses

3.1.6 Thermal Evaluation of Maximum Accessible Surface Temperature

3.1.7 Appendices

- Description of Test Facilities and Equipment
- Test Results
- Applicable Supporting Documents or Specifications
- Details of Analyses

3.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the thermal evaluation are as follows:

- The package design must be described and evaluated to demonstrate that it satisfies the thermal requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must be made of materials of construction that assure there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or between the packaging components and the package. The effects of radiation on the materials of construction must be considered. [§71.43(d)]
- The package must be designed, constructed, and prepared for transport so that in still air at 38°C (100°F) and in the shade the accessible surface temperature does not exceed 50°C (122°F) in a nonexclusive-use shipment or 85°C (185°F) in an exclusive-use shipment. [§71.43(g)]

- The package design must not rely on mechanical cooling systems to meet containment requirements. [§71.51(c)]
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- The performance of the package must be evaluated under the tests specified in §71.71 for normal conditions of transport. [§71.41(a)]
- The package must be designed, constructed, and prepared for shipment so there would be no loss or dispersal of contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]
- The performance of the package must be evaluated under the tests specified in §71.73 for hypothetical accident conditions. [§71.41(a)]

3.3 Review Procedures

The following procedures are generally applicable to the review of the Thermal Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 3.1 of this PRG.

3.3.1 Description of Thermal Design

3.3.1.1 Design Features

Review the thermal design features presented in the General Information and Thermal Evaluation chapters of the SARP, including:

- Structural and mechanical means for the transfer of heat (e.g., fill gas, baskets or other internal supporting structures, physical contacts between components, coolant receptacles, type and volume of coolants, cooling fins, and surface conditions of the packaging components)
- Insulating features, including gaps and insulating materials
- Configuration and materials of the contents.

Information on design features should include location, dimensions, tolerances, materials, and other data as appropriate.

Confirm that the text and sketches describing the thermal design features are consistent with the enginering drawings.

3.3.1.2 Decay Heat of Contents

Verify that the maximum decay heat is consistent with that described in the General Information chapter of the SARP, with the radioactivity of the contents, and with the source terms used in the Shielding Evaluation chapter. Coordinate as appropriate with the Shielding review.

3.3.1.3 Codes and Standards

Verify that any codes or standards applicable to the thermal design of the package are identified and appropriate, including those for material specifications and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information and Structural Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

3.3.1.4 Summary Tables of Temperatures

Review the tables that summarize the maximum temperatures of all materials and components affecting structural integrity, thermal performance, containment, shielding, and criticality. As a minimum, these tables should include:

- The maximum temperatures under normal conditions of transport
- The maximum temperatures under hypothetical accident conditions, and the time after initiation of the fire at which they occur
- The maximum temperatures for the post-fire steady-state condition.

Confirm that these temperatures are consistent with those of the General Information, Structural Evaluation, and Containment chapters.

Minimum package temperatures are discussed in Section 3.3.2.2 below. In general, the minimum temperature of all materials and components will be -40°C (-40°F).

3.3.1.5 Summary Table of Maximum Pressures

Verify that a summary table includes the maximum normal operating pressure and the maximum pressure in the containment system(s) under hypothetical accident conditions. Determine if other confined volumes of the package are subject to maximum pressure limitations (e.g., outer shell, neutron shielding system, contents) and that such limitations are included in the table as appropriate. Confirm that these pressures are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

3.3.2 Material Properties, Temperature Limits, and Component Specifications

3.3.2.1 Material Properties

Verify that appropriate properties are specified for materials that affect heat transfer through the package to (or from) the environment, pressures in the package, and thermal stresses. Material properties and the temperature range over which they are designated should be consistent with those used in the structural and thermal evaluations. If a property is specified as temperature independent, ensure that its value is conservative compared with a temperature-dependent specification. Note that a conservative value for heat removal under normal conditions of transport is not necessarily conservative for the thermal test under hypothetical accident conditions. The SARP should provide an authoritative reference for each material property. In general, textbooks are not acceptable references. If the applicant determines thermal properties experimentally, the experiments should be conducted under his/her quality assurance program, and the adequacy of the experiments should be reviewed.

Properties of package (packaging and contents) materials that may be applicable to the heat-transfer evaluation include density, thermal conductivity, specific heat, viscosity, emissivity, and absorptivity. Confirm that the absorptivities and emissivities are appropriate for the package surface conditions, geometries, and radiant spectra. If the SARP justifies an absorptivity less than unity for insolation based on external packaging surface conditions, ensure that controls and procedures are in place to maintain these conditions during service life. Coordinate with the Package Operations review as applicable.

Properties of package material that affect thermally induced pressures or stresses may include the coefficient of thermal expansion, modulus of elasticity, and Poisson's ratio. Verify that these properties are consistent with those in the Structural Evaluation chapter, as applicable.

If materials undergo chemical or physical changes (e.g., phase transformation, decomposition, dehydration, or combustion), verify that the temperatures at which these conditions occur are presented and that the corresponding material properties (e.g., conductivity, specific heat, density) are appropriate prior to and following the change.

3.3.2.2 Temperature Limits

Confirm that the maximum allowable temperatures are specified for each package material or component, as appropriate. If applicable, ensure that the SARP distinguishes between steady-state and short-term temperature limits.

For spent fuel, the SARP should justify the allowable fuel/cladding temperatures. This justification should consider fuel/cladding materials, irradiation conditions, transport environment (including the package fill gas), temperature history of the fuel since removal from the reactor, and intended post-transport storage or disposition. Temperature limits should address creep, creep rupture, diffusion controlled cavity growth, eutectic melting, and other conditions as appropriate.

The minimum temperature of all materials and components will generally be that of the ambient environment, and the minimum allowable temperatures should not exceed -40°C (-40°F) for the conditions of §71.71(c)(2) and -29°C (-20°F) for the other tests of §71.71 and §71.73.

Ensure that the temperatures listed in the summary tables are within the allowable temperature limits.

3.3.2.3 Component Specifications

Ensure that technical specifications are provided for package components (e.g., pressure relief valves, fusible plugs, valves, seals), as appropriate. Confirm that temperature and pressure specifications are not exceeded. Verify that appropriate specifications (e.g., rupture pressure) are included on the engineering drawings.

3.3.3 General Considerations for Thermal Evaluations

Thermal evaluations of the package design can be performed by analysis, test, or a combination of both methods. The evaluations should demonstrate that the thermal performance of the package meets the criteria discussed in Section 3.3.4 for normal conditions of transport and Section 3.3.5 for hypothetical accident conditions. The review of these evaluations should verify that:

- The most unfavorable initial regulatory conditions have been addressed. RG 7.8 provides guidance on selection of initial conditions. Note that the thermal evaluations should consider a package that has first been subjected to the structural tests under normal conditions of transport and hypothetical accident conditions, as appropriate. Coordinate with the Structural review.
- The most unfavorable orientations have been considered. The most unfavorable orientation for one component may not be the most unfavorable for another component.
- All regulatory test requirements have been included in the evaluation.
- The evaluation methods are appropriate for the thermal conditions considered and follow accepted practices and precepts.
- The time interval after the fire test is adequate to assure that maximum component temperatures and post-fire steady-state temperatures have been determined.
- The results are interpreted correctly.
- The thermal evaluations appropriately address pass/fail criteria and the design margins for package temperatures, pressures, and thermal stresses. Verify that these discussions include the effects of uncertainties in thermal properties, modeling, analytical methods, test conditions, and diagnostics, as appropriate.

3.3.3.1 Evaluation by Test

If the package is evaluated by test, the review should include the following:

- Verify that the test facility and instrumentation are adequately described and that the test methods and equipment are sufficient for determining the thermal response of the package. Also verify whether the equipment has to be calibrated before the test, and consider if there are differences between the conditions of the test and calibration. Section 3.3.7.1 provides additional detail on the type of information appropriate.
- Verify that the test procedures, test conditions, and test results are adequately documented. Section 3.3.7.2 provides additional detail on test documentation.
- Verify that the test specimen has been fabricated using the materials, methods, and quality assurance specified for the package design. Any differences should be identified and the effects evaluated in the SARP. The test specimen should include all components that could affect the test results. Substitutes for the contents or other simulated components should have the same weight, thermal properties, and interaction with the packaging as the actual contents. Thermal testing of reduced-scale packages should

generally be avoided. If scale models are used, the SARP should justify that the evaluation is applicable to the actual package design.

- Verify that decay heat of the contents is properly addressed in the tests or is otherwise included in post-test analysis of the results.
- Verify that all test results are evaluated and their implications correctly interpreted. Unexpected or unexplainable test results indicating possible testing problems or non-reproducible thermal performance should be described and evaluated.
- Verify that the interpretation of the test results addresses differences between test conditions and regulatory conditions. For example, decay heat and regulatory ambient temperature and insolation can result in package temperatures that differ from those of the tested package. Such test results may need to be extended to the regulatory conditions by detailed analysis.
- Review the video and photographs of the tests as appropriate.
- Verify that the test results are reliable and repeatable. Test results should convincingly show that any package fabricated in accordance with the approved design will meet regulatory requirements.
- Review the criteria for evaluating pass/fail for the test conditions. Compare the test results with these criteria. If acceptance tests are performed after the thermal testing, the acceptance tests should be performed according to appropriate codes and standards.

Additional guidance on thermal testing of packages is provided in UCRL-ID-110445.[3-1]

3.3.3.2 Evaluation by Analysis

If the package is evaluated by analysis, the review should include the following:

- Verify that the SARP clearly describes the analysis methods and models, and that they are appropriate for the thermal conditions considered.
- Verify that the initial and boundary conditions are appropriate.
- Verify that all assumptions, including those in modeling heat sources and heat transfer paths and modes, are clearly stated and justified.
- Verify that appropriate expressions are used for conductive, convective, and radiative heat transfer among package components and from the surfaces of the package to (and from) the environment.
- Verify that appropriate thermal properties for the package materials are correctly incorporated into the analysis.
- Verify that the computer codes, if applicable, are properly used, benchmarked, and maintained under an appropriate quality assurance program. At least one representative input and output file (or key section of the file) should generally be included in the SARP.

- Verify that the results are correctly interpreted and demonstrate adequate margin of safety based on uncertainties and assumptions of the analysis.
- Review the criteria for evaluating pass/fail for the analysis results. Compare these results with the criteria. The maximum temperatures should be compared to corresponding design-code allowables.

3.3.4 Thermal Evaluation under Normal Conditions of Transport

The package must be evaluated for the effects of the tests in §71.71 on the thermal performance of the package. A description of these tests is presented in Section 2.3.6 of this PRG.

3.3.4.1 Initial Conditions

Except as noted in the next paragraph, the initial conditions for tests under normal conditions of transport must be based on an ambient temperature preceding and following the tests remaining constant at that value between -29°C (-20°F) and 38°C (100°F) which is most unfavorable for the feature under consideration. The initial pressure in the containment system must be considered to be the maximum normal operating pressure unless a lower internal pressure consistent with the ambient temperature is more unfavorable. Note that the determination of maximum normal operating pressure must assume that the package is subjected to the insolation specified in §71.71(c)(1).

As specified in §71.71(c)(2), the effects of low temperature (cold) on the package must consider an ambient temperature of -40°C (-40°F) in still air and shade (no insolation).

3.3.4.2 Effects of Tests

Confirm that the thermal evaluation demonstrates that the tests for normal conditions of transport do not result in significant reduction in package effectiveness, including:

- Significant degradation of the heat-transfer capability (e.g., creation of new gaps between components) or significant degradation of insulating materials.
- Changes in material conditions or properties (e.g., expansion, contraction, thermal stresses, gas generation, and chemical, galvanic, or other reactions) that significantly affect the structural performance of the package. Coordinate with the Structural review.
- Changes in the packaging or contents that significantly affect containment, shielding, or criticality (e.g., thermal decomposition or phase changes of materials). Coordinate with the Containment, Shielding, and Criticality review as appropriate.
- Ability of the packaging to withstand the tests under hypothetical accident conditions. Coordinate also with the Structural review.

3.3.4.3 Maximum and Minimum Temperatures

Verify that the maximum and minimum temperatures of package components and materials under normal conditions of transport are properly evaluated and are consistent with those presented in the summary tables discussed in Section 3.3.1.4 above.

3.3.4.4 Maximum Normal Operating Pressure

Verify that the maximum normal operating pressure is properly evaluated and is consistent with that presented in the summary table discussed in Section 3.3.1.5 above. Maximum normal operating pressure is the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition of §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during shipment. The evaluation should include the effects of the appropriate local temperatures and total gas inventory within the containment system. Ensure that the evaluation considers all possible sources of gases within any confined volume, such as:

- Package fill gas
- Saturated vapor, including water vapor from the contents or packaging
- Helium from the radioactive decay of the contents
- Fill gas and fission product gas from spent fuel rods, including a justification for the leakage assumed (see NUREG/CR-6487[3-2])
- Hydrogen or other gases resulting from thermal or radiolytic decomposition of materials (e.g., water, plastics) or other reactions as appropriate.

Ensure that the SARP demonstrates that hydrogen and other flammable gases comprise less than 5% by volume of the total gas inventory within any confined volume, or otherwise addresses concerns for deflagration of such gases. For spent fuel, the release of fill gas from the fuel rods should not be considered for diluting the hydrogen concentration. Ensure that any operational controls (e.g., reduced shipment time), used to limit hydrogen production, are adequate and are appropriately addressed in the Package Operations chapter. Note that operational controls during shipment may not be used to limit the maximum normal operating pressure.

If other confined volumes of the package are subject to pressure limitations (e.g., secondary containment, outer shell, neutron shielding system, contents), confirm that pressures within these volumes are appropriately evaluated.

Ensure that these pressures are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

3.3.4.5 Maximum Thermal Stresses

Ensure that the evaluation determines thermal stresses caused by geometric constraints, temperature gradients, and other differential thermal expansions. The evaluation should include the maximum stresses as well as cyclic stresses during the service life of the package. Coordinate with the Structural review.

3.3.5 Thermal Evaluation under Hypothetical Accident Conditions

The package must be evaluated for the effects of the tests in §71.73 on the thermal performance of the package.

3.3.5.1 Initial Conditions

Prior to the fire test, the package design must be evaluated for the effects of the drop, crush (if applicable), and puncture tests. Ensure that the initial physical condition of the package design used in the thermal evaluations considers the most unfavorable effects of these tests. Note that the most unfavorable condition for the fire test is not necessarily the most overall structural damage of the package. Coordinate with the Structural review.

Verify that initial conditions of ambient temperature and internal pressure in the containment system are consistent with the requirements of §71.73(b). Although 10 CFR 71 does not specifically address insolation required for the thermal test, supplemental information[3-3] published with the 1996 rule stated that insolation may be neglected prior to and during the thermal test but should be considered in subsequent package evaluation after the fire. Neglecting insolation prior to the fire will result in an initial temperature in the containment system that is inconsistent with that corresponding to the maximum normal operating pressure and may result in peak temperatures during the fire that are less than those under normal conditions of transport with insolation. Consequently, for simplicity and conservatism, the SARP evaluation may frequently include insolation as an initial condition for the fire test.

3.3.5.2 Effects of Thermal Tests

Verify that the package design is evaluated for the effects of a fully engulfing fire, as specified in §71.73(c)(4). Ensure that temperature, heat-transfer boundary conditions (including fire-enhanced convection), and an appropriate supply of oxygen are maintained for at least 30 minutes.

Confirm that after the fire:

- No artificial cooling is applied to the package
- The package is subjected to full insolation
- An adequate supply of oxygen is maintained
- All combustion is allowed to proceed until it terminates naturally.

Additional guidance on thermal evaluation of packages is provided in UCRL-ID-110445.

Ensure that the physical condition of the package is clearly identified and appropriately considered in the Containment, Shielding Evaluation, and Criticality Evaluation chapters of the SARP. Coordinate with those reviews as appropriate. In addition, if the package is subjected to the water immersion test of §71.73(c)(5), coordinate with the Structural review to ensure that the post-fire condition of the package has been appropriately addressed.

3.3.5.3 Maximum Temperatures and Pressures

Verify that the evaluation appropriately determines the peak transient temperatures of package components as a function of time after the fire and the maximum temperatures from the post-fire steady-state condition. Ensure that temperatures are corrected for differences between regulatory and test conditions, if applicable. Confirm that these temperatures do not exceed their maximum

allowable values. Verify that lead shielding does not reach melting temperature (see Section 5.3.3.2).

Confirm that the evaluation of the maximum pressure in the containment system is based on the maximum normal operating pressure (Section 3.3.4.4) as it is affected by fire-caused increases in package component temperatures. Verify that possible increases in gas inventory resulting from the hypothetical accident condition tests (e.g., from thermal combustion, decomposition, release of fill/fission product gases of spent fuel rods) have been accounted for in the pressure determination.

Ensure that the SARP demonstrates that hydrogen and other flammable gases comprise less than 5% by volume of the total gas inventory within any confined volume, or otherwise addresses concerns for deflagration of such gases, as discussed in Section 3.3.4.4.

If other confined volumes of the package are subject to maximum pressure limitations (e.g., secondary containment, outer shell, neutron shielding system, contents), confirm that pressures in these volumes are appropriately evaluated and are acceptable.

Ensure that these pressures are consistent with those in the General Information, Structural Evaluation, and Containment chapters.

3.3.5.4 Maximum Thermal Stresses

Ensure that the evaluation determines the thermal stresses caused by geometric constraints from temperature gradients and differential thermal expansions. Verify that the maximum thermal stresses, which can occur either during or after the fire, are consistent with those in the Structural Evaluation chapter.

3.3.6 Thermal Evaluation of Maximum Accessible Surface Temperature

Confirm that the maximum temperature of the accessible package surface is less than 50°C (122°F) for a nonexclusive-use shipment or 85°C (185°F) for an exclusive-use shipment when the package is subjected to the heat conditions of §71.43(g). For packages with a significant heat load, coordinate with the Package Operations review to ensure that the requirements of §71.87(k) are satisfied.

3.3.7 Appendices

3.3.7.1 Description of Test Facilities and Equipment

Confirm that the descriptions of a test facility include:

- Type of facility (e.g., fire, furnace)
- Method of heating the package (e.g., pool fire, gas burners, electrical heaters)
- Volume and emissivity of the furnace interior
- Types, locations, calibration curves, and measurement uncertainties of all sensors used to measure the fire heat fluxes, fire temperatures, and test package component temperatures and pressures

- The post-fire environment for a time period adequate to attain the post-fire, steady-state condition
- Methods for ensuring an adequate supply and circulation of oxygen for initiating and maintaining the combustion of any burnable package component throughout the fire and post-fire periods until natural termination.

3.3.7.2 Test Results

Verify that appropriate test reports are included in the appendices. These reports should include:

- Test procedures
- Test package description
- Test initial and boundary conditions
- Test chronologies (planned and actual)
- Photographs of the package components, including any structural or thermal damage, before and after the tests
- Test measurements, including documentation of test package physical changes and temperature and heat-flux histories, as appropriate
- Test results corrected to regulatory conditions
- Methods used to obtain these corrected results.

Confirm that all sensors that measure heat fluxes and temperatures are appropriately positioned and have proper operating ranges for the test conditions. Verify that possible perturbations caused by the presence of these sensors (e.g., by disturbing local convective and radiative heat-transfer conditions) are appropriately considered.

For a pool-fire facility, verify that the fire dimensions and test package relative location conform to the specification in §71.73(c)(4):

- The fire width should extend horizontally between one and three meters beyond any external surface of the package
- The package should be positioned one meter above the surface of the fuel source.

Since the method of supporting the package in the test facility may locally perturb fire conditions adjoining the test package, verify that such an effect has been appropriately incorporated into the thermal evaluation.

3.3.7.3 Applicable Supporting Documents or Specifications

Verify that appropriate selections from reference documents are included in these appendices. In addition to the documents noted in Sections 3.3.7.1 and 3.3.7.2, these may include a variety of items such as thermal specifications of O-rings and other components, documentation of the thermal properties, computer input and output files, and other appropriate information.

3.3.7.4 Details of Analyses

Supplemental calculations may be required to support evaluations presented in the Thermal Evaluation chapter. Verify that all such special analyses are prepared in a manner consistent with Section 3.3.3.2.

3.4 Evaluation Findings

3.4.1 Findings

The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 3.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the thermal design has been adequately described and evaluated, and that the thermal performance of the package meets the thermal requirements of 10 CFR 71.

3.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the Certificate of Compliance (CoC). In addition to specifications of authorized contents and information specified on the engineering drawings, other conditions of approval that may be applicable to the Thermal Evaluation chapter of the SARP include:

- Decay heat limits
- Requirement for exclusive-use shipment due to package surface temperatures
- Maximum duration of shipment (e.g., to limit hydrogen production).

3.5 References

[3-1] VanSant, J. H., R. W. Carlson, L. E. Fischer, and J. Hovingh, *A Guide for Thermal Testing Transport Packages for Radioactive Material—Hypothetical Accident Conditions*, UCRL-ID-110445, Lawrence Livermore National Laboratory, February 9, 1993.

[3-2] U.S. Nuclear Regulatory Commission, *Containment Analysis for Type B Packages Used to Transport Various Contents,* NUREG/CR-6487, UCRL-ID-124822, November 1996.

[3-3] U.S. Nuclear Regulatory Commission, *Compatibility with the International Atomic Energy Agency*, Federal Register, Volume 60, No. 188, September 28, 1995, p. 50257.

4.0 CONTAINMENT REVIEW

This review verifies that the package design satisfies the containment requirements of 10 CFR 71 under normal conditions of transport and hypothetical accident conditions.

The Containment review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Packaging (SARP). Similarly, results of the Containment review are considered in the review of Package Operations, Acceptance Tests and Maintenance Program, and Quality Assurance. An example of the information flow for the Containment review is shown in Figure 4.1.

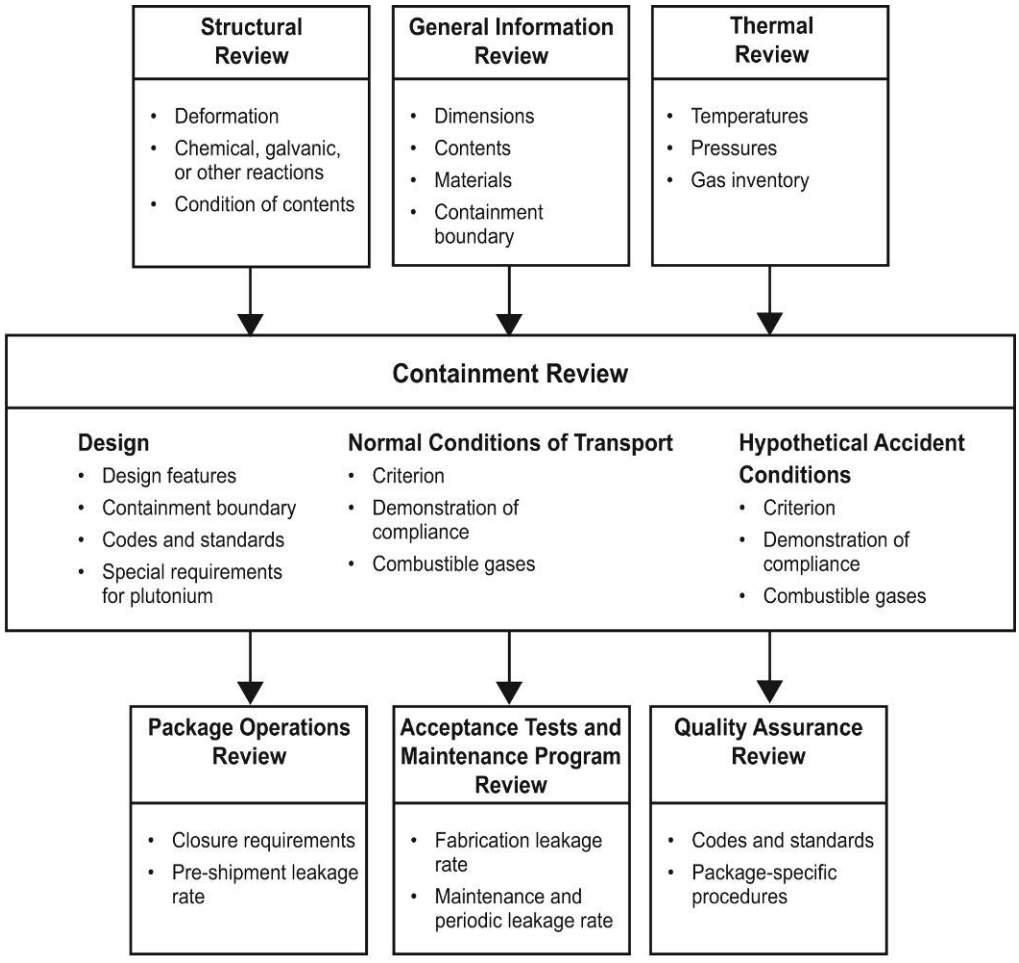

Figure 4.1 Example of Information Flow for the Containment Review

4.1 Areas of Review

The description and evaluation of the containment design should be reviewed. The Containment review should include the following:

4.1.1 Description of the Containment Design

- General Considerations for Containment Evaluations
  - — Fissile Type A Packages
  - — Type B Packages
  - — Combustible-Gas Generation
- Design Features
- Codes and Standards
- Special Requirements for Plutonium
- Special Requirements for Spent Fuel

4.1.2 Containment under Normal Conditions of Transport

- Containment Design Criteria
- Demonstration of Compliance with Containment Design Criteria

4.1.3 Containment under Hypothetical Accident Conditions

- Containment Design Criteria
- Demonstration of Compliance with Containment Design Criteria

4.1.4 Leakage Rate Tests for Type B Packages

4.1.5 Appendices

4.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Containment review are as follows:

- The package design must be described and evaluated to demonstrate that it meets the containment requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The package must include a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by pressure that may arise within the package. [§71.43(c)]

- The package must be made of materials and constructed to assure that there will be no significant chemical, galvanic, or other reactions, including reactions due to possible inleakage of water, among the packaging components, among package contents, or between the packaging components and the contents. The effects of radiation on the materials of construction must be considered. [§71.43(d)]
- Any valve or similar device on the package must be protected against unauthorized operation and, except for a pressure relief valve, must be provided with an enclosure to retain any leakage. [§71.43(e)]
- The package must be designed, constructed, and prepared for shipment to ensure no loss or dispersal of radioactive contents under the tests specified in §71.71 ("Normal conditions of transport") there would be no loss or dispersal of radioactive contents. [§71.43(f)]
- The package may not incorporate a feature intended to allow continuous venting during transport. [§71.43(h)]
- A Type B package must meet the containment requirements of §71.51(a)(1) under the tests specified in §71.71 for Normal Conditions of Transport.
- A Type B package must meet the containment requirements of §71.51(a)(2) under the tests specified in §71.73 for Hypothetical Accident Conditions.
- The maximum activity of radionuclides in a Type A package must not exceed the limits of 10 CFR 71, Appendix A, Table A-1. For a mixture of radionuclides, the provisions of Appendix A, paragraph IV apply, except that for krypton-85, where an effective A_2 equal to $10A_2$ may be used. [Appendix A, §71.51(b)]
- Compliance with the permitted activity release limits for Type B packages may not rely on filters or on a mechanical cooling system. [§71.51(c)]
- For packages that contain radioactive contents with activity greater than 10^5A_2, the requirements of §71.61 must be met. [§71.51(d)]
- A Type B package containing more than 10^5A_2 must be designed so that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than 1 hour without collapse, buckling, or inleakage of water. [§71.61]
- A package containing plutonium in excess of 0.74 TBq (20 Ci) must have the contents in solid form for shipment. [§71.63]

4.3 Review Procedures

The following procedures are generally applicable to the review of the Containment chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 4.1 of this PRG.

4.3.1 Description of the Containment Design

4.3.1.1 General Considerations for Containment Evaluations

4.3.1.1.1 Fissile Type A Packages

Verify that the contents do not exceed a Type A quantity of radioactive material as specified by Appendix A to 10 CFR 71. Note that the only Type A packages subject to 10 CFR 71 are fissile-material packages (i.e., Type AF packages), §71.22(a).

For Type A packages, no loss or dispersal of radioactive material is permitted under normal conditions of transport, as specified in §71.43(f), and as specified in 49 CFR 173.24(b)(1). Although 10 CFR 71 does not provide quantitative release limits for containment under hypothetical accident conditions (as it does for Type B packages), the containment must be adequate to ensure subcriticality. Coordinate with the Criticality review as appropriate.

4.3.1.1.2 Type B Packages

Type B packages must satisfy the quantitative *release* rates of §71.51(a)(1) and (a)(2). As is noted in Reg. Guide 7.4, the guidance contained in American National Standards Institute (ANSI) N14.5[4-1] provides an acceptable method to determine the maximum permissible volumetric *leakage* rates based on the allowed regulatory *release* rates under both normal conditions of transport and hypothetical accident conditions (i.e., L_N and L_A, respectively). These two volumetric leakage rates should be converted to maximum allowable *air* leakage rates under reference conditions (temperature, pressures) in accordance with ANSI N14.5. The smaller of L_N and L_A (when converted to reference conditions) is defined as the reference air leakage rate, L_R.

In general, the normal condition leakage rate is the most restrictive. Hence, L_N, when converted to reference conditions, is generally equal to L_R. This situation is assumed in the discussion of containment criteria in Sections 4.3.2 and 4.3.3 below. In the very rare case in which L_R is determined by L_A, the reviewer should refer to ANSI N14.5 to ensure the containment criteria are properly evaluated. Note that this situation can occur only if the releasable source term under hypothetical accident conditions is approximately three orders of magnitude greater than the releasable source term under normal conditions of transport.

The maximum permissible release rate (and leakage rate) for a package that contains different radionuclides is based on an effective A_2, which must be determined according to the provisions of §71.51(b).

Representative analyses for determining simplified containment criteria are provided in NUREG/CR-6487[4-2] for Type B packages that contain powders, liquids, irradiated fuel rods, gases, or solids. If the SARP uses these analyses, ensure that the assumptions of that document are applicable to the package under consideration. Guidance on containment analyses for aluminum-based spent fuel is provided by WSRC-TR-98-00317.[4-3]

4.3.1.1.3 Combustible-Gas Generation

Confirm that the SARP demonstrates that any combustible gases generated in the package during a period of one year do not exceed 5% (by volume) of the free gas volume in any confined region of the package, or otherwise addresses concerns related to deflagration of such gases. Additional guidance on issues concerning combustible-gas generation can be found in

NUREG-1609,[4-4] NUREG-1617,[4-4] and the NRC's Interim Staff Guidance (ISG) Document, ISG-15.[4-5] All reviews on combustible-gas generation issues should be coordinated with the Structural and Thermal reviews as appropriate.

4.3.1.2 Design Features

Review the containment design features presented in the General Information and Containment chapters of the SARP. Design features important to containment include:

- Containment vessel(s)
- Welds
- Seals
- Valves
- Pressure relief devices
- Lids, cover plates, and similar closure devices
- Bolts and bolt torque
- Special containment features for plutonium
- Special containment features for spent fuel.

Information on containment design features should include, as appropriate:

- Location, dimensions, and tolerances
- Materials of construction
- Maximum and minimum allowable temperatures of components, including seals
- Maximum and minimum temperatures of components under the tests for normal conditions of transport and hypothetical accident conditions
- Maximum normal operating pressure and maximum pressure in the containment system under hypothetical accident conditions.

The SARP should include a figure or sketch that defines the exact boundary of the containment system. Confirm that all containment boundary penetrations and their method of closure are adequately described. Verify that the containment system is securely closed by a positive fastening device that cannot be opened unintentionally or opened by a pressure that may arise within the package. Coordinate with the Structural and Thermal reviews as appropriate. If penetrations are closed with two seals (e.g., to enable leakage testing), verify which seal is defined as the containment boundary. Ensure that all components of the containment system are shown on the drawings.

Verify that the seal material is appropriate for the package. Ensure that the seal will undergo no galvanic, chemical, or other reaction with the packaging or its contents, will not degrade due to irradiation, and will not be permeable to radioactive gases in the contents. Confirm that the seal

grooves are properly sized. Coordinate with the Structural review as appropriate to verify that the specified bolt torque will provide proper seal compression. Cover plates and lids should be recessed or otherwise protected.

Confirm that all containment closure systems can be leakage tested as appropriate. If vent/drain ports or similar penetrations utilize quick-disconnect valves that are not part of the containment boundary, ensure that such valves do not preclude leakage testing of the containment.

Review the maximum and minimum temperatures of all containment system components, including seals, under normal conditions of transport and hypothetical accident conditions. Confirm that the allowable temperature range for each component is not exceeded. Compliance with the containment requirements for Type B packages may not rely on filters or a mechanical cooling system. Coordinate with the Thermal review as appropriate.

Performance specifications for components such as valves and pressure relief devices should be identified, and no device may allow continuous venting. Ensure that the maximum pressure under normal conditions of transport or hypothetical accident conditions does not exceed the specification of pressure relief devices. Coordinate with the Thermal review as appropriate.

Any valve or similar device on the package must be protected against unauthorized operation and, except for a pressure relief valve, must be provided with an enclosure to retain any leakage. (Note: The requirement to provide an enclosure to retain leakage is not intended to require a second containment boundary for Type B packages.)

Confirm that the information regarding the containment system is consistent with that presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the SARP.

4.3.1.3 Codes and Standards

Verify that any codes or standards applicable to the containment design of the package are identified and appropriate, including those for material specifications and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information, Structural, and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

Evaluation of release rates and performance of leakage testing should be in accordance with ANSI N14.5.

4.3.1.4 Special Requirements for Plutonium

Prior to the rule changes in October 2004, Special Requirements for plutonium shipments were mandated by the regulations. Specifically, if the contents include more than 0.74 TBq (20 Ci) of plutonium, the reviewer would have had to verify that the plutonium was in solid form, and that double containment was provided as specified in §71.63(b) at that time. In addition, the reviewer would have had to verify that each containment system could separately meet the requirements of §71.51(a)(1) for normal conditions of transport and §71.51(a)(2) for hypothetical accident conditions. Both containment systems would have to be reviewed in the same manner. Although

this information is no longer current, it is included here for completeness because 1) the use of double containment systems for plutonium is not prohibited by the regulations, 2) there are still a relatively large number of double-containment plutonium packagings in service, and 3) it is expected that these double-containment plutonium packagings will be in service for another decade or longer.

Since the double-containment requirement for plutonium was eliminated with the rule change in October 2004, the reviewer need only verify that, if the contents include more than 0.74 TBq (20 Ci) of plutonium, the plutonium must be in solid form as specified in §71.63.

4.3.1.5 Special Requirements for Spent Fuel

Special containment requirements for spent fuel depend on the condition of the fuel:

- As per the guidance in ISG-1,[4-6] damaged fuel or suspect damaged fuel should be canned in a separate inner canister for handling and criticality control. Appropriate material specifications and the design/fabrication criteria for the inner container should be specified, and any credit for the canning in the containment evaluation should be justified. If a screen-type container is used, an appropriate mesh size should be justified. Review the design of the inner container, as applicable.
- Spent fuel debris, particles, loose pellets, or fragmented rods/assemblies are not considered to be fuel elements and require a separate (inner) canister for criticality control purposes. Coordinate with the Criticality review as appropriate.

The determination of undamaged fuel should be based, as a minimum, on a review of records to verify that the fuel is undamaged, followed by a visual examination for any obvious damage prior to loading. For fuel in which reactor records are not available, the level of proof should be evaluated on a case-by-case basis. Coordinate with the Package Operations review as appropriate.

4.3.2 Containment under Normal Conditions of Transport

4.3.2.1 Containment Design Criteria

Confirm that the radionuclides and physical form of the contents evaluated in the Containment chapter are consistent with those presented in the General Information chapter of the SARP. Ensure that the radionuclides include daughter products as appropriate.

Verify that the SARP identifies the constituents that comprise the releasable source term, which could include radioactive solids, radioactive liquids, radioactive gases, aerosols, and/or spent fuel. If less than 100% of the contents are considered releasable, evaluate the justification for the lower fraction.

Based on the releasable source term, ensure that the maximum permissible release rate and the maximum permissible leakage rate (L_N) are calculated in accordance with ANSI N14.5. Verify that the maximum normal operating pressure and maximum temperature under normal conditions of transport are consistent with those determined in the Thermal Evaluation chapter of the SARP. Using this pressure and temperature, ensure that the maximum permissible leakage

rate L_N is converted to reference cubic centimeters per second (i.e., ref·cc/s, or ref·cm^3/s) in accordance with ANSI N14.5.

Note: If the applicant has elected to adopt the ANSI N14.5 definition of *leaktight*, i.e., $\leq 1 \times 10^{-7}$ ref·cm^3/s, for their containment criterion for normal conditions of transport, then the applicant need not supply any calculations to further justify their position.

4.3.2.2 Demonstration of Compliance with Containment Design Criteria

Confirm that the SARP demonstrates that the package meets the containment requirements of §71.51(a)(1) under normal conditions of transport.

If compliance is demonstrated by test:

- Confirm that prior to the test, the leakage rate of the test specimen (when converted to reference conditions) is demonstrated to be less than or equal to L_R, as defined in ANSI N14.5.
- Coordinate with the Structural and Thermal reviews to ensure that a full-scale specimen has been properly tested under the requirements of §71.71. While scale-model testing may yield valuable information for the designer, it is not a reliable, or an acceptable, method for quantifying the leakage rate of a full-scale specimen.
- Verify that the leakage rate of the specimen that has been subjected to the tests of §71.71 does not exceed the maximum allowable leakage rate for normal conditions of transport. To ensure a comparison using consistent units, the leakage rate after the test should generally be converted to reference conditions and then compared with L_R.

If compliance is demonstrated by analysis:

- Confirm that the allowable leakage rate for the fabrication, periodic, and maintenance leakage rate tests is less than or equal to L_R.
- Verify that the structural evaluation shows that the containment system closure region (e.g., bolts, seal, or flange) does not undergo plastic deformation under the tests of §71.71. Coordinate with the Structural review.

4.3.3 Containment under Hypothetical Accident Conditions

The review procedures for containment under hypothetical accident conditions are similar to those under normal conditions of transport. Differences relevant to hypothetical accident conditions are noted below.

4.3.3.1 Containment Design Criteria

The releasable source term, maximum permissible release rate, and maximum permissible leakage rate should be based on package conditions and the 10 CFR 71 containment requirements under hypothetical accident conditions. Verify that the temperatures, pressure, and physical conditions of the package (including the contents) are consistent with those determined in the Structural Evaluation and Thermal Evaluation chapters of the SARP. Using this pressure

and temperature of the contents under hypothetical accident conditions, ensure that the maximum permissible leakage rate L_A is converted to reference cubic centimeters per second (ref·cc^3/s, or ref·cm^3/s) in accordance with ANSI N14.5.

Note: If the applicant has elected to adopt the ANSI N14.5 definition of *leaktight*, i.e., $\leq 1 \times 10^{-7}$ ref·cm^3/s, for their containment criterion for hypothetical accident conditions, the applicant need not supply any calculations to further justify their position.

4.3.3.2 Demonstration of Compliance with Containment Design Criteria

Ensure that the SARP demonstrates that the package satisfies the containment requirements of §71.51(a)(2) under hypothetical accident conditions. Demonstration is similar to that discussed in Section 4.3.2.2, except that the package should be subjected to the tests of §71.73 and the maximum allowable leakage rate at reference conditions must be less than L_A converted to reference conditions.

4.3.4 Leakage Rate Tests for Type B Packages

Using the reference air leakage rate, confirm that the maximum allowable leakage rates for the following tests are determined in accordance with ANSI N14.5:

- Fabrication leakage rate test
- Periodic leakage rate test
- Maintenance leakage rate test
- Pre-shipment leakage rate test.

The fabrication, periodic, and maintenance leakage rate tests should be addressed in the Acceptance Tests and Maintenance Program review (see Chapter 8 of this PRG). The pre-shipment leakage rate test for assembly verification should be addressed in the Package Operations review (see Chapter 7 of this PRG). Coordinate with those reviews as appropriate.

4.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, test results, and any additional supplemental information as appropriate.

4.4 Evaluation Findings

4.4.1 Findings

The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 4.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the containment design has been adequately described and evaluated and that the package design meets the containment requirements of 10 CFR 71.

4.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the Certificate of Compliance. In addition to specifications of authorized contents and information specified on the engineering drawings, other conditions of approval that may be applicable to Containment chapter of the SARP include:

- Requirement to place damaged fuel in a canister
- Maximum duration of shipment (e.g., to limit hydrogen production)
- Other conditions as appropriate.

4.5 References

[4-1] American National Standards Institute, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

[4-2] U.S. Nuclear Regulatory Commission, *Containment Analysis for Type B Packages Used to Transport Various Contents*, NUREG/CR-6487, UCRL-ID-124822, November 1996.

[4-3] Westinghouse Savannah River Company, *Bases for Containment Analyses for Transportation of Aluminum-Based Spent Nuclear Fuel*, WSRC-TR-98-00317, Aiken, SC, October 1998.

[4-4] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Radioactive Material*, NUREG-1609, Washington, DC, March 31, 1999.

[4-4] U.S. Nuclear Regulatory Commission, *Standard Review Plan for Transportation Packages for Spent Nuclear Fuel*, NUREG-1617, Washington, DC, March 2000.

[4-5] U.S. Nuclear Regulatory Commission, Spent Fuel Project Office, *Interim Staff Guidance 15, Materials Evaluation*, Washington, DC, January 10, 2001.

[4-6] U.S. Nuclear Regulatory Commission, Spent Fuel Project Office, *Interim Staff Guidance 1, Damaged Fuel*, Washington, DC, October 25, 2002.

5.0 SHIELDING REVIEW

This review verifies that the package design meets the external radiation requirements of 10 CFR 71 under normal conditions of transport and hypothetical accident conditions.

The Shielding review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Packaging (SARP). Results of the Shielding review are considered in the review of Package Operations, the Acceptance Tests and Maintenance Program, and the Quality Assurance Program. An example of the information flow for the Shielding review is shown in Figure 5.1.

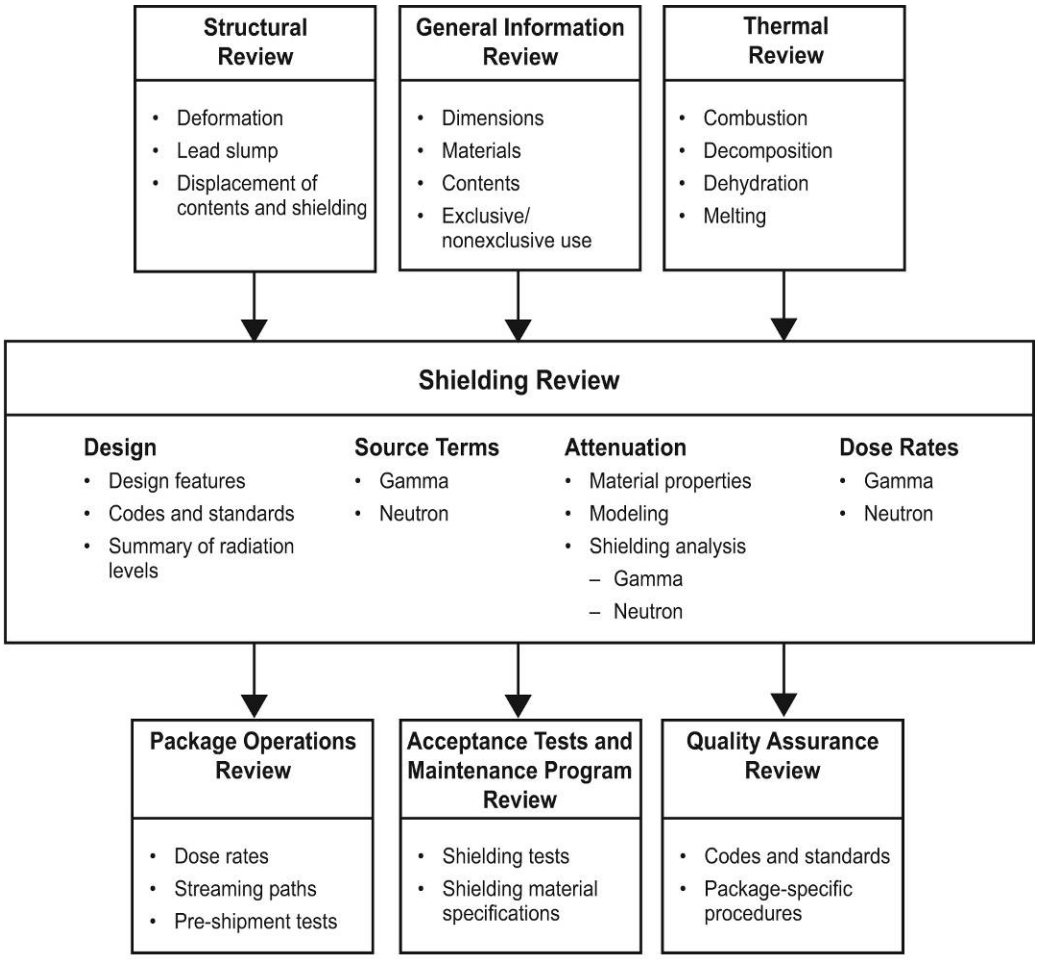

Figure 5.1 Example of Information Flow for the Shielding Review

5.1 Areas of Review

The description and evaluation of the shielding design should be reviewed. The Shielding review should include the following:

5.1.1 Description of Shielding Design

- Design Features
- Codes and Standards
- Summary Table of Maximum Radiation Levels

5.1.2 Radiation Source

- Gamma Source
- Neutron Source

5.1.3 Shielding Model

- Configuration of Source and Shielding
- Material Properties

5.1.4 Shielding Evaluation

- Methods
- Input and Output Data
- Flux-to-Dose-Rate Conversion
- External Radiation Levels

5.1.5 Appendices

5.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Shielding review are as follows:

- The package design must be described and evaluated to demonstrate that it meets the shielding requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- Under the tests specified in §71.71 for normal conditions of transport, the external radiation levels must meet the requirements of §71.47(a) for nonexclusive-use or §71.47(b) for exclusive-use shipments. [§71.47]
- The package must be designed, constructed, and prepared for shipment so that the external radiation levels will not significantly increase under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1)]

- Under the tests specified in §71.73 for hypothetical accident conditions, the external radiation level must not exceed 10 mSv/h (1 rem/h) at one meter from the surface of a Type B package. [§71.51(a)(2)]

5.3 Review Procedures

The following procedures are generally applicable to the review of the Shielding Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 5.1 of this PRG.

5.3.1 Description of Shielding Design

5.3.1.1 Design Features

Review the shielding design features presented in the General Information and Shielding Evaluation chapters of the SARP. Design features important to shielding include:

- Location, dimensions, tolerances, and densities of material for neutron or gamma shielding, including those packaging components considered in the shielding evaluation
- Structural components that maintain the integrity of the shielding
- Structural components that maintain the contents in a fixed position within the package
- Heat transfer and insulating features that maintain allowable temperatures of the shielding
- Dimensions of the transport vehicle that are considered in the shielding evaluation, if applicable.

Confirm that the text and sketches describing the shielding design features are consistent with the engineering drawings and the models used in the shielding evaluation.

5.3.1.2 Codes and Standards

Verify that any codes or standards applicable to the shielding design of the package are identified and appropriate, including those for material specifications and fabrication. Ensure that such codes and standards are consistent with those specified in the General Information, Structural, and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

Flux-to-dose-rate conversion factors should be consistent with American National Standards Institute (ANSI)/ANS6.1.1-1977,[5-1] as discussed below in Section 5.3.4.3.

5.3.1.3 Summary Table of Maximum Radiation Levels

Review the summary table of maximum radiation levels. Ensure that the maximum levels are presented for both normal conditions of transport and hypothetical accident conditions at the appropriate locations for nonexclusive or exclusive use (or both), as applicable. Table 5.1 is an example of the information that should be presented for nonexclusive use. A similar table should be presented for exclusive use shipment as appropriate.

Verify that the radiation levels are within the regulatory limits as indicated in Table 5.2. Review the variation of dose rates at different package locations for general consistency. For example, confirm that dose rates decrease as either the distance from the source or as the shielding effectiveness (e.g., thickness) increases.

Table 5.1 Example for Summary Table of External Radiation Levels (Nonexclusive Use)

Normal Conditions of Transport	Package Surface mSv/h (mrem/h)			1 Meter from Package Surface mSv/h (mrem/h)		
Radiation	**Top**	**Side**	**Bottom**	**Top**	**Side**	**Bottom**
Gamma						
Neutron						
Total						
10 CFR 71.47(a) Limit	2 (200)	2 (200)	2 (200)	0.1 (10)*	0.1 (10)*	0.1 (10)*

* Transport index may not exceed 10 for nonexclusive-use shipment.

Hypothetical Accident Conditions*	1 Meter from Package Surface mSv/h (mrem/h)		
Radiation	**Top**	**Side**	**Bottom**
Gamma			
Neutron			
Total			
10 CFR 71.51(a)(2) Limit*	10 (1000)	10 (1000)	10 (1000)

* Applicable to Type B packages only.

Table 5.2 Package and Vehicle Radiation Level Limits[a]

Transport Vehicle Use:	**Nonexclusive**	**Exclusive**		
Transport Vehicle Type:	Open or closed	Open (flat-bed)	Open w/enclosure[b]	Closed
Package (or Freight Container) Limits, mSv/h (mrem/h):				
External surface	2 (200)	2 (200)	10 (1000)	10 (1000)[c]
1 m from external surface	0.1 (10) [d]	No limit		
Roadway or Railway Vehicle (or Freight Container) Limits, mSv/h (mrem/h):				
Any point on the outer surface	N/A	N/A	N/A	2 (200)
Vertical planes projected from outer edges		2 (200)	2 (200)	N/A
Top of . . .		load: 2 (200))	enclosure: 2 (200)	vehicle: 2 (200)
2 m from . . .		vertical planes: 0.1 (10)	vertical planes: 0.1 (10)	outer lateral surfaces: 0.1 (10)
Underside		2 (200)		
Occupied position	N/A[e]	0.02 (2)[f]		

a. The limits in this table are applicable under normal conditions of transport. For Type B packages, the external radiation levels at one meter from the package surface may not exceed 10 mSv/h (1 rem/h) under hypothetical accident conditions. The limits in this table do not apply to excepted packages—see 49 CFR 173.421-426.

b. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures.

c. Package secured within vehicle so that its position remains fixed during transportation; no loading or unloading operations between beginning and end of transportation. Otherwise limit is 2 mSv/h (200 mrem/h).

d. Transport index may not exceed 10 for nonexclusive-use shipment.

e. No dose limit is specified, but separation distances apply to packages with Radioactive Yellow-II or Radioactive Yellow-III labels–see 49 CFR 177.842(b).

f. Does not apply to private carriers if exposed personnel under their control wear dosimetry devices in conformance with 10 CFR 20.1502.

5.3.2 Radiation Source

Confirm that the contents, used in the shielding evaluation, are consistent with those specified in the General Information chapter of the SARP. If the package is designed for multiple types of contents, ensure that the contents producing the highest external dose rate at each location are clearly identified and evaluated.

If the contents include spent fuel, verify that limitations on burnup, enrichment, and cooling time have been properly addressed. Although the maximum fuel enrichment is important for criticality analysis, the neutron source term for shielding evaluations can increase significantly with decreasing initial enrichment (for constant burnup and cooling time). Ensure that the SARP specifies a minimum initial enrichment for the fuel as appropriate. Verify that the cross sections used to calculate the source terms are applicable for the burnup indicated; some cross-section libraries are not valid for higher burnup.

In addition to increasing with decreasing enrichment, in the case of spent fuel, the source terms can be a strong function (usually the neutron source term) of the burnup. In the event that the relationship between burnup and the source term is non-linear, the average source term, $\overline{S}$, is not the same as the source at average burnup, $S(\overline{B})$. In cases where the source term has been determined at an average burnup, a multiplication factor, r, to obtain the average source from the spent fuel with axially varying burnup can be derived as

$$r = \frac{\overline{S}}{S(\overline{B})} = \frac{\frac{1}{H}\int_0^H f(B(z))dz}{f(\overline{B})}$$

where, H is the height of the fuel and $f(B(z))$ is the functional relationship between the source and burnup at different axial locations, z. The application of the factor r to the source at average burnup, $S(\overline{B})$, will give the correct average source term for the spent fuel. If this is applicable, verify that the proper factor to account for axial variability in burnup has been applied to obtain the bounding source term. In addition to the factor, r, verify that any other applicable peaking factors (radial and axial) have been applied to the source term for spent fuel.

5.3.2.1 Gamma Source

Review the method used to determine the gamma source term. Ensure that the source contribution from radioactive daughter products is included if it produces higher dose rates than the contents without decay. If the radioactive nuclides and gamma spectra are calculated with a computer code, review the key parameters described in the SARP or listed in the input file. Verify that the production of secondary gammas (e.g., from (n,γ) reactions in shielding material or bremsstrahlung from beta decay) is either calculated as part of the shielding evaluation (see Section 5.3.4) or otherwise appropriately included in the source term.

If the contents include spent fuel, verify that the gamma source terms are determined for both the spent fuel and activated hardware. If the package is intended to transport other hardware such as control assemblies or shrouds, ensure that the source terms from these components are also included if applicable. Note whether the source terms are specified per fuel rod, per assembly, per total assemblies, or per metric ton, and ensure that the total source is correctly used in the shielding evaluation. In the case of spent fuel where the source term is not calculated at the peak

burnup, ensure that all applicable factors as discussed in Section 5.3.2 have been accounted for in determining the source term.

Confirm that the results of the source term determination are presented as a listing of gammas per second, or MeV per second, as a function of energy. The activity (or mass) of each nuclide that contributes significantly to the source term should also be provided as supporting information.

5.3.2.2 Neutron Source

Review the method used to determine the neutron source term. Verify that the method considers, as appropriate, neutrons from both spontaneous fission and from (α,n) reactions. If the SARP assumes that either of these source contributions is negligible, ensure that an appropriate justification is provided. Verify that the production of neutrons from subcritical multiplication is either calculated as part of the shielding evaluation (see Section 5.3.4) or otherwise appropriately included in the source term. In the case of spent fuel where the source term is not calculated at the peak burnup, ensure that all applicable factors as discussed in Section 5.3.2 have been accounted for in determining the source term.

Confirm that the results of the source term calculation, if applicable, are presented as a listing of neutrons per second as a function of energy. The contributions from spontaneous fission and (α,n) should be separately identified. The activity (or mass) of each nuclide that contributes significantly to the source terms should also be provided as supporting information.

5.3.3 Shielding Model

Review the Structural and Thermal Evaluation chapters of the SARP to determine the effects that the tests for normal conditions of transport and hypothetical accident conditions have on the packaging and its contents. Verify that the models used in the shielding calculation are consistent with these effects and with the engineering drawings. Coordinate with the Structural and Thermal reviews as appropriate.

5.3.3.1 Configuration of Source and Shielding

Verify the dimensions of the source and packaging used in the shielding models, and ensure that tolerances have been appropriately considered. If contents can be positioned at varying locations or with varying densities, ensure that the location and physical properties of the contents used in the evaluation are those resulting in the maximum external radiation levels. For example, the source configuration that maximizes the radiation level on the side of the package might not be the same source configuration that maximizes the radiation level on the top or bottom. Ensure that any changes in configuration (e.g., displacement of source or shielding, reduction in shielding) resulting under normal conditions of transport or hypothetical accident conditions have been included, as appropriate.

For spent fuel, confirm that the spent-fuel region and activated-hardware regions (e.g., top/bottom end-pieces, spacers, and plenum) are properly located in the model. Verify that flux peaking, both radially and axially within the fuel, has been treated appropriately if they have not already been accounted for in the source term (see Section 5.3.2).

In general, the shielding model and evaluation need address radiation levels from only one package and show that the requirements of §71.47 are satisfied. Based on external radiation levels measured prior to shipment, multiple packages may be combined in conveyance in accordance with 49 CFR 177.842 (nonexclusive use), 49 CFR 173.441 (exclusive use), and other applicable Department of Transportation (DOT) regulations. (Combining packages with fissile material must also address criticality-safety restrictions, as discussed in Section 6 of this PRG.)

For exclusive-use shipments in which the analysis is based on the radiation levels of §71.47(b), confirm that dimensions of the transport vehicle and package location are included as appropriate. These dimensions or vehicle type, as well as positioning of the packages, become limiting conditions in the Certificate of Compliance (CoC) if used in the evaluation. For some packages, the use of radiation levels at distances from the package surface instead of the vehicle surface may be sufficient to demonstrate compliance without the need to specify vehicle dimensions.

Verify that the dose point locations in the shielding model include all locations prescribed in §71.47(a) or §71.47(b), and §71.51(a)(2) as appropriate. Ensure that these points are chosen to identify the location of the maximum radiation levels. Confirm that voids, streaming paths, and irregular geometries are included in the model or otherwise treated in an adequate manner. For exclusive-use shipments, ensure that the determination of the radiation levels on the bottom surface of the vehicle, at 2 m from the vehicle, and in normally occupied positions account for the contribution from ground scatter, as appropriate.

5.3.3.2 Material Properties

Verify the appropriate material properties (e.g., mass densities and atom densities) used in the shielding models of the packaging, contents, and conveyance (if applicable). For uncommon materials, especially foams, plastics, and other hydrocarbons, the source of data should be referenced. Material specifications should be consistent with those in the engineering drawings. Any deviations from these specifications should be clearly justified, e.g. for added conservatism etc. Confirm that shielding properties will not degrade significantly during the service life of the packaging (e.g., degradation of foam or dehydration of hydrogenous materials).

Ensure that any changes resulting under normal conditions of transport or hypothetical accident conditions have been included, as appropriate. Loss of external shielding, such as that sometimes used for neutron attenuation in spent-fuel packages or lead slump, may be acceptable if it produces no other deleterious effects on the package and if the external radiation levels remain within allowable limits.

If the shielding model considers a homogenous source region (rather than a detailed heterogeneous model of the contents), ensure that such an approach is justified, and verify that the homogenized mass densities are correct. Atom densities should also be confirmed if used as input to shielding calculations.

If reduced densities are used for fissile material contents to decrease self-shielding for the sake of conservatism, ensure that the correct contribution to the sub-critical multiplication of neutrons is properly accounted for unless it has already been accounted for in the source term.

5.3.4 Shielding Evaluation

The review of the shielding evaluation presented in the SARP should consider that §71.87(j) requires actual external radiation levels to be measured prior to shipment in order to verify that the limits of §71.47 are not exceeded. Other factors that should be considered in determining the level of effort for the shielding review include the expected magnitude of the radiation levels, the margin between calculations and regulatory limits, similarity with previously reviewed packages, thoroughness of the review of source terms and other input data, and bounding assumptions in the analysis.

5.3.4.1 Methods

Ensure that the methods used for the shielding evaluation are appropriate. Well-known computer programs should be referenced. Other codes or methods should be described in the SARP, and appropriate supplemental information should be provided. Verify that the number of dimensions of the code is appropriate for the package geometry, including streaming paths, if applicable.

Confirm that the cross-section library used by the code is applicable for the shielding calculations. Ensure that the code accounts for subcritical multiplication and secondary gamma production unless these conditions have been otherwise appropriately considered (e.g., in the source-term specification).

5.3.4.2 Input and Output Data

Verify that key input data for the shielding calculations are identified. These data will depend on the type of code (e.g., deterministic or Monte Carlo), as well as the code itself. The SARP should also include representative input files used in the analyses. Verify, as appropriate, that the information from the shielding models is properly input into the code.

At least one representative output file (or key sections of the file) should generally be included in the SARP. Ensure that proper convergence is achieved and that the calculated radiation levels in the output files agree with those reported in the text.

5.3.4.3 Flux-to-Dose-Rate Conversion

Ensure that the evaluation properly converts the gamma and neutron fluxes to dose rates. This conversion should generally use ANSI/ANS 6.1.1-1977, although other conversions may be used for point-kernel gamma calculations.

Verify the accuracy of the flux-to-dose rate conversion factors, which should be tabulated as a function of the energy group structure used in the shielding calculation.

5.3.4.4 External Radiation Levels

Confirm that the external radiation levels under normal conditions of transport and hypothetical accident conditions agree with the summary tables discussed in Section 5.3.1.3 and that they meet the limits in §71.47(a) or §71.47(b), and §71.51(a)(2), as applicable. Verify that the analysis shows that the locations selected are those of maximum dose rates. To determine maximum dose rates, radiation levels may be averaged over the cross-sectional area of a probe of reasonable size.[5-2] For packages with streaming paths or voids, averaging should not be used to

reduce the radiation levels resulting from such features. Averaging is also not acceptable for assessing cracks, pinholes, uncontrollable voids, or other defects as required by §71.85(a).

Ensure that the external radiation levels are reasonable and that their variations with location are consistent with the geometry and shielding characteristics of the package. Verify that the radiation levels presented in the shielding evaluation section are consistent with those in the summary table reviewed in Section 5.3.1.3 above.

Confirm that the evaluation addresses damage to the shielding under normal conditions of transport and hypothetical accident conditions. Verify that any damage under normal conditions of transport (§71.71) does not result in a significant increase in the external dose rates, as required by §71.43(f) and §71.51(a)(1). Any increase should be explained and justified as not significant.

5.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, computer code descriptions, input and output files, test results, flux-to-dose-rate conversion factors, and other appropriate supplemental information.

5.4 Evaluation Findings

5.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 5.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the shielding design has been adequately described and evaluated and that the package meets the external radiation requirements of 10 CFR 71.

5.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. In addition to specifications of authorized contents and information specified on the engineering drawings, other conditions of approval applicable to the Shielding Evaluation chapter of the SARP may include:

- Restriction for exclusive-use shipment
- Limitations on vehicle dimensions or package position/orientation for exclusive-use shipments
- Requirement for personnel in normally occupied positions of the vehicle to wear dosimetry devices in accordance with 10 CFR 20.1502.

5.5 References

[5-1] American Nuclear Society, *American National Standard for Neutron and Gamma-Ray Flux to Dose Rate Factors,* ANSI/ANS 6.1.1-1977, LaGrange Park, Illinois.

[5-2] U.S. Nuclear Regulatory Commission, *Averaging of Radiation Levels Over the Detector Probe Area*, HPPOS-13, in *Health Physics Positions Data Base*, NUREG/CR-5569, Rev. 1, 1992.

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6.0 CRITICALITY REVIEW

This review verifies that the package design meets the criticality safety requirements of 10 CFR 71 under normal conditions of transport and hypothetical accident conditions.

The Criticality review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, and Thermal Evaluation chapters of the Safety Analysis Report for Packaging (SARP). Similarly, the results of the Criticality review are considered in the review of the Package Operations, the Acceptance Tests and Maintenance Program, and Quality Assurance. An example of this information flow for the Criticality review is shown in Figure 6.1.

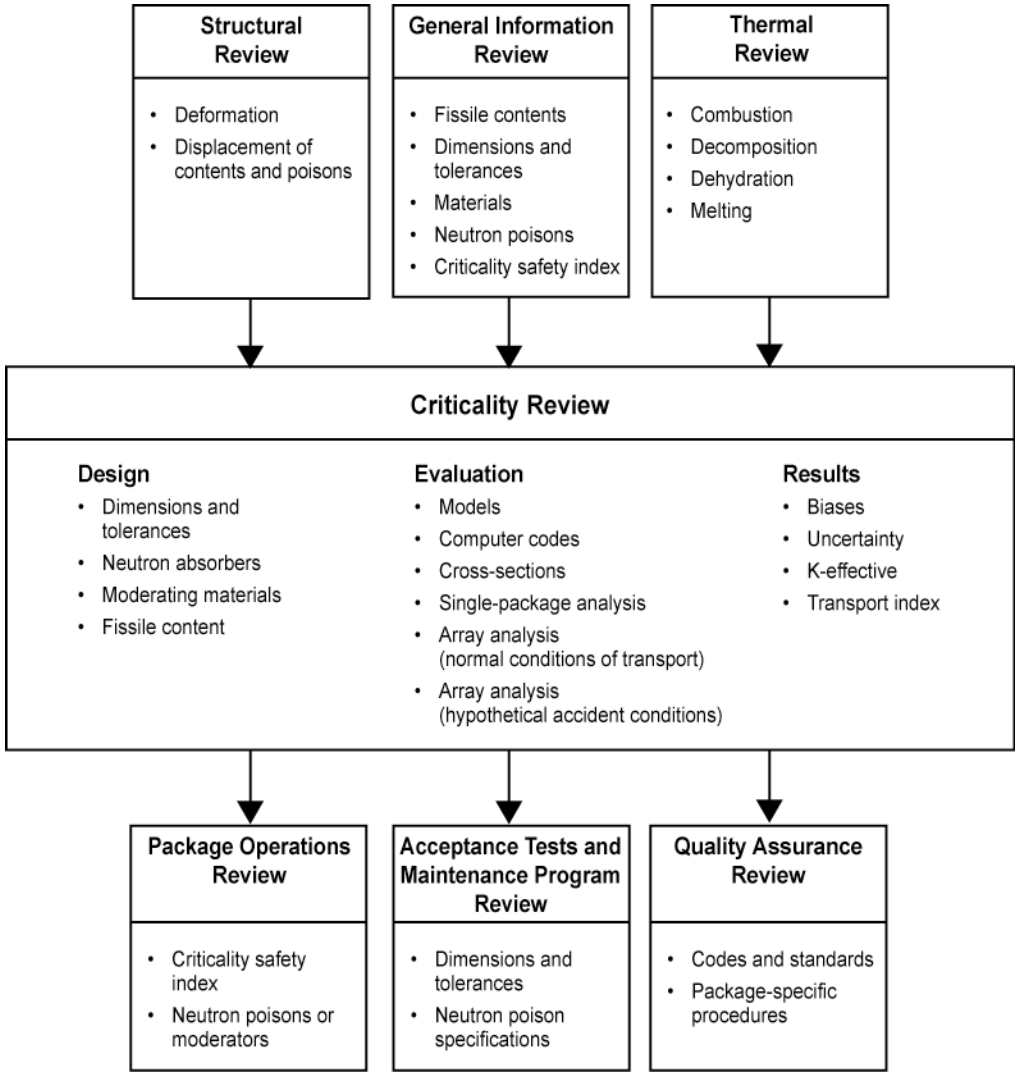

Figure 6.1 Example of Information Flow for the Criticality Review

6.1 Areas of Review

The description and evaluation of the criticality design should be reviewed. The criticality review should include the following:

6.1.1 Description of Criticality Design

- Design Features
- Codes and Standards
- Summary Table of Criticality Evaluations

6.1.2 Fissile Material and Other Contents

6.1.3 General Considerations for Criticality Evaluations

- Model Configuration
- Material Properties
- Demonstration of Maximum Reactivity
- Computer Codes and Cross-Section Libraries

6.1.4 Single Package Evaluation

- Configuration
- Results

6.1.5 Evaluation of Undamaged-Package Arrays (Normal Conditions of Transport)

- Configuration
- Results

6.1.6 Evaluation of Damaged-Package Arrays (Hypothetical Accident Conditions)

- Configuration
- Results

6.1.7 Criticality Safety Index for Nuclear Criticality Control

6.1.8 Benchmark Evaluations

- Applicability of Benchmark Experiments
- Bias Determination

6.1.9 Appendices

6.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Criticality review of fissile material packages are as follows:

- The package design must be described and evaluated to demonstrate that it meets the criticality requirements of 10 CFR 71. [§71.31(a)(1), §71.31(a)(2), §71.33, §71.35(a)]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- A single package must be subcritical under the conditions of §71.55(b), §71.55(d), and §71.55(e).
- A fissile material packaging design to be transported by air must meet the requirements of §71.55(f).
- An array of undamaged packages must be subcritical under the conditions of §71.59(a)(1).
- An array of damaged packages must be subcritical under the conditions of §71.59(a)(2).
- A fissile material package must be assigned a criticality safety index for nuclear criticality control to limit the number of packages in a single shipment. [§71.59(b), §71.59(c), §71.35(b)]
- The package must be designed, constructed, and prepared for shipment so that there will be no significant reduction in the effectiveness of the packaging under the tests specified in §71.71 for normal conditions of transport. [§71.43(f), §71.51(a)(1), §71.55(d)(4)]
- Unknown properties of fissile material must be assumed to be those that will credibly result in the highest neutron multiplication. [§71.83]

6.3 Review Procedures

The following procedures are generally applicable to the review of the Criticality Evaluation chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 6.1 of this PRG.

6.3.1 Description of Criticality Design

6.3.1.1 Design Features

Review the General Information chapter of the SARP and any additional description of the criticality design presented in the Criticality Evaluation chapter. Design features important for criticality include:

- Dimensions and tolerances of the containment system for fissile material
- Structural components that maintain the fissile material or neutron poisons in a fixed position within the package or in a fixed position relative to each other

- Locations, dimensions, and densities (concentration) of neutron absorbing materials and moderating materials, including neutron poisons and shielding
- Dimensions and tolerances of floodable voids and flux traps within the package
- Dimensions and tolerances of the overall package that affect the physical separation of the fissile material contents in package arrays.

Confirm that the text and sketches describing the criticality design features are consistent with the engineering drawings and the models used in the criticality evaluation.

6.3.1.2 Codes and Standards

Verify that any codes or standards applicable to the criticality design of the package are identified and appropriate, including those for material specifications and fabrication (see Tables D.1 and D.2). Ensure that such codes and standards are consistent with those specified in the General Information, Structural, and Thermal Evaluation chapters of the SARP. Determine if these codes or standards specify temperature limits for materials.

If codes, standards, or similar documents that provide subcritical limits are used in the criticality evaluation, ensure that the conditions specified in those documents are applicable to a package or array of packages under normal conditions of transport and hypothetical accident conditions.

6.3.1.3 Summary Table of Criticality Evaluation

Review the summary table of the criticality evaluation, which should address the following cases, as described in Sections 6.3.4 through 6.3.6:

- A single package, under the conditions of §71.55(b), §71.55(d), and §71.55(e)
- An array of undamaged packages, under the conditions of §71.59(a)(1)
- An array of damaged packages, under the conditions of §71.59(a)(2).

Verify that the table shows that the maximum multiplication factor for each case, including all uncertainties and the bias from benchmark calculations, does not exceed 0.95. (The administrative margin should be 0.05.) The table should include the number of packages evaluated and a brief description of the conditions of the package and array, as applicable. Because of the requirements of §71.43(f), the condition of an undamaged package should be that of a package subjected to the tests for normal conditions of transport. Table 6.1 illustrates an example table summarizing calculations performed with a Monte Carlo code. The terminology for the uncertainties and bias in Table 6.1 is consistent with that in NUREG/CR-5661[6-1] and NUREG/CR-6361.[6-2] Because variations in the details of bias determination have been used over the years, the reviewer should ensure that the approach is adequately described. See Section 6.3.8 of this PRG.

Review of the Criticality Safety Index (CSI) for nuclear criticality control, as listed in the summary table, is discussed in Section 6.3.7 below.

Table 6.1 Example of Summary Table for Criticality Evaluations

Type of evaluation/ package condition	Number of packages*	$k + 2\sigma$ (package or array)	Bias (β)	Uncertainty in bias ($\Delta\beta$)	$k + 2\sigma - \beta^{\S} + \Delta\beta$
Single Package (Description of package condition)	1				
Undamaged Array (Description of package condition, array configuration)					
Damaged Array (Description of package condition, array configuration)					

* Criticality Safety Index for Nuclear Criticality Control = _____.

§ Positive biases are not subtracted.

6.3.2 Fissile Material and Other Contents

Ensure that the specifications for the contents used in the criticality evaluation are consistent with those in the General Information chapter of the SARP. Specifications relevant to the criticality evaluation include fissile material mass, dimensions, enrichment or isotopic composition, physical and chemical form, density, moisture, and other characteristics depending on the specific contents. In addition, nonfissile materials, used as moderators, absorbers and impurities must be specified if they are to be included as authorized contents in the Certificate of Compliance (CoC).

Specifications for fuel assemblies and rods should include:

- Type of fuel assemblies or rods and vendor/model, as appropriate
- Dimensions/tolerances of fuel (including annular pellets), cladding, fuel-cladding gap, pitch, and rod length
- Number of rods per assembly, and locations and dimensions of guide tubes and burnable poisons (see Section 6.3.3.2)
- Materials and densities
- Active fuel length
- Enrichment (variation by rod if applicable) before irradiation (see below)
- Chemical and physical form
- Mass of initial heavy metal per assembly or rod
- Number of fuel assemblies or individual rods per package
- Other information affecting the criticality evaluation, as applicable.

To date, burnup credit (to account for depletion of fissile material or increase in fission product poisons due to irradiation) has been accepted only on a very limited basis,[6-3] which is generally not applicable to material shipped by DOE. Consequently, the enrichment for spent fuel should be that of the unirradiated fuel, except in rare cases where irradiated material has a higher reactivity. If assemblies contain fuel with several enrichments, the evaluation should either assume the maximum enrichment or demonstrate that another approach (e.g., average enrichment) is bounding. Section 6.3.3.2 discusses consideration of poison densities and the depletion of burnable poisons.

Any differences in the contents specifications from those in the General Information chapter should be clearly identified and justified.

Because a partially filled container may allow more physical space for moderators (e.g., water), the most reactive case is not necessarily that with the maximum allowable contents. Fuel rods that have been removed from an assembly should be replaced with dummy rods that displace an equal amount of water unless the criticality analysis considers the additional moderation resulting from their absence. The requirement for dummy rods, if applicable, should be specified as a condition of approval in the CoC.

If the package is designed for multiple types of contents, the SARP may include a separate criticality evaluation and propose different criticality controls for each contents type. Any assumptions that certain contents need not be evaluated because they are less reactive than those evaluated should be properly justified.

6.3.3 General Considerations for Criticality Evaluations

The considerations discussed below are applicable to the review of criticality evaluations of a single package and arrays of packages under normal conditions of transport and hypothetical accident conditions.

General guidance for preparing criticality evaluations of transportation packages is provided in NUREG/CR-5661.

6.3.3.1 Model Configuration

Examine the Structural and Thermal Evaluation chapters of the SARP to determine the effects of the normal conditions of transport and hypothetical accident conditions on the packaging and its contents. Verify that the models, used in the criticality evaluation, are consistent with these effects and with the engineering drawings. Coordinate with the Structural and Thermal reviews as appropriate.

Review the configuration and dimensions of the contents and packaging used in the criticality models. For some types of packagings and contents (e.g., powders), the contents can be positioned at various locations and densities. The relative location and physical properties of the contents within the packaging should be justified as those that result in the maximum reactivity.

Ensure that the SARP considers deviations from nominal design configurations in the manner that maximizes reactivity. Examples of such deviations include:

- Dimensional tolerances, e.g., for cavity sizes and poison thickness
- Off-centered positioning of contents within the containment vessel or spent-fuel basket
- Off-centered positioning of basket or containment vessel within the package
- Preferential flooding of regions within the package.

Determine if the SARP includes any specifications regarding the condition of the contents. If the contents permit damaged fuel, the maximum extent of damage should be specified and addressed in the criticality analyses, as appropriate. Additional information on canning of damaged fuel is discussed in Section 4.3.1.5 of this PRG.

The contents of some packages (e.g., fuel assemblies) may be in the form of a finite lattice. With current computational capability, homogenization of the fissile region should generally be avoided. If a homogenized configuration is used, the SARP should demonstrate its appropriateness (e.g., by comparing k_{eff} of heterogeneous and homogeneous models and by consistently evaluating benchmark experiments).

6.3.3.2 Material Properties

Verify that the appropriate mass densities and atom densities are provided for materials used in the models of the packaging and contents. Material properties should be consistent with the condition of the package under the tests of §71.71 and §71.73, and any differences between normal conditions of transport and hypothetical accident conditions should be addressed.

Ensure that materials relevant to the criticality design (e.g., poisons, foams, plastics, and other hydrocarbons) are properly specified and the data sources referenced. Verify that materials will not degrade during the service life of the packaging. No more than 75% of the specified minimum neutron poison concentration in packaging components or in unirradiated contents should generally be considered in the criticality evaluation. No credit should be taken for burnable poisons in irradiated contents (e.g., spent fuel).

Unknown properties of fissile material must be assumed to be those that will credibly result in the highest neutron multiplication, §71.83.

6.3.3.3 Demonstration of Maximum Reactivity

Verify that the analyses evaluate the most reactive configuration of each case listed in Section 6.3.1.3 (single package, array of undamaged packages, and array of damaged packages). Assumptions and approximations should be clearly identified and justified.

Ensure that the analysis determines the optimum combination of internal moderation (within the package) and interspersed moderation (between packages), as applicable. Confirm that preferential flooding of different regions within the package, including the fuel-cladding gap, is considered as appropriate. As noted in Section 6.3.2, the maximum allowable fissile material is not necessarily the most reactive contents.

Additional guidance on determining the most reactive configurations is presented in NUREG/CR-5661 and in Sections 6.3.4 to 6.3.6 below.

6.3.3.4 Computer Codes and Cross-Section Libraries

Confirm that an appropriate computer code (or other acceptable method) is used for the criticality evaluation. Well-known codes should be clearly referenced. Other codes or methods should be described in the SARP, and appropriate supplemental information should be provided.

Ensure that the criticality evaluations use an appropriate cross-section library. If multi-group cross sections are used, confirm that the neutron spectrum of the package has been appropriately considered and that the cross sections are properly processed to account for resonance absorption and self-shielding. Additional information regarding cross-sections is provided in ORNL/M-5003[6-4] and NUREG/CR-6686.[6-5]

Confirm that the computer code has been properly used in the criticality evaluation. Key input data for the criticality calculations should be identified. Depending on the code used, these data include number of neutrons per generation, number of generations, convergence criteria, mesh selection, etc. The SARP should include at least one representative input file for a single package, undamaged array, and damaged array evaluation. Verify, as appropriate, that the information from the criticality model, material properties, and cross-sections is properly input into the code.

An output file (or key sections) should generally be included in the SARP for each representative input file. Ensure that the calculations have properly converged and that the calculated multiplication factors from the output files agree with those reported in the evaluation.

The review should generally include a detailed confirmatory analysis of the criticality calculations reported in the SARP. As a minimum, perform an independent calculation of the most reactive case, as well as sensitivity analyses to confirm that the most reactive case has been correctly identified. To the extent practical, use an independent model of the package and a different code and cross-section set from that of the SARP evaluation.

6.3.4 Single Package Evaluation

6.3.4.1 Configuration

Ensure that the criticality evaluation analyzes a single package under the most reactive condition of §71.55(d) (normal conditions of transport) and §71.55(e) (hypothetical accident conditions), with water moderation as required by §71.55(b). The evaluations should consider:

- Fissile material in its most reactive credible configuration consistent with the condition of the package and the chemical and physical form of the contents

- Water moderation to the most reactive credible extent, including water inleakage to the containment system
- Full water reflection on all sides of the package, including close reflection of the containment system or reflection by the package materials, whichever is more reactive.

Verify that the package also meets the specifications of §§71.55(d)(2) through 71.55(d)(4) under normal conditions of transport. Coordinate with the Structural review.

6.3.4.2 Results

Confirm that most reactive single-package conditions are evaluated and that the results are consistent with the information presented in the summary table discussed in Section 6.3.1.3. If the package is shown to be subcritical by reference to a standard such as ANSI/ANS 8.1[6-6] in lieu of calculations, verify that the standard is applicable to the package conditions.

6.3.5 Evaluation of Undamaged-Package Arrays (Normal Conditions of Transport)

6.3.5.1 Configuration

Ensure that the criticality evaluation analyzes an array of 5N undamaged packages. N cannot be less than 0.5. The evaluation should consider:

- The most reactive configuration of the array (e.g., pitch, package orientation, and shape of the array) with nothing between the packages.
- The most reactive credible configuration of the packaging and its contents under normal conditions of transport. If the evaluation of the water spray test has demonstrated that water would not leak into the package, water inleakage need not be assumed.
- Full water reflection on all sides of a finite array.

6.3.5.2 Results

Confirm that the most reactive array conditions are evaluated and that the results of the analysis are consistent with the information presented in the summary table discussed in Section 6.3.1.3.

6.3.6 Evaluation of Damaged-Package Arrays (Hypothetical Accident Conditions)

6.3.6.1 Configuration

Ensure that the criticality evaluation analyzes an array of 2N damaged packages. N cannot be less than 0.5. The evaluation should consider:

- The most reactive configuration of the array (e.g., pitch, package orientation, internal moderation, and shape of the array)
- Optimum interspersed hydrogenous moderation
- Full water reflection on all sides of a finite array
- The most reactive credible configuration of the packaging and its contents under hypothetical accident conditions.

The analysis of arrays of damaged packages should generally assume water inleakage into the individual packages (including the containment vessel). Demonstrating that an array of leaking packages remains subcritical is more straightforward than designing and demonstrating that a package does not leak. The immersion test of §71.73(c)(5) is not required if water inleakage is assumed in the criticality analysis.

If the array analysis assumes that water does not leak into the packages in arrays, the SARP should clearly justify the basis for that assumption, and the package evaluation should adequately demonstrate that the package can reliably exclude water when it is subjected to the hypothetical accident condition tests in §71.73. The justification for neglecting water inleakage should show, at a minimum, that:

- No inleakage of water occurs when the package is subjected to the immersion tests of §§71.73(c)(5) and 71.73(c)(6).
- The testing or analysis clearly demonstrates that the most unfavorable conditions for water inleakage have been addressed (e.g., initial test conditions, orientations for drop, crush, puncture, fire, and water immersion tests).
- The package is designed and fabricated in accordance with accepted codes and standards.
- If the package is evaluated by analysis, the design margin is in accordance with these codes and standards. If the package is evaluated by testing, the effects of the tests on the condition of the package can be consistently reproduced and demonstrate an adequate margin of safety.
- The quality and characteristics of the tested package are representative of, and no better than, actual packages fabricated in accordance with the design specifications.
- The design leakage rate for the package is sufficient to preclude water inleakage under both normal conditions of transport and hypothetical accident conditions.
- The package is maintained and periodically inspected to ensure that its performance during its service life is representative of the package evaluated in the application. Fabrication, maintenance, and periodic leakage tests are conducted in accordance with ANSI N14.5.[6-7]
- The package is tested prior to each shipment to show that the leakage rate is less than that which would allow inleakage of water.
- The sensitivity of the criticality analysis to water inleakage is addressed as appropriate. For example, would water inleakage into most packages in a large array be required before criticality could be achieved, or would an array with only a few leaking packages be critical?
- Any other issues relevant to reliably precluding water inleakage are addressed as appropriate.

6.3.6.2 Results

Confirm that the most reactive array conditions are evaluated and that the results of the analysis are consistent with the information presented in the summary table discussed in Section 6.3.1.3.

6.3.7 Criticality Safety Index for Nuclear Criticality Control

Based on the number of packages demonstrated to be subcritical in the array analyses reviewed in Sections 6.3.5 and 6.3.6, verify that the SARP has determined the appropriate value of N and has calculated the CSI in accordance with §71.59. The appropriate N must be the smaller value that assures subcriticality for both 5N packages under normal conditions of transport and 2N packages under hypothetical accident conditions. Note that due to round-off and differences between exclusive and nonexclusive use, N is not necessarily the number of packages that can be included in a shipment.

Ensure that the criticality safety index is consistent with that reported in the summary table of Section 6.3.3 above and in the General Information chapter of the SARP. This criticality safety index is typically specified in the CoC as the minimum criticality safety index.

6.3.8 Benchmark Evaluations

Ensure that the computer codes for criticality calculations are benchmarked against critical experiments. Verify that the analysis of the benchmark experiments uses the same computer code, computer hardware, and cross-section library as those used to calculate the k_{eff} values for the package.

Additional guidance on benchmarking of nuclear criticality codes is provided in NUREG/CR-6361. Numerous well-documented benchmark experiments have been published by the Nuclear Energy Agency, Organization for Economic Co-Operation and Development.[6-8]

6.3.8.1 Applicability of Benchmark Experiments

Review the general description of the benchmark experiments and confirm that they are appropriately referenced.

Verify that the benchmark experiments are applicable to the actual packaging design and contents. The benchmark experiments should have, to the maximum extent possible, the same materials, neutron spectra, and configuration as the package evaluations. Key package parameters that should be compared with those of the benchmark experiments include type of fissile material, enrichment, moderator-to-fissile ratio, poison, and configuration. Confirm that differences between the package and benchmarks are identified and properly considered.

In addition, the SARP should address the overall quality of the benchmark experiments and the uncertainties in experimental data (e.g., mass, density, dimensions). Ensure that these uncertainties are treated in a conservative manner, i.e., they result in a lower multiplication factor for the benchmark experiment.

6.3.8.2 Bias Determination

Examine the results of the calculations for the benchmark experiments and the method used to account for biases, including the contribution from uncertainties in experimental data.

Ensure that a sufficient number of applicable benchmark experiments are analyzed and that the results of these benchmark calculations are used to determine an appropriate bias for the package calculations. Statistical and convergence uncertainties of both benchmark and package calculations should be addressed. Confirm that the benchmark evaluations address trends in the bias with respect to parameters such as moderator-to-fissile ratio, pitch-to-rod diameter, assembly separation, neutron absorber material, etc. As indicated in Table 6.1, positive biases should not be used to reduce the calculational uncertainty. Additional information on determining biases and their range of applicability is provided in NUREG/CR-5661, NUREG/CR-6361, and NUREG/CR-6698.[6-9]

6.3.9 Appendices

Confirm that the appendices include a list of references, copies of applicable references if not generally available to the reviewer, computer code descriptions, input and output files, test results, and any other appropriate supplemental information.

6.4 Evaluation Findings

6.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements in Section 6.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the nuclear criticality safety design has been adequately described and evaluated and that the package meets the nuclear criticality safety requirements of 10 CFR 71.

6.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in Section 5 of the CoC. In addition to specifications of authorized contents and information specified on the engineering drawings, other conditions of approval applicable to the Criticality Evaluation of the SARP may include:

- Minimum CSI
- Restriction for exclusive-use shipment
- Requirement to have specific neutron absorbers in place
- Requirement to replace vacant positions in fuel assemblies with dummy rods
- Specification of the allowed extent of damage for spent fuel.

6.5 References

[6-1] U.S. Nuclear Regulatory Commission, *Recommendations for Preparing the Criticality Safety Evaluation of Transportation Packages*, NUREG/CR-5661, ORNL/TM-11936, April 1997.

[6-2] U.S. Nuclear Regulatory Commission, *Criticality Benchmark Guide for Light-Water-Reactor Fuel in Transportation and Storage Packages*, NUREG/CR-6361, ORNL/TM-13211, January 1997.

[6-3] U.S. Nuclear Regulatory Commission, *Burnup Credit in the Criticality Safety Analysis of PWR Spent Fuel in Transport and Storage Casks*, ISG-8, Rev. 2, Spent Fuel Project Office, September 27, 2002.

[6-4] *The Radioactive Materials Packaging Handbook:*, *Design, Operations, and Maintenance*, ORNL/M-5003, 1998, prepared by Oak Ridge National Laboratory, Oak Ridge, Tennessee.

[6-5] S. M. Bowman et. Al., *Experience the SCALE Criticality Safety Cross-Section Libraries*, NUREG/CR-6686, ORNL/TM-1999/322, 2000, prepared by Oak Ridge National Laboratory, Oak Ridge, Tennessee.

[6-6] American Nuclear Society, *American National Standard for Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors*, ANSI/ANS 8.1-1983 (R1988), LaGrange Park, Illinois.

[6-7] American National Standards Institute, ANSI N14.5-1997, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, New York.

[6-8] Organization for Economic Co-Operation and Development, *International Handbook of Evaluated Criticality Safety Benchmark Experiments*, NEA/NSC/Doc(95)03, Nuclear Energy Agency, September 2006.

[6-9] *Guide for Validation of Nuclear Criticality Safety Calculational Methodology*, NUREG/CR-6698, 2000, prepared for Fuel Cycle Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC.

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7.0 PACKAGE OPERATIONS REVIEW

This review verifies that the operating controls and procedures for the package meet the requirements of 10 CFR 71 and are adequate to assure that the package will be operated in a manner consistent with its evaluation for approval.

The Package Operations chapter of the Safety Analysis Report for Packaging (SARP) should establish the minimum steps necessary to assure safe performance of the package under normal conditions of transport and hypothetical accident conditions. Detailed procedures, or procedures unrelated to the safe operation of the package, should not be included. Commitments specified in the Package Operations chapter of the SARP are typically included by reference into the Certificate of Compliance (CoC) as conditions of package approval. Consequently, operating procedures cannot be site-specific.

The Package Operations review is based in part on the descriptions and evaluations presented in the General Information, Structural Evaluation, Thermal Evaluation, Containment, Shielding Evaluation, and Criticality Evaluation chapters of the SARP. Similarly, results of the Package Operations review are considered in the Acceptance Tests and Maintenance Program review and in the Quality Assurance review. An example of the information flow for the Package Operations review is shown below in Figure 7.1.

Because the Package Operations chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

7.1 Areas of Review

All operations should be reviewed to assure that the package will be operated in a manner consistent with its evaluation for approval. The Package Operations review should include the following:

7.1.1 Package Loading

- Preparation for Loading
- Loading of Contents
- Preparation for Transport

7.1.2 Package Unloading

- Receipt of Package from Carrier
- Removal of Contents

7.1.3 Preparation of Empty Package for Transport

7.1.4 Other Operations

7.1.5 Appendices

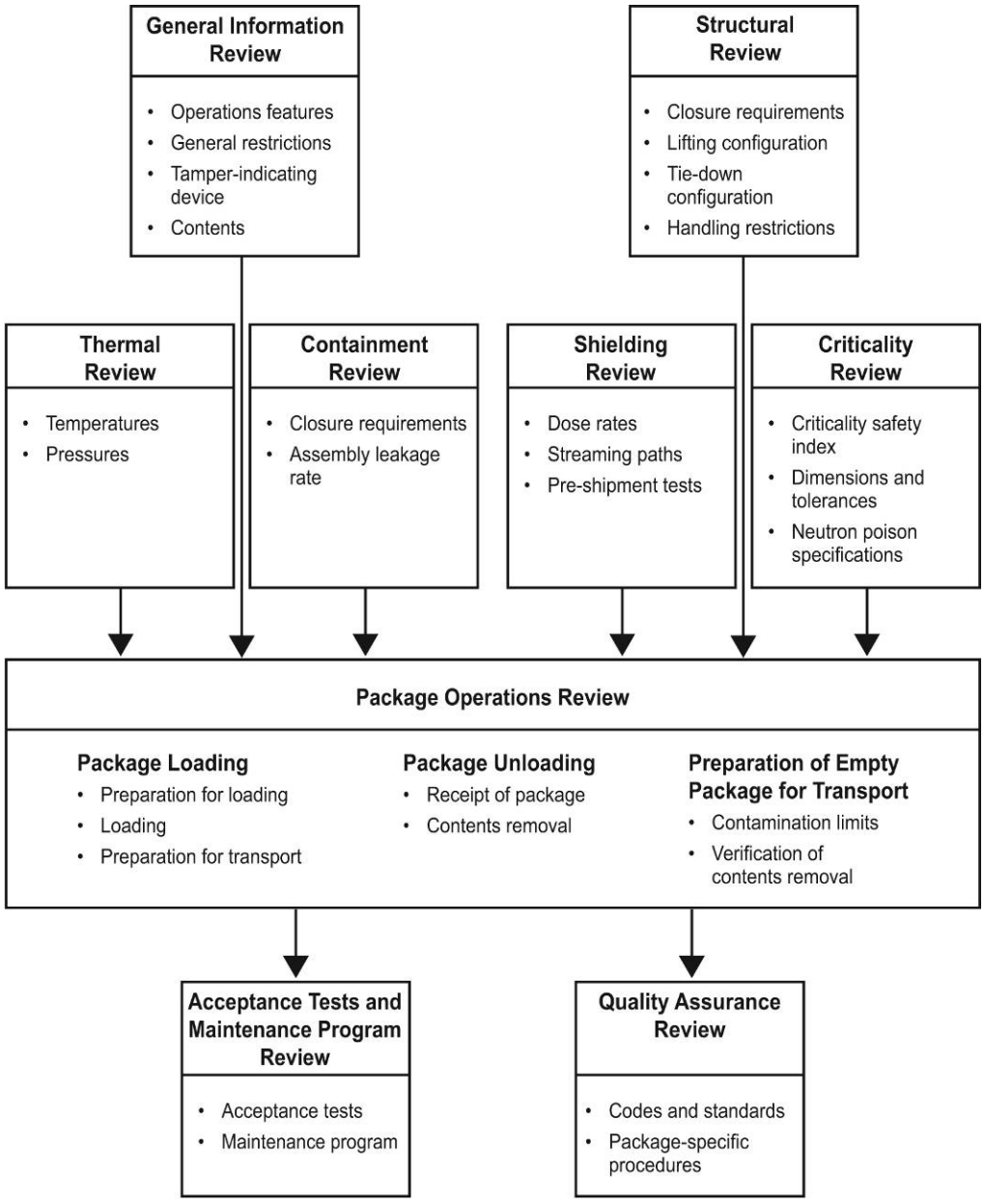

Figure 7.1 Example of Information Flow for the Package Operations Review

7.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the Package Operations review are as follows:

- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]

- The application must include any special controls and precautions for transport, loading, unloading, and handling of a fissile material shipment, and any special controls in case of accident or delay. [§71.35(c)]
- The transport index of a package in a nonexclusive-use shipment must not exceed 10, and the sum of the Criticality Safety Indices (CSI) of all packages in the shipment must not exceed 50. [§71.47(a), §71.59(c)(1)]
- Packages that require exclusive-use shipment because of increased radiation levels must be controlled by providing written instructions to the carrier. [§71.47(b-d)]
- The sum of the CSIs for nuclear criticality control of all packages in an exclusive-use shipment must not exceed 100. [§71.59(c)(2)]
- The application must include Package Operations that ensure that the package meets the routine-determination requirements of §71.87. [§71.81, §71.87]
- Unknown properties of fissile material must be assumed to be those that will credibly result in the highest neutron multiplication. [§71.83]
- A package must be conspicuously and durably marked with the model number, serial number, gross weight, and package identification number. [§71.85(c), §71.19(a)(2), §71.19(b)(3)]
- Prior to delivery of a package to a carrier, any special instructions needed to safely open the package must be provided to the consignee for the consignee's use in accordance with 10 CFR 20.1906(e). [§71.89]
- Each type B(U) or Type B(M) package design must have on the outside of the outermost receptacle a fire resistance radiation symbol in accordance with 49 CFR 172.310(d).

7.3 Review Procedures

The following procedures are generally applicable to the review of the Package Operations chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 7.1 of this PRG.

The Package Operations in the SARP should generally be listed in sequential order. Additional guidance on Package Operations is provided in NUREG/CR-4775.[7-1]

7.3.1 Package Loading

7.3.1.1 Preparation for Loading

Review the procedures for preparing the package for loading. At a minimum, the procedures should:

- Specify that the package should be loaded and closed in accordance with written procedures
- Describe any special controls and precautions for handling
- Verify that the package is in unimpaired physical condition and that all required periodic maintenance has been performed

- Ensure that the package is conspicuously and durably marked with the model number, serial number, gross weight, and package identification number
- Determine that the package is proper for the contents to be shipped, including the need for canning of damaged fuel or for a second containment vessel, if applicable
- Ensure that the use of the package complies with all other conditions of approval in the CoC.

7.3.1.2 Loading of Contents

Review the procedures for loading the contents. At a minimum, the procedures should:

- Identify any special handling equipment needed
- Describe any special controls and precautions for loading
- Indicate the method of loading the contents
- Ensure that any required moderator or neutron absorber is present and in proper condition
- Describe the method to remove water from the package, as appropriate
- Identify any requirement to vent gases from the package or add fill gas, as appropriate
- Ensure that each closure device of the package, including seals and gaskets, is properly installed, secured, and free of defects
- Verify that the bolt torques described in the procedures are consistent with those shown on the drawings
- Confirm that the package has been loaded and closed appropriately.

7.3.1.3 Preparation for Transport

Review the procedures for preparing the package for transport. At a minimum, the procedures should:

- Ensure that non-fixed (removable) radioactive contamination on external surfaces is as low as reasonably achievable, and, depending on the availability, within the limits specified in Appendix D to 10 CFR 835, or 49 CFR 173.443, whichever is more appropriate
- Describe the radiation survey requirements to confirm that the allowable external radiation levels specified in §71.47 are not exceeded
- Describe the temperature survey requirements, as applicable, to verify that limits specified in §71.43(g) are not exceeded
- Specify the assembly verification leakage rate, and ensure package closures are leak tested in accordance with ANSI N14.5[7-2]
- Ensure that any system for containing liquid is properly sealed and has adequate space or other specified provision for expansion of the liquid

- Verify that any pressure relief devices are set, and operable, as appropriate
- Ensure that any structural components that could be used for lifting or tie-down during transport are rendered inoperable for those purposes unless it meets the design requirements of §71.45
- Ensure that the tamper-indicating device(s) is/are installed
- Specify the attachment of impact limiters, personnel barriers, or similar devices as applicable
- Describe, for a fissile material shipment, any special controls and precautions for transport, loading, unloading, and handling and any appropriate actions in case of an accident or delay which should be provided to the carrier or consignee
- Identify any special controls which should be provided to the carrier for a package shipped by exclusive use under the provisions of §71.47(b)(1)(2)(3)(4)
- Identify any special controls which should be provided to the carrier for a fissile-material package in accordance with §71.35(c)
- Describe any special instructions that should be provided to the consignee for opening the package
- Ensure that the CSI for each package and the sum of the CSIs for the shipment are appropriate for the type of shipment as appropriate.

7.3.2 Package Unloading

7.3.2.1 Receipt of Package from Carrier

Review the procedures for receiving the package. At a minimum, the procedures should:

- Ensure that the package is examined for visible damage, status of the tamper-indicating device, surface contamination, and external radiation levels
- Describe any special actions to be taken if the package is damaged, if the tamper-indicating device is not intact, or if surface contamination or radiation survey levels are too high
- Identify any special handling equipment needed
- Describe any proposed special controls and precautions for handling and unloading.

7.3.2.2 Removal of Contents

Review the procedures for removing the contents. At a minimum, the procedures should:

- Describe the appropriate method to open the package
- Identify the appropriate method to remove the contents
- Ensure that the contents are completely removed.

7.3.3 Preparation of Empty Package for Transport

Review the procedures for preparing an empty package for transport. At a minimum, the procedures should:

- Verify that the package is empty
- Ensure that external surface contamination levels meet the requirements specified in Appendix D to 10 CFR 835 or 49 CFR 173.443
- Ensure that the internal surface contamination levels meet the requirements specified in 49 CFR 173.428
- Describe the package closure requirements
- Identify any other special controls or procedures as appropriate.

7.3.4 Other Operations

Confirm that the SARP identifies any other operational controls, as applicable. For example, some packages have a maximum allowable shipping duration due to potential generation of hydrogen gas.

7.3.5 Appendices

Confirm that the appendices include a list of references, copies of applicable references, if not generally available to the reviewer, test results, and any additional supplemental information, as appropriate.

7.4 Evaluation Findings

7.4.1 Findings

The review should ensure that the information presented supports a conclusion that the regulatory requirements specified in Section 7.2 above are satisfied.

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the package operations described meet the requirements of 10 CFR 71 and are adequate to assure that the package will be operated in a manner consistent with its evaluation for approval.

7.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. The entire Package Operations chapter of the SARP is typically included by reference into the CoC as a condition of the package approval.

7.5 References

[7-1] U.S. Nuclear Regulatory Commission, *Guide for Preparing Operating Procedures for Shipping Packages*, NUREG/CR-4775, UCID-20820, Washington, DC, July 1988.

[7-2] American National Standards Institute, *American National Standard for Radioactive Materials—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

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8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW

This review verifies that the acceptance tests for the packaging meet the requirements of 10 CFR 71 and that the maintenance program is adequate to assure packaging performance during its service life.

The Acceptance Tests and Maintenance Program chapter of the Safety Analysis Report for Packaging (SARP) should establish the minimum steps necessary to assure that the package will perform throughout its service life in the manner in which it was evaluated. Detailed procedures or site-specific requirements should not be included. Commitments specified in the Acceptance Tests and Maintenance Program chapter of the SARP are typically included in the Certificate of Compliance (CoC) as conditions of package approval.

The Acceptance Tests and Maintenance Program review is based in part on the descriptions and evaluations presented in previous chapters of the SARP. Similarly, the results of this review are considered in the Quality Assurance review. In addition, the review of other chapters of the SARP may depend on the Acceptance Test and Maintenance Program review (e.g., operating procedures for leakage testing prior to shipment may depend on the maintenance leakage test). An example of the information flow for this review is shown in Figure 8.1.

Because the Acceptance Tests and Maintenance Program chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

8.1 Areas of Review

The description of the acceptance tests and maintenance program should be reviewed. The review should include:

8.1.1 Acceptance Tests

- Visual Inspections and Measurements
- Weld Examinations
- Structural and Pressure Tests
- Leakage Tests
- Component and Material Tests
- Shielding Tests
- Thermal Tests
- Miscellaneous Tests

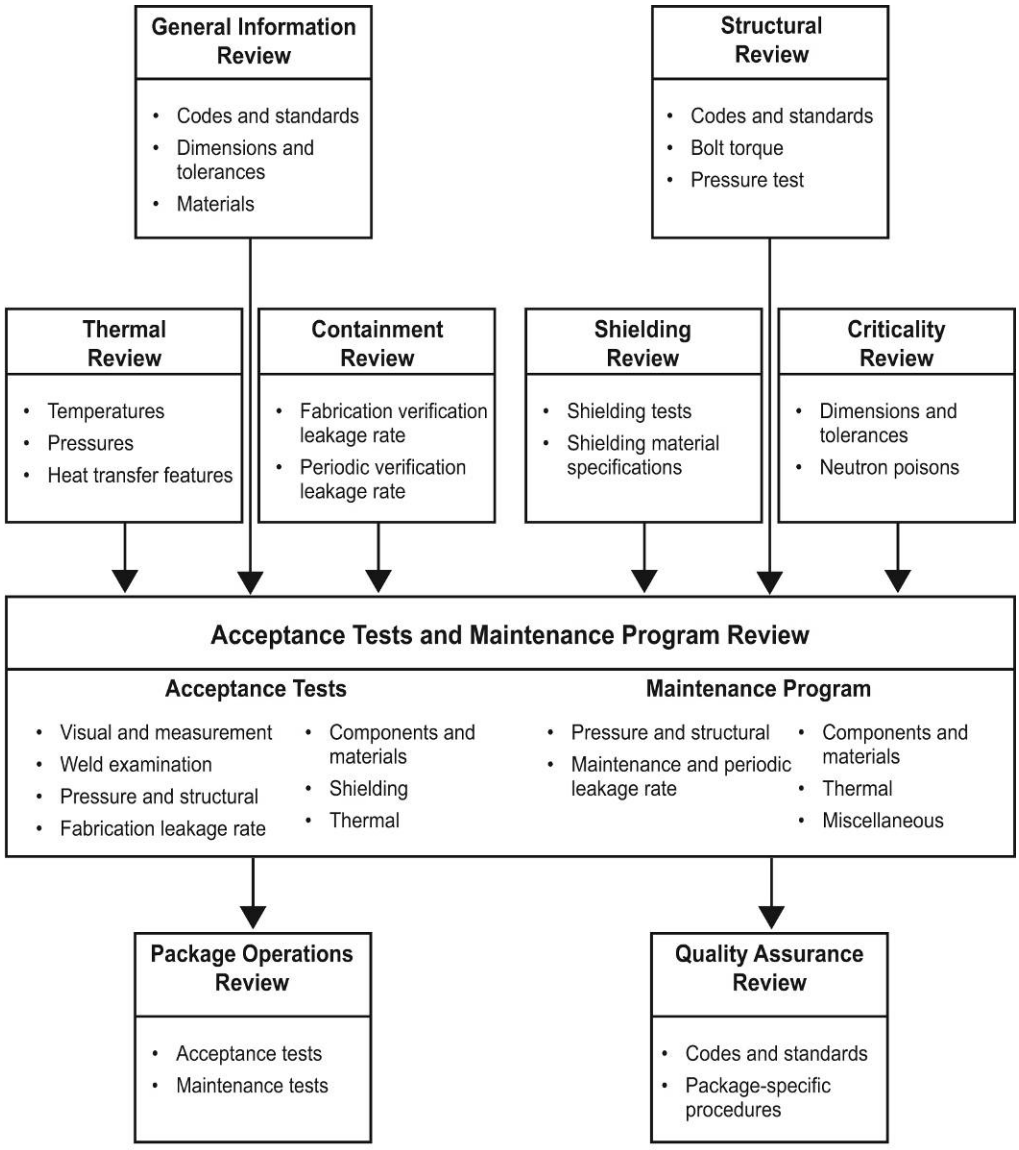

Figure 8.1 Example of Information Flow for the Acceptance Tests and Maintenance Program Review

8.1.2 Maintenance Program

- Structural and Pressure Tests
- Leakage Tests
- Component and Material Tests
- Thermal Tests
- Miscellaneous Tests

8.1.3 Appendices

8.2 Regulatory Requirements

Regulatory requirements of 49 CFR Part 172 and 10 CFR 71 applicable to the Acceptance Tests and Maintenance Program review are as follows:

8.2.1 Acceptance Tests

- The applicant shall identify the location, on the outermost receptacle (i.e., on the outside of the package), where the package has been plainly marked with a trefoil radiation symbol that is resistant to the effects of fire and water. [49 CFR 172.310(d)]
- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The applicant shall describe the quality assurance program for the design, fabrication, assembly, testing, … and use of the proposed package. [§71.37(a)]
- The applicant shall identify any specific provisions of the quality assurance program that are applicable to the particular package design under consideration, including a description of the leak testing procedures. [§71.37(b)]
- Before first use, each packaging must be inspected for cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce its effectiveness. [§71.85(a)]
- Before first use, if the maximum normal operating pressure of a package exceeds 35 kPa (5 psi) gauge, the containment system of each packaging must be tested at an internal pressure at least 50% higher than maximum normal operating pressure to verify its ability to maintain structural integrity at that pressure. [§71.85(b)]
- Before first use, each packaging must be conspicuously and durably marked with its model number, serial number, gross weight, and a package identification number. [§71.85(c)]
- Before first use, the fabrication of each packaging must be verified to be in accordance with the approved design. [§71.85(c)]
- The applicant must perform any tests deemed appropriate by the certifying authority. [§71.93(b)]

8.2.2 Maintenance Program

- The application must identify the established codes and standards used for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of such codes, the application must describe the basis and rationale used to formulate the quality assurance program. [§71.31(c)]
- The applicant shall describe the quality assurance program for the … testing, maintenance, repair, modification, and use of the proposed package. [§71.37(a)]
- The packaging must be maintained in unimpaired physical condition except for superficial defects such as marks or dents. [§71.87(b)]

- The presence of any moderator or neutron absorber, if required, in a fissile material package must be verified prior to each shipment. [§71.87(g)]
- The applicant must perform any tests deemed appropriate by the certifying authority. [§71.93(b)]
- Each type B(U) or Type B(M) package design must have on the outside of the outermost receptacle a fire resistance radiation symbol in accordance with 49 CFR 172.310(d).

8.3 Review Procedures

The following procedures are generally applicable to the review of the Acceptance Tests and Maintenance Program chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 8.1 of this PRG.

8.3.1 Acceptance Tests

Verify that the following tests, as applicable, are to be performed prior to the first use of each package. Information presented on each test should include a description of the test and its acceptance criteria as appropriate. Applicable sections of the quality assurance program and procedures may be referenced if applicable.

Each package must be fabricated in accordance with the engineering drawings listed in the CoC.

Additional guidance on acceptance tests is provided in NUREG/CR-3854.[8-1]

8.3.1.1 Visual Inspections and Measurement

Ensure that inspections are performed to verify that the packaging has been fabricated and assembled in accordance with the engineering drawings. Dimensions and tolerances specified on the drawings should be confirmed by measurement.

8.3.1.2 Weld Examinations

Verify that welding examinations and acceptance criteria are specified to verify fabrication in accordance with the codes and standards cited in the SARP. Location, type, and size of the welds should be confirmed by visual examination. For weld surface and volumetric integrity, nondestructive examination and acceptance criteria should be verified as appropriate. Additional guidance on welding criteria is provided in NUREG/CR-3019.[8-2]

8.3.1.3 Structural and Pressure Tests

Verify that the structural or pressure tests are identified and described. Such tests should comply with §71.85(b), as well as applicable codes or standards specified in the SARP (e.g., in the Structural Evaluation chapter).

8.3.1.4 Leakage Tests

Verify that the containment system of the packaging will be subjected to the fabrication leakage test specified in ANSI N14.5.[8-3] Verify that all closures, including drains and vents, are leak-tested. The acceptable leakage criterion should be consistent with that identified in the Containment chapter of the SARP.

8.3.1.5 Component and Material Tests

8.3.1.5.1 Component Tests

Confirm that appropriate tests and acceptance criteria are specified for components that affect package performance. Examples of such components include seals, gaskets, valves, fluid transport systems, and rupture disks or other pressure-relief devices. Components should be tested to meet the performance specifications shown on the engineering drawing of the package. When tests adversely affect the continued performance of a component (e.g., rupture disks), applicable quality assurance procedures should be described to justify that the tested component is equivalent to the component that will be used in the packaging.

8.3.1.5.2 Material Tests

Verify that methods are in place to demonstrate that the materials meet the specifications shown on the engineering drawing of the package. Ensure that material examinations are performed in accordance with the codes and standards specified. Confirm that appropriate tests and acceptance criteria are specified for non-code materials. Tests for neutron absorbers (e.g., boron, gadolinia) and insulating materials (e.g., foams, fiberboard) should assure that minimum specifications for density and composition are achieved.

8.3.1.6 Shielding Tests

Ensure that appropriate shielding tests are specified for both neutron and gamma radiation. The tests and acceptance criteria should be sufficient to assure that no voids or streaming paths exist in the shielding.

8.3.1.7 Thermal Tests

Verify that appropriate tests are specified to demonstrate the heat transfer capability of the packaging. These tests should confirm that the heat transfer performance, determined in the evaluation, is achieved in the fabrication process.

8.3.1.8 Miscellaneous Tests

Verify that any additional tests are described, as applicable, to demonstrate that the package has been fabricated in accordance with its approved design. Confirm that tests specified in the SARP are sufficient to meet the requirements of §71.85(a) and (b). Verify that after the acceptance tests are completed, the package will be durably marked in accordance with §71.85(c).

8.3.2 Maintenance Program

Confirm that the maintenance program is adequate to assure that packaging effectiveness is maintained throughout its service life. Maintenance tests and inspections should be described with schedules for each test or replacement of parts and criteria for minor refurbishment and replacement of parts, as applicable.

8.3.2.1 Structural and Pressure Tests

Verify that any periodic structural or pressure tests are identified and described. Such tests would generally be applicable to codes, standards, or other procedures specified in the SARP.

8.3.2.2 Leakage Tests

Confirm that the containment system of the packaging will be subjected to the periodic and maintenance leakage rate tests specified in ANSI N14.5. The acceptable leakage rate criterion should be consistent with that identified in the Containment chapter of the SARP. Ensure that replacement schedules for seals are described, as appropriate.

8.3.2.3 Component and Material Tests

8.3.2.3.1 Component Tests

Verify that periodic tests and replacement schedules for components are described, as appropriate. Elastomeric seals should generally be replaced and leak tested within the 12-month period prior to shipment. Metallic seals are generally replaced prior to each shipment.

8.3.2.3.2 Material Tests

Confirm that the SARP identifies any process that could result in deterioration of packaging materials, including loss of neutron absorbers, reduction in hydrogen content of shields, and density changes of insulating materials. Appropriate tests and their acceptance criteria to ensure packaging effectiveness for each shipment should be specified.

8.3.2.4 Thermal Tests

Verify that periodic tests to assure the heat transfer capability during the service life of the packaging are described. Tests similar to the acceptance tests discussed in Section 8.3.1.7 may be applicable. The typical interval for periodic thermal tests is five years.

8.3.2.5 Miscellaneous Tests

Confirm that any additional tests are described, as applicable, to demonstrate that the package will perform throughout its service life in accordance with its approved design.

8.3.3 Appendices

Confirm that the appendices include a list of references, copies of applicable references, if not generally available to the reviewer, test results, and any additional supplemental information, as appropriate.

8.4 Evaluation Findings

8.4.1 Findings

The Technical Review Report (TRR) should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the acceptance tests for the packaging meet the requirements of 10 CFR 71, and that the maintenance program is adequate to assure packaging performance during its service life.

8.4.2 Conditions of Approval

The TRR should clearly identify any conditions of approval that should be included in the CoC. The entire Acceptance Tests and Maintenance Program chapter of the SARP is typically included by reference into the CoC as a condition of package approval.

8.5 References

[8-1] U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR-3854, UCRL-53544, March 1985.

[8-2] U.S. Nuclear Regulatory Commission, *Recommended Welding Criteria for Use in the Fabrication of Radioactive Material Shipping Containers*, NUREG/CR-3019, UCRL-53044, March 1984.

[8-3] American National Standards Institute, *American National Standard for Radioactive Material—Leakage Tests on Packages for Shipment*, ANSI N14.5-1997, New York, New York, 10036.

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9.0 QUALITY ASSURANCE REVIEW

This review verifies that the applicant has a quality assurance (QA) program that meets the requirements of 10 CFR 71 and that specific QA requirements for the package are adequate to assure that it is designed, fabricated, assembled, tested, used, maintained, modified, and repaired in a manner consistent with its evaluation in the Safety Analysis Report for Packaging (SARP).

The QA chapter of the SARP should assure that adequate control is provided over all activities important to safety. The review focuses on two specific areas: (1) the applicant's QA program and (2) package-specific QA requirements applicable to all organizations that perform activities with the proposed package. Because the applicant's QA program description presented in the SARP is site-specific, it cannot be referenced in the Certificate of Compliance (CoC) as a condition of approval. Package-specific QA requirements, however, are appropriate for all organizations and should be included as conditions of approval in the CoC. Note that Section 4 of the certificate specifies that package approval is also conditional on the fulfillment of the applicable QA requirements of 49 CFR Parts 100–185 and 10 CFR 71.

In addition to the QA-program requirements in Subpart H (Quality Assurance), 10 CFR 71 includes other quality-related provisions in Subpart D (Application for Package Approval), Subpart E (Package Approval Standards), Subpart F (Package, Special Form, and LSA-III Tests), and Subpart G (Operating Controls and Procedures). Consequently, other SARP chapters also address quality-related requirements, many of which are incorporated as conditions of approval in the CoC. For example, the drawings in the General Information chapter include dimensions and tolerances and codes or standards for fabrication and material specifications, and the requirements for operation, acceptance testing/maintenance are specified in the Package Operations chapter and in the Acceptance Tests and Maintenance Program chapter, respectively. The Structural, Thermal, Containment, Shielding, and Criticality Evaluation chapters may specify codes, standards, or other QA-related requirements that affect the package design, and the evaluation of the package design in these chapters addresses those components of the packaging that are important to safety. An example of the information flow for the QA review is shown in Figure 9.1.

Because the QA chapter of the SARP addresses information relevant to other SARP chapters, it should be reviewed by all review team members.

9.1 Areas of Review

The applicant's QA-program description and package-specific QA requirements should be reviewed. The QA review should include the following:

9.1.1 Description of Applicant's QA Program

- Scope
- Program Documentation and Approval
- Summary of 18 Quality Criteria
- Cross-Referencing Matrix

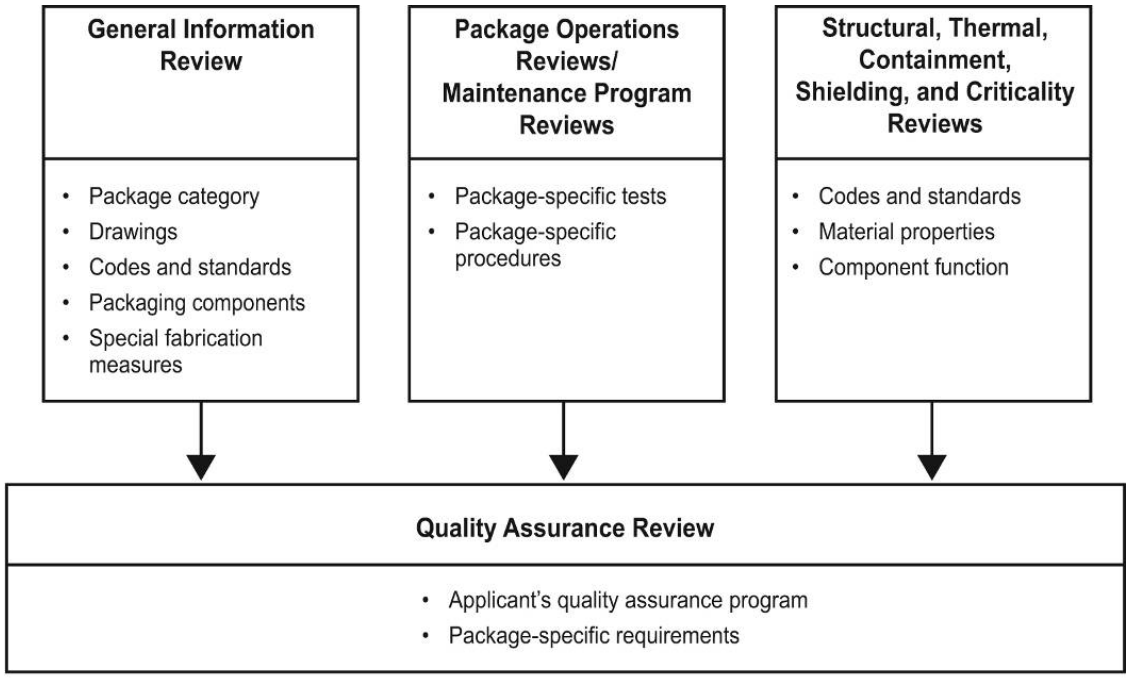

Figure 9.1 Example of Information Flow for the Quality Assurance Review

9.1.2 Package-Specific QA Requirements

- Graded Approach for Structures, Systems, and Components Important to Safety
- Package-Specific Quality Criteria and Package Activities

9.1.3 Appendices

9.2 Regulatory Requirements

Regulatory requirements of 10 CFR 71 applicable to the QA review are as follows:

- The application must describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the package. [§71.31(a)(3), §71.37]
- The application must identify established codes and standards proposed for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the application must describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
- Package activities must be in compliance with the quality assurance requirements of Subpart H (§71.101-§71.137). A graded approach is acceptable. [§71.101(b)]
- Sufficient written records must be maintained to furnish evidence of the quality of the packaging. These records include results of the determinations required by §71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of maintenance, modification, and repair activities; and other information

identified in §71.91(d). Records must be retained for three years after the life of the packaging. [§71.91(b)]

- Records identified in §71.91(a) must be retained for three years after shipment of radioactive material. [§71.91(a)]
- Records must be available for inspection. Records are valid only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. [§71.91(c)]
- Any significant reduction in the effectiveness of a packaging during use must be reported to the certifying authority. [§71.95(a)(1)]
- Details of any defects with safety significance in a package after first use, with the means employed to repair the defects and prevent their reoccurrence, must be reported. [§71.95(a)(2), §71.95(c)(4)]
- Instances in which a shipment does not comply with the conditions of approval in the CoC must be reported to the certifying authority. [§71.95(a)(3)]

9.3 Review Procedures

The following procedures are generally applicable to the review of the QA chapter of the SARP. These procedures correspond to the Areas of Review listed in Section 9.1 of this PRG.

9.3.1 Description of Applicant's QA Program

9.3.1.1 Scope

Confirm that the SARP identifies those package activities for which the applicant has QA-responsibility. These activities may include design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification. Applicants should be considered responsible if they perform, contract, or otherwise oversee the activity. Although applicants are typically responsible for packaging design, responsibility for other activities may be assigned to other DOE organizations. For example, the applicant may design, fabricate, assemble, and perform acceptance testing of a packaging, but another DOE organization may assume responsibility for its use, periodic inspection, and maintenance.

9.3.1.2 Program Documentation and Approval

Verify that the applicant has an approved QA program applicable to packaging. This will likely be an "umbrella" program that provides QA requirements for all quality-related packaging activities (i.e., not specific to the package submitted for approval). This program will also likely supplement the applicant's overall site QA program. The SARP should specify QA-program documentation by title, number, revision, and date. The approving organization, document, and date of approval should also be identified.

Confirm that the SARP specifies on which QA-requirements document (e.g., DOE O 414.1C,[9-1] Subpart H of 10 CFR 71) the QA program and its approval are based. Although DOE organizations are generally required to comply with DOE O 414.1C* and 10 CFR 830 Subpart A, QA programs for packages must also comply with Subpart H (and other applicable

* Earlier versions of DOE O 414.1x may still be applicable because of contractual relationships.

subparts) of 10 CFR 71. The SARP should explicitly state that the QA program complies with Subpart H. Justification for this compliance, if not cited in the approval documentation, should be presented as discussed below. In general, QA program for packages approved under American Society of Mechanical Engineers (ASME) NQA-1[9-2] or Appendix B, 10 CFR Part 50, will meet the requirements of Subpart H.

In addition to his umbrella QA program, the applicant will generally need to develop detailed QA procedures specific to the package proposed in the SARP. Depending on the applicant's scope of responsibility, these procedures might address design, testing, implementation of material and fabrication requirements, control of vendor activities, acceptance tests, maintenance and operational requirements, and record keeping. The SARP should describe existing package-specific procedures and documentation and identify those that are intended to be prepared in the future. As a minimum, detailed procedures for all activities performed during SARP preparation should be completed as described in Regulatory Guide (RG) 7.10.

9.3.1.3 Summary of 18 Quality Criteria

The level of detail reviewed in this section depends on the type of approval applicable to the applicant's QA program. For example, if the applicant has a QA program that has been approved as meeting the requirements of Subpart H by DOE, significantly less review will be necessary than if the program is approved only in accordance with DOE O 414.1C or 10 CFR 830 Subpart A. In general, programs based solely on these documents will require supplementation in order to address all Subpart H requirements.

Verify that the SARP demonstrates compliance with each of the 18 criteria of Subpart H (§71.103 to §71.137) appropriate to the scope of the applicant's responsibilities, as reviewed in Section 9.3.1.1 above. Guidance on evaluating these criteria is provided in RG 7.10.[9-3]

If the applicant's QA program for packaging augments a site program based on DOE O 414.1C or 10 CFR 830, Subpart A, the SARP should demonstrate compliance with the 18 criteria of Subpart H. The review should specifically address compliance with the requirement for audits (§71.137).

9.3.1.4 Cross-Referencing Matrix

Confirm that the SARP provides a cross-referencing matrix that demonstrates that each of the 18 criteria is addressed by written procedures. An example of such a matrix is presented in Table 1 of RG 7.10. Because of the inter-relationship of the 18 criteria in Subpart H, more than one quality procedure will generally be applicable to each criterion.

Since information presented on the applicant's QA program is both site-specific and subject to modification, it cannot be incorporated directly as a condition of package approval in the CoC. Site-specific methods of accomplishing tasks and implementing quality cannot generally be imposed on other organizations involved with the packaging. Similarly, a revision to the site QA program, an organizational change, or renumbering of the program documentation should not necessitate a revision of the SARP. The requirement for the applicant to maintain an appropriate QA program is specified in Section 4 of the certificate.

9.3.2 Package-Specific QA Requirements

The SARP should describe QA requirements for the proposed package. Requirements should be based on a graded approach, considering the importance to safety of package structures, systems, components, and activities. The review should address controls necessary for design, fabrication, testing, operations, maintenance, and repair to assure that the package will meet the requirements of 10 CFR 71 during its service life. Importance to safety should be based primarily on the ability of the package to provide:

- Containment of radioactive material
- Subcriticality of fissile material
- Shielding of radiation.

The graded approach should consider the complexity and proposed use of the package and its components. In addition to the impact of malfunction or failure of the item to safety, the following additional factors should be considered in the graded approach, as described in §71.105(c):

- Design and fabrication complexity or uniqueness of the item
- Need for special controls and surveillance over processes and equipment
- Degree to which functional compliance can be demonstrated by inspection or test
- Quality history and degree of standardization of the item.

9.3.2.1 Graded Approach for Structures, Systems, and Components Important to Safety

Verify that the SARP provides a package-specific listing (Q-List) of all structures, systems, and components (SSCs) important to safety and that these SSCs are consistent with the parts list or similar information presented in the packaging drawings. Justification should be provided for any item identified on the drawings but not defined as important to safety in the Q-list.

Confirm that the SARP identifies a quality category (e.g., A, B, C) for each SSC important to safety and that these categories are appropriately defined. Ensure that the assigned categories are properly justified based on their definition, the package type, and the safety function of each SSC. Coordinate with the review of other SARP chapters as appropriate. Appendix A of RG 7.10 provides guidance on defining quality categories and QA requirements. Definitions of typical categories and representative safety classifications for SSCs of transportation packagings are also presented in Table 2 and Table 5, respectively, of NUREG/CR-6407.[9-4]

In some cases, commercial grade items and services are used for quality category A and B SSCs. The commercial grade item and service dedication process should be described in the SARP. Refer to ASME NQA-1 for further guidance.

9.3.2.2 Package-Specific Quality Criteria and Package Activities

Verify that the SARP addresses each of the 18 quality criteria in Subpart H as they apply to the proposed package. The SARP should identify for each criterion, as applicable, the appropriate

level of QA effort for package activities based on their importance to safety. Guidance on QA requirements applicable to each category is provided in Appendix A of RG 7.10. Other guidance is presented in Chapter 4 of NUREG/CR-6407, which also describes typical design and fabrication records maintained for each QA category. Table 9.1 below identifies typical levels of QA effort for each of the 18 criteria of Subpart H that should be considered in the review, based on quality category. Note that the omission of Category C items from QA effort may not be appropriate if they involve a condition of approval specified in the CoC.

Table 9.1 Typical Level of QA Effort by Quality Category

QA Element/Level of Effort	Category A	Category B	Category C
1. QA Organization			
Responsibility established	X	X	X
Authority and duties written	X	X	X
QA functions executed	X	X	X
Reporting levels clearly defined	X	X	X
Independence from cost and schedule assured	X	X	X
2. QA Program			
Procedures written	X	X	X
Activities affecting quality controlled	X	X	X
Graded approach established	X	X	X
Indoctrination and training provided	X	X	X
3. Package Design Control			
Most stringent codes and standards	X		
Codes and standards		X	
Prototype test and/or analysis	X	X	
Formal design review	X	X	
Internal peer review	X	X	
Software QA	X	X	
Off-the-shelf items			X
Conditions of approval controlled	X	X	X
4. Procurement Document Control			
Traceabililty	X		
Qualified vendor lists	X		
Suppliers required to meet Subpart H	X	X	
Off-the-shelf items			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
5. Instructions, Procedures, and Drawings			
Written and documented	X	X	
Qualitative or quantitative acceptance criteria	X	X	
Changes to conditions of approval listed in certificate controlled	X	X	X
6. Document Control			
Controlled issue	X	X	
Controlled changes	X	X	
7. Control of Purchased Material, Equipment, and Services			
Source evaluation and selection	X		
Inspection at contractor	X		
Formal receiving inspection	X	X	
Audits or surveillance at vendor plants	X		
Evidence of QA at contractor	X	X	
Objective proof that all specifications are met	X	X	
Commercial grade item/services dedication	X	X	
Incoming inspection for damage only			X
8. Identification and Control of Materials, Parts, and Components			
Positive identification and traceability	X		
Identification and traceability to heats, lots, or other groupings	X	X	
Identification to end use drawings			X
9. Control of Special Processes			
Welding, heat treating, and NDE performed with qualified/certified personnel and procedures	X		
Qualification records and training of personnel	X		
Only specified critical operations by qualified personnel		X	
No special processes			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
10. Internal Inspection			
Documented inspection of all specifications	X		
Process monitoring if required by quality	X		
Examination, measurement, or test of material or processed product to assure quality	X	X	
Inspectors independent of those performing operations	X	X	
Qualified inspectors only	X	X	
Visual receiving inspection only			X
11. Test Control			
Written test program	X	X	
Written test procedures	X	X	
Documentation of testing and evaluation	X	X	
Observation of supplier acceptance tests as appropriate	X		
12. Control of Measuring and Test Equipment			
Tools, gauges, and instruments in formal calibration program	X	X	
13. Handling, Storage, and Shipping Control			
Written plans and procedures	X	X	
Routine handling			X
14. Inspection, Test, and Operating Status			
Individual items identified as to status or condition	X	X	
Status indicated by stamps, tags, labels, etc.	X	X	
Visual examination only			X
15. Nonconforming Materials, Parts, or Components			
Written procedures to prevent inadvertent use	X	X	X
Nonconformance documented and closed	X	X	X
Disposal (scrap) without records			X

Table 9.1 Typical Level of QA Effort by Quality Category (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
16. Corrective Action			
Conditions adverse to quality identified and corrected	X	X	X
Cause and corrective action documented	X	X	
Safety significant events reported	X	X	X
17. QA Records			
Design and use records	X	X	
Results of reviews, inspections, tests, audits, surveillances, and materials analysis	X	X	
Personnel qualifications	X	X	
Records of design, fabrication, acceptance testing, and maintenance retained for life of package plus 3 years	X	X	
Shipping records retained for 3 years after shipment	X	X	X
Records managed by a written procedure for retention and disposal	X	X	X
18. Audits			
Written plan of periodic audits	X	X	X
Implementation by written procedures	X	X	X
Lead auditor qualified	X	X	
All auditors qualified	X		

In discussing the 18 quality criteria and the general areas illustrated in Table 9.1, the SARP should also identify specific QA requirements applicable to:

- Material specifications
- Fabrication specifications
- Package Operations
- Acceptance tests
- Maintenance program
- Package records.

Requirements for many fabrication processes (e.g., welding, heat treating, and nondestructive examination) are often included in the code or standard used for design and fabrication (and specified on the drawing), and special processes (e.g., pouring lead and resin shielding, applying

special coatings, and injecting foam) are generally specified by more detailed procedures to ensure that the process is appropriately controlled. Similarly, many material requirements may be specified by codes or standards, but some components (e.g., neutron poisons, honeycomb, or special foams) may need to be specified by other means.

Quality assurance requirements for all Package Operations and Acceptance Tests/Maintenance Program presented in the SARP should be addressed as appropriate. Because the procedures and tests specified in the Package Operations chapter and Acceptance Tests and Maintenance Program chapter are those important to the safe operation and performance of the package throughout its service life, each activity described in these chapters of the SARP should generally be subject to the quality assurance requirements of Subpart H, including (but not limited to) written procedures, training of personnel, verification, documentation, nonconformance control, record retention, and audit. Justification should be provided for any activity presented in these chapters that is not subject to Subpart H QA requirements.

Verify that the SARP identifies package records that affect quality. General requirements for package records are specified in §71.91 and §71.135. Additional guidance on types of records that should be retained for each quality category is provided in Chapter 4 of NUREG/CR-6407. Retention periods for records should be consistent with the requirements of §71.91.

The review should also address reporting requirements of §71.95. The QA program should ensure that occurrences of these events are reported to the DOE Headquarters Certifying Official.

9.3.3 Appendices

Confirm that the appendices include a list of references, copies of appropriate references not generally available to the reviewer, audit results, and other appropriate supplemental information. Detailed QA procedures should not be provided in the SARP but may be requested during the SARP review.

9.4 Evaluation Findings

9.4.1 Findings

The reviewer should ensure that the information presented supports a conclusion that the regulatory requirements in Section 9.2 above are satisfied.

The TRR should include a finding similar to the following:

> Based on review of the statements and representations in the SARP, the staff concludes that the quality assurance program has been adequately described and meets the quality assurance requirements of 10 CFR 71.

9.4.2 Conditions of Approval

The Technical Review Report (TRR) should clearly identify any conditions of approval that should be included in the CoC. In addition to information specified on the package drawings, Package Operations, and acceptance tests/maintenance program, other conditions of approval

that may be applicable to the Quality Assurance chapter of the SARP include those items discussed in Section 9.3 above.

Care should be taken to ensure that conditions of approval apply to all organizations that may be involved in packaging activities. Conditions of approval should not include site-specific requirements or procedures.

9.5 References

[9-1] Department of Energy, *Quality Assurance*, DOE O 414.1C, June 17, 2005.

[9-2] American Society of Mechanical Engineers, *Quality Assurance Requirements for Nuclear Facility Applications,* ASME NQA-1-2004 Edition, December 22, 2004, New York, New York.

[9-3] U.S. Nuclear Regulatory Commission, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Rev. 2, March 2005.

[9-4] U.S. Nuclear Regulatory Commission, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*, NUREG/CR-6407 (INEL-95/0551), February 1996.

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APPENDICES

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APPENDIX A
DEFINITIONS

The majority of package terms are defined in 10 CFR 71.4 or 49 CFR 173.403, and are repeated in Table A.1 for convenience. Where applicable, the source of each definition is indicated. In many cases, terms defined in 10 CFR 71.4 are also defined in 49 CFR 173.403.

Table A.1 Definitions

A_1	The maximum activity of special form radioactive material permitted in a Type A package. [10 CFR 71.4]
A_2	The maximum activity of radioactive material, other than special form, low specific activity, and surface contaminated object material, permitted in a Type A package. [10 CFR 71.4]
Carrier	A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft. [10 CFR 71.4]
Certificate holder	A person who has been issued a Certificate of Compliance or other package approval. [10 CFR 71.4]
Certificate of Compliance (CoC)	A certificate issued by DOE approving for use, with specified limitations, a specific packaging. Certificates of compliance are also issued by NRC.
Close reflection by water	Immediate contact by water of sufficient thickness for maximum reflection of neutrons. [10 CFR 71.4]
Closed transport vehicle	A transport vehicle or conveyance equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the Class 7 (radioactive) materials. The enclosure may be either temporary or permanent, and in the case of packaged materials may be of the "see-through" type, and must limit access from the top, sides, and bottom. [49 CFR 173.403]
Confirmatory analysis	Use of alternate calculations/methods to verify correctness of the original calculations or analyses.
Containment system	The assembly of components of the packaging intended to retain the radioactive material during transport. [10 CFR 71.4]

Table A.1 Definitions (cont.)

Conveyance	For transport by public highway or rail, any transport vehicle or large freight container; for transport by water, any vessel or any hold, compartment, or defined deck area of a vessel, including any transport vehicle on board the vessel; and for transport by aircraft, any aircraft. [10 CFR 71.4]
Criticality Safety Index (CSI)	The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages containing fissile material during transportation [§10CFR71.4].
Damaged fuel	Fuel with known or suspected cladding defects greater than a hairline crack or a pinhole leak.
Exclusive use	The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor. [10 CFR 71.4]
Fissile material	Plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15. [10 CFR 71.4]
Fissile material package	A fissile material packaging together with its fissile material contents. [10 CFR 71.4]
Low specific activity (LSA) material	Radioactive material with limited specific activity that satisfies the descriptions and limits specified in 10 CFR 71.4.
Maximum normal operating pressure (MNOP)	The maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport. [10 CFR 71.4]
Natural thorium	Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium 232). [10 CFR 71.4]

Table A.1 Definitions (cont.)

Normal form radioactive material	Radioactive material that has not been demonstrated to qualify as "special form radioactive material." [10 CFR 71.4]
Optimum interspersed hydrogenous moderation	The presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results. [10 CFR 71.4]
Package	The packaging together with its radioactive contents as presented for transport. [10 CFR 71.4]
Packaging	The assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR 71. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging. [10 CFR 71.4]
Quality assurance	All planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. [10 CFR 71.101]
Radiation level	The radiation dose-equivalent rate expressed in millisievert(s) per hour or mSv/h (millirem(s) per hour or mrem/h). Neutron flux densities may be converted into radiation levels according to Table 1, 49 CFR 173.403. [49 CFR 173.403]
Radioactive contents	A Class 7 (radioactive) material together with any contaminated liquids or gases within the package. [49 CFR 173.403]
Radioactive material	Any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in the table 49 CFR 173.436 values derived according to the instructions in 49 CFR 173.433
Reference air leakage rate	The allowable leakage rate converted to reference cubic centimeters per second. [ANSI N14.5]
Reference cubic centimeter per second (ref·cm^3/s)	A volume of one cubic centimeter of dry air per second at one atmosphere absolute pressure (760 mm Hg) and 25°C. [ANSI N14.5]
Safety Evaluation Report (SER)	A report issued by the DOE Headquarters Certifying Official that documents DOE's review of the package for compliance with DOE O 460.1B and 10 CFR 71.
Special form radioactive material	Radioactive material that satisfies the conditions specified in 10 CFR 71.4.

Table A.1 Definitions (cont.)

Specific activity of a radionuclide	The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material. [10 CFR 71.4]
Spent nuclear fuel or spent fuel	Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year of decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.
Surface contaminated object (SCO)	A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the limits specified in 10 CFR 71.4.
Technical Review Report (TRR)	A report prepared by the DOE review staff that documents the technical review of the package for compliance with DOE O 460.1B and 10 CFR 71. The TRR provides the justification for the technical information included in the SER.
Transport index (TI)	The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows: (1) for non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)).
Type A quantity	A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A.1 of 10 CFR 71, or may be determined by procedures described in Appendix A of 10 CFR 71. [10 CFR 71.4]
Type A packaging	A packaging approved to transport a Type A quantity of radioactive contents.

Table A.1 Definitions (cont.)

Type B package	A Type B packaging together with its radioactive contents. On approval, a Type B package design is designated as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 psi) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments. B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983 was designated only as Type B. Limitations in its use are specified in §71.19. [10 CFR 71.4]
Type B packaging	A packaging approved to transport a Type B quantity of radioactive contents.
Type B quantity	A quantity of radioactive material greater than a Type A quantity. [10 CFR 71.4]
Uranium–natural	Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder essentially uranium-238). [10 CFR 71.4]
Uranium–depleted	Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]
Uranium–enriched	Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes. [10 CFR 71.4]

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APPENDIX B
SUMMARY LISTING OF 10 CFR 71 REQUIREMENTS

This appendix provides a summary listing of the sections in 10 CFR 71 and the primary sections of this PRG to which they apply. In several cases, the applicability is a subjective judgment, which may depend on the package design as well as on the specific format in which the Safety Analysis Report for Packaging is organized. The user is cautioned accordingly.

Table B.1 Summary Listing of 10 CFR 71 Requirements

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.0(d)(2)	X									Application for package approval
71.15	X									Exemption from classification as fissile material
71.19	X						X			Previously approved package
71.19(a)(2)							X			Serial number
71.19(b)(3)							X			Serial number
71.19(e)	X									-96 packages
71.22(a)				X						General license
71.31(a)(1)	X	X	X	X	X	X				Package description
71.31(a)(2)		X		X	X	X				Package evaluation
71.31(a)(3)	X								X	Description of QA program
71.31(b)	X									See also 71.13 for grandfathering
71.31(c)	X	X	X	X	X	X	X	X	X	Identification of codes and standards. Primary interest is ASME B&PV Code but applicable to ANSI N14.5 and perhaps others
71.33	X	X	X	X	X	X				Packaging and content description
71.33(a)	X									Description must include with respect to the packaging
71.33(b)	X									Description must include with respect to the contents of the package

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.35(a)		X	X	X	X	X				Package evaluation
71.35(b)	X					X				Max. packages/shipment based on criticality
71.35(c)							X			Special fissile material controls
71.37	X	X							X	QA
71.37(a)		X								QA-applicant
71.38	X									Renewal of certificate or QA program approval
71.38(b)	X									Application for renewal
71.39										Any additional information may be required.
71.41(a)		X	X							Demonstration of compliance
71.41(b)										Vehicle may be considered in evaluation.
71.41(c)										Variations in §§71.71 and 71.73 may be approved by NRC.
71.43	X									General standards
71.43(a)	X									Size
71.43(b)	X									Tamper-indicating device
71.43(c)				X						Positive closure
71.43(d)		X	X	X						Chemical or galvanic reactions
71.43(e)				X						Valves
71.43(f)		X	X	X	X	X				Package effectiveness
71.43(g)	X		X				X			Temperature limits
71.43(h)				X						Venting

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.45	X	X					X			Lifting and tie-down
71.45(a)		X								Lifting attachments
71.45(b)		X								Tie-down devices
71.47	X	X			X		X			External radiation standards
71.47(a)	X				X		X			Dose rates, nonexclusive use
71.47(b)	X				X		X			Dose rates, exclusive use
71.47(b)(1)							X			200 mreh/hr limit on external surface of package
71.47(b)(2)							X			200 mrem/hr limit on outer surface of vehicle
71.47(b)(3)							X			10 mrem/hr limit at 2 meters from lateral surfaces of vehicle
71.47(b)(4)							X			2 mrem/hr limit for normally occupied space in vehicle
71.47(c)										Instructions for exclusive use shipments
71.47(d)										Instructions for exclusive use shipments
71.51	X									Additional requirements
71.51(a)(1)		X	X	X	X	X				NCT leakage, shielding, package effectiveness
71.51(a)(2)				X	X					HAC leakage and shielding
71.51(b)	X			X						A_2 for mixture
71.51(c)			X	X						Filters and mechanical cooling
71.55	X	X								General requirements
71.55(a)										Criticality, general
71.55(b)						X				Water inleakage analysis

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.55(c)										Exemption from water inleakage
71.55(d)		X				X				NCT criticality
71.55(d)(2)		X				X				Geometric form of package
71.55(d)(3)		X				X				No leakage of water
71.55(d)(4)		X				X				No substantial reduction in effectiveness of package
71.55(e)						X				HAC criticality
71.55(f)	X	X	X			X				Fissile shipments by air
71.59	X					X				Criticality, arrays, CSI
71.59(a)(1)		X				X				Five times “N” packages
71.59(a)(2)						X				Two times “N” packages
71.59(b)						X				Determination of CSI
71.59(c)	X					X				CSI values
71.59(c)(1)							X			CSI less than 50
71.59(c)(2)							X			CSI sum less than 100
71.61	X	X								Deep water immersion for spent fuel only
71.63	X			X						Special requirements for Pu
71.64	X									Pu air shipment
71.65										Any other requirements may be imposed to protect public health or minimize danger to life or property.
71.71	X	X	X	X	X	X				NCT tests
71.71(c)(1)			X							NCT heat
71.71(c)(2)			X							NCT cold

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.73	X	X	X	X	X	X				HAC tests
71.73(b)			X							Test conditions
71.73(c)(2)		X								Crush test
71.73(c)(3)		X								Puncture test
71.73(c)(4)		X	X							Thermal test
71.73(c)(5)	X		X			X				Immersion-fissile material
71.73(c)(6)						X				Immersion-all packages
71.74										HAC tests for Pu air shipments
71.75										Special form
71.77										LSA-III
71.81							X		X	Operating controls
71.83						X	X			Assumptions for unknown properties
71.85									X	Preliminary determinations
71.85(a)					X			X		Cracks, voids
71.85(b)		X						X		Pressure test
71.85(c)	X						X	X		Data plate
71.87							X			Routine determinations
71.87(a)										Proper contents
71.87(b)								X		Undamaged packaging

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.87(c)										Closure devices
71.87(d)										Liquid systems
71.87(e)										Pressure relief devices
71.87(f)										Loaded by procedures
71.87(g)								X		Moderator/absorber present
71.87(h)										Tie-down devices
71.87(i)										Non-fixed contamination
71.87(j)					X					External radiation levels
71.87(k)			X							Accessible package surface temperature limits
71.88	X									Pu air shipment
71.89							X			Opening instructions
71.91									X	Records
71.91(a)									X	Maintenance of shipping records
71.91(b)									X	Maintenance of packaging records
71.91(c)									X	Records availability for Commission
71.91(d)									X	Records of packaging quality
71.93										Inspection and tests
71.93(b)								X		Tests
71.95									X	Reports of problems
71.95(a)(1)									X	Reduction in effectiveness of package
71.95(a)(2)									X	Defects in safety significance

Table B.1 Summary Listing of 10 CFR 71 Requirements (cont.)

Section/ Chapter	General Information	Structural	Thermal	Containment	Shielding	Criticality	Package Ops.	Acc. Tests & Maint.	Quality Assurance	Comments
71.95(a)(3)									X	Conditions of approval not observed
71.95(c)(4)									X	Description of corrective actions
71.97										Advance notification of spent fuel and HLW shipments
71.99										Violations
71.101(b)									X	Establishment of QA program
71.103									X	QA (Subpart H)
71.105(c)									X	Considerations for QA program
71.107(c)	X								X	Design Changes
71.135									X	Quality Assurance records
71.137									X	Audits

APPENDIX C
SUMMARY OF CHANGES RESULTING FROM THE 2004 (AS AMENDED) REVISION OF 10 CFR 71

The attached table summarizes changes resulting from the 2004 revision of 10 CFR 71. The primary purpose of this revised rule was to conform NRC regulations to those of the International Atomic Energy Agency.*

Package designs that satisfy the 1996 revision of 10 CFR 71 are designated with the identification number suffix "-85." The changes listed in this appendix are applicable to all packages with initial approval after April 1, 1996, and to other applications requesting the addition of the "-85" suffix. Package designs that satisfy the 2004 revision of 10 CFR 71 are designated with the identification number suffix "-96." The changes listed in this appendix are applicable to all packages with initial approval after December 31, 2004, and to other applications requesting the addition of the "-96" suffix. Because DOE generally expects that its packages comply with the most current regulations, these changes should also be addressed during the re-certification of previously approved DOE packages.

Subsequent to the 1996 revision of 10 CFR 71, two changes have been promulgated: (1) several additional restrictions for fissile material exemptions and general license provisions, and (2) an additional exemption from the double containment requirements for plutonium. These changes are also addressed in the table below.

Changes in the following general areas are *excluded* from the table because they are seldom applicable to packages certified by DOE: limited specific activity (LSA), surface contaminated objects (SCO), air shipments of plutonium, and special form qualification. The reviewer is cautioned that if these areas are applicable to the package, the changes may be very significant.

Based on review experience to date, the following changes to 10 CFR 71 appear to be the most significant for packages reviewed by DOE:

- Reflection requirements for the criticality analysis of the containment system of a single package, §71.55(b)(3)
- Replacement of Fissile Class by a Criticality Safety Index (CSI) based on criticality control, and a possible change in the number of packages that must be analyzed in an array of previous Fissile Class III or Fissile Class I packages, §71.59 and §71.4
- Requirement for dynamic crush test of certain lightweight, low-density packages with significant quantities of radioactive material, §71.73(c)(2)
- Thermal test requirements under hypothetical accident conditions, §71.73(c)(4)
- Reduction in A_2 value for uranium enriched between 5% and 20%, Table A-1.

* Safety Requirements No. TS-R-1, *Regulations for the Safe Transport of Radioactive Material*, 1996 Edition (As Amended 2000), International Atomic Energy Agency, Vienna, 2000.

SECTION-BY-SECTION ANALYSIS

Several sections in Part 71 have been redesignated in this rulemaking to improve consistency and ease of use. For some sections, only the section number is changed. However, for other sections, revisions are being made to the regulatory language. The following table is provided to aid the public in understanding the numerical changes to sections of Part 71.

Redesignation Table

New section number	Existing section number
§ 71.8 ……	§ 71.11
§ 71.9 ……	New Section
§ 71.10 ……	New Section
§ 71.11 (Reserved) ...	NA
§ 71.12 ……	§ 71.8
§ 71.13 ……	§ 71.9
§ 71.14 ……	§ 71.10
§ 71.15 ……	§ 71.53
§ 71.16 (Reserved) ...	NA
§ 71.17 ……	§ 71.12
§ 71.18 (Reserved)……	New Section
§ 71.19 ……	§ 71.13
§ 71.20 ……	§ 71.14
§ 71.21 ……	§ 71.16
§ 71.22 ……	§ 71.18
§ 71.23 ……	§ 71.20
§ 71.24 (Reserved) ...	§ 71.22 (Section removed)
§ 71.25 (Reserved) ...	§ 71.24 (Section removed)
§ 71.53 (Reserved) ...	§ 71.53 (Section re-designated)

Subpart A—General Provisions

Section 71.0 Purpose and Scope

Paragraph (d) has been reformatted into three paragraphs to simplify this regulation and to better use plain language. Paragraph (d)(1) indicates that general licenses, for which no NRC package approval is required, are issued in new §71.20 through §71.23. This change reflects the removal of existing §71.22 and §71.24 (re-designated §71.24 and §71.25 (Reserved)). Paragraph (d)(2) indicates that an application for package approval must be completed in accordance with Subpart D. Paragraph (d)(3) continues to require a licensee transporting, or delivering material to a carrier for transport, to meet the requirements of the applicable portions of Subparts A, G, and H.

New paragraph (e) has been added to indicate that persons who hold, or apply for, a Part 71 CoC for Type AF, Type B, Type BF, Type B(U)F, or Type B(M)F packages are within the scope of Part 71 regulations.

Existing paragraphs (e) and (f) have been re-designated as new paragraphs (f) and (g), respectively. The rule text in new paragraph (f) is the same as existing paragraph (e) text. New paragraph (g) has been revised to reflect the re-designation of existing §71.11 as new §71.8.

Section 71.1 Communications and Records

In §71.1, paragraph (a) has been revised to indicate that documents submitted to the NRC should be addressed to the attention of the "Document Control Desk," not the "Director of the Office of Nuclear Material Safety and Safeguards." Provisions have also been added to provide requirements when a due date for a document falls on a Saturday, Sunday, or Federal holiday. In that case, the document would be due the next Federal workday. This change is identical to a change made to §72.4 in a recent Part 72 final rule (see 64 FR 33178; June 22, 1999).

Section 71.2 Interpretations

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.3 Requirement for License

No changes were made to the text of this section; however, it has been retained in the revision of this subpart for completeness.

Section 71.4 Definitions

The existing definitions for "A_1," "Fissile material," "Low Specific Activity (LSA) material," "Package," and "Transport index (TI)" are revised as conforming changes. New definitions for "A_2," "Certificate of Compliance," "Consignment," "Criticality Safety Index (CSI)," "Deuterium," "U.S. Department of Transportation (DOT)," "Graphite," "Spent fuel," and "unirradiated uranium" have been added as conforming changes.

The definition of "A_1" has been revised to split the previous combined definition for "A_1" and "A_2" into two individual definitions. This approach is consistent with the standard in TS-R-1. Furthermore, no change has been made to the current technical content of the definition for "A_1"; however, the text is revised to improve readability.

A definition for "A_2" has been added, because the previous joint definition for "A_1" and "A_2" has been split into two definitions. (See also definition for "A_1.")

A definition for "Certificate of Compliance (CoC)" has been added. This definition is similar to the definition for the same term found in § 72.3.

A definition for "Consignment" has been added.

A definition of "Criticality Safety Index (CSI)" has been added.

A definition of "Deuterium" has been added that applies to new §71.15 and §71.22.

A definition of "U.S. Department of Transportation (DOT)" has been added.

The definition of "Fissile material" has been revised by removing ^{238}Pu from the list of fissile nuclides; clarifying that "fissile material" means the fissile nuclides themselves, not materials containing fissile nuclides; and re-designating the reference to exclusions from fissile material controls from §71.53 to new §71.15.

A definition of "Graphite" has been added that applies to new §71.15 and §71.22.

The definition of "Low Specific Activity (LSA)" material (LSA-I, LSA-II, and LSA-III) has been revised to be consistent with DOT, and to reflect the existence of §71.77 (§71.77 provides requirements on the qualification of LSA-III material).

A definition for "Optimum interspersed hydrogenous moderation" has been added (the definition itself was included in the proposed rule §71.4, but, inadvertently, no mention of that fact was made in this Section).

The definition of "Package" has been revised by clarifying in paragraph (1) that Fissile material package also means a Type AF, Type BF, Type B(U)F, or Type B(M)F package. New paragraph (2) has been added defining Type A packages in accordance with DOT regulations contained in 49 CFR Part 173. Existing paragraph (2) defining Type B packages has been re-designated as subparagraph (3). No changes have been made to the re-designated text.

A definition of "Spent nuclear fuel" or "Spent fuel" has been added. This definition is the same as that currently found in §72.3.

The definition for "Transport index (TI)" has been revised to reflect the new definition of Criticality Safety Index; however, the method for determining the TI of a package, based on the package's radiation dose rate, remains unchanged.

A definition for "unirradiated uranium" has been added as it is part of the LSA-I definition.

Section 71.5 Transportation of Licensed Material

No changes were made to the text of this section; however, it has been included in the revision of this subpart for completeness.

Section 71.6 Information Collection Requirements: OMB Approval

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Paragraph (b) of this section has been revised as a conforming change to reflect the addition of new information collection requirements. Additionally, the existing information collection requirement in Appendix A to Part 71, paragraph II, was inadvertently omitted from the list of approved information collection requirements in a previous rulemaking; consequently, NRC staff has added Appendix A, paragraph II, to paragraph (b) to correct this error. Furthermore, the reference to §71.6a has been removed, because no such section currently exists in Part 71.

Section 71.7 Completeness and Accuracy of Information

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, paragraphs (a) and (b) have been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.8 Deliberate Misconduct

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions. Further, in Subpart A, §71.11 has been re-designated as §71.8. However, the current text of §71.11 has not changed in the re-designated §71.8.

Section 71.9 Employee Protection

New §71.9 has been added to provide requirements on employee protection. Currently, requirements relating to the protection of employees against firing or other discrimination when the employee engages in certain "protected activities" are provided under the parts of Title 10 for which a specific license was issued to possess radioactive material. However, no provisions were provided in Part 71 relating to the protection of employees against firing or other discrimination when employees engage in certain "protected activities" when they are the employees of a certificate holder or applicant for a CoC.

The NRC believes these employees should also be afforded the same rights and protection as is currently afforded employees of licensees. The new section is identical to the existing § 72.10, "Employee protection." By including licensees in the new §71.9, the NRC recognizes that the potential for duplication occurs for licensees regulated under multiple Title 10 parts. However, the NRC believes that by including licensees along with certificate holders and applicants for a CoC, improved regulatory clarity would be achieved, and any potential confusion would be minimized.

Section 71.10 Public Inspection of Application

A new section has been added indicating that applications and documents submitted to the Commission, in connection with an application for a package approval, shall be available for public review in accordance with the provisions of Parts 2 and 9. This new section is similar to existing §72.20. Existing §71.10 has been redesignated §71.14 with changes to the text as discussed under §71.14, below.

Section 71.11 (Reserved)

This section has been redesignated from Subpart B, Exemptions, to Subpart A, General Provisions, and is reserved. Existing §71.11 has been re-designated as §71.8.

Subpart B—Exemptions

Section 71.12 Specific Exemptions

Existing §71.8 has been redesignated as §71.12. No changes have been made to the contents of this section. Existing §71.12 has been re-designated as §71.17, with changes to the text as discussed under §71.17, below.

Section 71.13 Exemption of Physicians

Existing §71.9 has been re-designated as §71.13. No changes have been made to the contents of this section. Existing §71.13 has been re-designated as §71.19, with changes to the text as discussed under §71.19, below.

Section 71.14 Exemption for Low-Level Materials

Existing §71.10 has been redesignated as §71.14. Existing §71.14 has been redesignated as §71.20, with no changes to the text.

In new §71.14, paragraph (a) has been revised by removing the existing single 70 Bq/g (0.002 μCi/g) specific activity value. Additionally, paragraph (a) has been reformatted by adding two new paragraphs. Subparagraph (a)(1) provides an increased exemption for natural radioactive materials and ores. Subparagraph (a)(2) provides an exemption for radioactive material based on the "Activity Concentration for Exempt Material" and the "Activity Limit for Exempt Consignment" found in Table A-2 in Appendix A to Part 71.

Paragraph (b) has been revised to consolidate the exemption provisions for LSA and SCO material. The LSA and SCO exemptions contained in existing paragraphs (b)(2) and (c) of this section have been consolidated into a revised paragraph (b)(3). The reference to material exempt from classification as fissile material has been revised from §71.53 to §71.15, because of the redesignation of the section.

Existing paragraph (b)(3) has been removed. The 0.74-TBq (20-Ci) exemption for special form americium and special form plutonium has been removed. However, the 0.74-TBq (20-Ci) exemption for special form plutonium-244, transported in domestic commerce, has been retained as new paragraph (b)(2). For international shipments, the A_1 quantity limit for special form plutonium-244 continues to apply.

Section 71.15 Exemption from Classification as Fissile Material

Existing §71.53 has been re-designated as §71.15, and relocated to Subpart B with the other Part 71 exemptions. This section has been revised by providing mass-ratio based limits in classifying fissile-exempt material. This approach removes the concentration- and consignment-based limits of the current §71.53 and returns to package-based mass limits, with required minimum ratios of nonfissile-to-fissile mass.

The title has been changed to "Exemption from classification as fissile material."

New paragraph (a) has been added and allows for small samples of fissile material to be shipped. In paragraph (b), the fissile mass per package is limited to 15 grams with a nonfissile-to-fissile mass ratio of 200:1. In paragraph (c), provided there is less than 150 g of fissile material per 360 kg ratio of nonfissile-to-fissile material is also raised to 2000:1. The mass of any lead, graphite, beryllium, and deuterium in the package cannot be included in determining the nonfissile material mass.

In current §71.53, paragraph (c) has been redesignated as paragraph (e), and has been reformatted and revised to clarify that the nitrogen to uranium atomic ratio, for shipments of liquid uranyl nitrate, must be greater than or equal to 2.0. A new requirement has been added specifying the use of DOT Type A packaging.

In current §71.53, paragraph (d) has been redesignated as paragraph (f), and has been reformatted and revised to clarify the mass limits for plutonium. No substantive changes have been made to this paragraph.

Section 71.16 (Reserved)

This section has been redesignated from Subpart C, General Licenses, to Subpart B, Exemptions, and is reserved. Further, existing §71.16 has been re-designated as §71.21. However, the current text of §71.16 has not been changed in the re-designated §71.21.

Subpart C—General Licenses

Section 71.17 General License: NRC-Approved Package

Existing §71.12 has been re-designated as §71.17. The text of paragraphs (a) and paragraph (b) has not been changed.

Paragraph (c)(3) has been revised using plain language and to reflect the NRC's requirement to address information submitted to the NRC to the attention of the NRC's Document Control Desk, in accordance with §71.1.

Paragraph (d) has not been changed.

Paragraph (e) has been revised to reflect the redesignation of §71.13 to § 71.19. No other change was made for this paragraph.

Section 71.18 Reserved

Section 71.19 Previously Approved Package

Existing §71.13 has been re-designated as §71.19. Paragraph (a) has been revised to reflect the current package designators (*e.g.*, B(U)F, B(M)F, AF) and to reflect the re-designation of §71.12 to §71.17. Additionally, the contents of paragraph (a)(2) have been removed to reflect that these packages are no longer recognized internationally. Existing paragraph (a)(3) has been re-designated as (a)(2) with no change to the contents. Also, an expiration date for grandfathering these packages has been established in new paragraph (a)(3). Paragraph (b) has been updated to remove the LSA packages, as these packages no longer exist, and to reflect the re-designation of §71.12 to §71.17. No other changes were made. A new paragraph (c) has been added to reflect the type B(U) and B(M) packages that have met the requirements of IAEA Safety Series 6 1985 (as amended 1990) and to correct a typographical error. Additionally, a date by which fabrication of these packages must be complete has been added. Existing paragraph (c) has been re-designated as paragraph (d). Existing paragraph (d) has been re-designated as paragraph (e) and updated to reflect the identification number suffix of "-96" for previously approved package designs that have been resubmitted for review by the NRC and have been approved, and to remove the package designated as Type A from this paragraph.

Section 71.20 General License: DOT Specification Container

Existing §71.14 has been re-designated as §71.20. No changes have been made to the contents of paragraphs (a) through (d). New paragraph (e) has been added to indicate that these types of packages will be phased out 4 years after the effective date of this final rule.

Section 71.21 General License: Use of Foreign Approved Package

Existing §71.16 has been re-designated as §71.21. No changes have been made to the contents of this section.

Section 71.22 General License: Fissile Material

Existing § 71.18 has been re-designated as §71.22. The current §71.22 has been removed. This section has been amended by consolidating and simplifying the current fissile general license provisions contained in existing §71.18, §71.20, §71.22, and §71.24 into a new §71.22. The new §71.22, while retaining some of the provisions of the existing general licenses, principally uses mass-based limits and a Criticality Safety Index (CSI). Concentration-based limits have been removed. Exceptions relating to plutonium-beryllium sealed sources in existing §71.18 and §71.22 have been relocated to new §71.23. The values contained in new Tables 71-1 and 71-2 have been revised from the values contained in the table in existing §71.22 and in Table 1 in existing §71.20, respectively; and are based on new minimum critical mass calculations described in NUREG/CR-5342. In some instances, the allowable mass limit has been increased from the current limits in existing §71.18, §71.20, §71.22, and §71.24; in other instances, the allowable mass limit has been reduced. The values contained in new Tables 71-1 and 71-2 are used as the variables X, Y, and Z in the equation in paragraph (e)(1).

The title has been revised to indicate that this general license is not restricted to a specific type of fissile material shipment.

Paragraph (a) has been revised to require that fissile material shipped under this general license be contained in a DOT Type A package. Additionally, while the existing exception from Subparts E and F requirements has been maintained, the DOT Type A package regulations of 49 CFR Part 173 have also been specified.

Paragraph (b) remains unchanged.

Paragraph (c) has been revised to remove the specific gram limits for uranium and plutonium but retains the existing Type A quantity limit. Revised gram limits have been relocated to new Table 71-1, which is associated with new paragraphs (d) and (e). A requirement has also been added to limit the amount of special moderating materials beryllium, graphite, and hydrogenous material enriched in deuterium present in a package to less than 500 g.

Existing paragraph (d) has been removed. Revised gram limits for fissile material mixed with material having a hydrogen density greater than water (i.e., a moderating effectiveness greater than H_2O) have been placed in new Table 71-1. A note has been added to new Table 71-1 to indicate "when mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O."

New paragraph (d) has been added to require that shipments of packages containing fissile material be labeled with a CSI, that the CSI per package be less than or equal to 10, and that the sum of the CSIs in a shipment of multiple fissile material packages be limited to less than or equal to 50 for a nonexclusive use conveyance, and to less than or equal to 100 for an exclusive use conveyance.

Existing Paragraphs (e) and (f) have been removed.

New paragraph (e) has been added to require that the CSI be calculated via a new equation for any of the fissile nuclides. Guidance on applying the equation and the mass limit input values of Tables 71-1 and 71-2 is also contained in this paragraph.

Section 71.23 General License: Plutonium-Beryllium Special Form Material

The existing §71.20, "General license: Fissile material, limited moderator per package," has been removed. A new section on the shipment of plutonium-beryllium (Pu-Be) special-form fissile material (*i.e.*, sealed sources) has been added as a new §71.23. New §71.23 consolidates regulations on shipment of Pu-Be sealed sources contained in existing §71.18 and §71.22 into one location in Part 71. The new §71.23 reduces the maximum quantity of fissile plutonium Pu-Be sealed sources that could be shipped on a single conveyance through changes in the mass limits and calculation of the CSI. Currently, a Pu-Be sealed source package can contain up to 400 g of fissile plutonium with a CSI equal to 10. Consequently, the current conveyance limits are 4,000 g per shipment for an exclusive-use vehicle and 2,000 g per shipment for a nonexclusive use vehicle. The new §71.23 increases the maximum CSI per package from 10 to 100; however, the maximum quantity of plutonium per conveyance (*i.e.*, shipment) would be reduced to 1,000 g. The 1,000-g per shipment limit and 240 g of fissile plutonium limit are equivalent to those in new §71.23(c)(2) (1,000 g per shipment and 200 g of fissile plutonium). The 240 g versus 200 g of fissile plutonium per package is due to the increased confidence that the fissile plutonium, within a sealed source capsule, would not escape from the capsule during an accident and reconfigure itself into an unfavorable geometry.

New §71.23 has been titled: "General license: Plutonium-beryllium special form material." Paragraph (a) describes the applicability of this section, exceptions to the requirements of Subparts E and F, and the requirement to ship Pu-Be sealed sources in DOT Type A packages.

Paragraph (b) requires that shipments of Pu-Be sealed sources be made under an NRC-approved QA program.

Paragraph (c) requires a 1,000 g per package limit. In addition, plutonium-239 and plutonium-241 constitute only 240 g of the 1,000 g limit.

Paragraph (d) requires that a CSI be calculated per paragraph (e), and the CSI must be less than or equal to 100. For shipments of multiple packages, the sum of the CSIs is limited to less than or equal to 50 for a nonexclusive use conveyance and to less than or equal to 100 for an exclusive use conveyance.

Paragraph (e) provides an equation to calculate the CSI for Pu-Be sources. This equation is based upon the 240-g mass limit for fissile nuclide plutonium-239 and plutonium-241 in paragraph (c).

Section 71.24 (Reserved)

Section 71.25 (Reserved)

Existing §71.22 and §71.24 have been redesignated as §71.24 and §71.25. New §71.24 and §71.25 have been removed and reserved.

Subpart E—Application for Package Approval

Section 71.41 Demonstration of Compliance

Paragraph (a) has been revised to require that a Type B package which contains radioactive contents with activity greater than 10^5A_2 of any radionuclide must meet the enhanced deep immersion test found in §71.61. A new paragraph (d) has been added to provide special package authorizations.

Section 71.51 Additional Requirements for Type B Packages

Paragraph (a) has been revised to remove the reference to §71.52, because the requirements of §71.52 have expired. Paragraph (d) has been added to require that a package which contains radioactive contents with activity greater than 10^5 A_2 of any radionuclide must also meet the enhanced deep immersion test found in §71.61.

Section 71.53 Fissile Material Exemptions (Reserved)

This section has been removed and reserved; its contents have been moved to §71.15.

Section 71.55 General Requirements for Fissile Material Packages

New paragraphs (f) and (g) have been added. Paragraph (f) specifies design and testing for fissile material package designs for transport by aircraft, and paragraph (g) addresses UF_6 criticality exception from §71.55(b). Additionally, as a conforming change, paragraph (b) has been updated to support new paragraph (g).

Section 71.59 Standards for Arrays of Fissile Material Packages

Paragraphs (b) and (c) have been revised to use the term CSI (criticality safety index).

Paragraph (b) has been revised to refer to a CSI rather than a TI for nuclear criticality control. The method for calculating a CSI is the same as the existing method for a TI for nuclear criticality control.

Paragraph (c) has been revised to provide direction to licensees when the CSI is exactly equal to 50 and to use plain language. Subparagraph (1) has been revised by replacing the term "not in excess of 10," with the term "less than or equal to 50." New paragraph (c)(2) has been added to provide for shipment of packages with a CSI of less than 50 on an exclusive use conveyance. The current conveyance limit of 100 has been retained. Existing paragraph (c)(2) has been redesignated as new paragraph (c)(3) and has been revised by replacing the term "in excess of 10," with the term "greater than 50." These three changes: (1) Provide greater clarity and mathematical consistency among paragraphs (c)(1), (c)(2), and (c)(3); (2) clarify the CSI limits for storage incident to transport; and (3) increase the CSI limit per package from 10 to 50 for shipments made with nonexclusive use conveyances.

Section 71.61 Special Requirements for Type B Packages Containing More Than 10^5A_2

This section has been revised to require an enhanced water immersion test for packages used for radioactive contents with activity greater than 10^5A_2. The title of this section has also been revised to reflect that the scope has been broadened beyond irradiated nuclear fuel.

Section 71.63 Special Requirement for Plutonium Shipments

The title has been revised to reflect only a single "requirement" rather than multiple requirements.

Paragraph (b) has been removed.

The designation of the remaining text as paragraph (a) has been removed, because only one paragraph remains. The text of former paragraph (a) has been revised to use plain language. The 0.74-TBq (20-Ci) limit and solid form requirement have been retained.

Section 71.73 Hypothetical Accident Conditions

A new paragraph (c)(2) has been added to require a crush test for fissile material packages.

Subpart G—Operating Controls and Procedures

Section 71.88 Air Transport of Plutonium

Paragraph (a)(2) has been revised to remove the 70-Bq/g (0.002-μCi/g) specific activity value and substitute activity concentration values for plutonium found in Appendix A, Table A-2, of this part. This revision is a conforming change to the revision to new §71.14 to ensure consistent treatment of plutonium between these two sections.

Section 71.91 Records

As a conforming change to Subpart H, paragraphs (b) and (c) have been redesignated as paragraphs (c) and (d), respectively, and are revised by adding the terms "certificate holder" and "applicant for a CoC." New paragraph (b) has been added to require a certificate holder to keep records on the model, serial number, and date of manufacture of a packaging. These requirements are similar to the requirements in paragraph (a), though less information is required. No change has been made to paragraph (a).

Section 71.93 Inspection and Tests

As a conforming change to Subpart H, paragraphs (a) and (b) have been revised by adding the terms "certificate holder" and "applicant for a CoC." Paragraph (c) has been revised to require the certificate holder to notify the NRC before it begins fabrication of a packaging that can contain material having a decay heat load in excess of 5 kW or a maximum normal operating pressure of 103 kPa (kilo Pascals) (15 ft-lb/in^2) gauge. This notification could be for either fabricating a single packaging or the beginning of a campaign for fabricating multiple packagings. This notification is in accordance with the requirements of §71.1, rather than an NRC Regional Administrator. This change in notification location reduces confusion in identifying the appropriate Regional Administrator when the certificate holder and fabrication location are overseas. Licensees have been removed from this paragraph because the NRC believes that requiring a licensee, who does not own the packaging, to notify the NRC in advance of a packaging fabrication, when the licensee may not use the packaging for years, is inappropriate and an unreasonable burden. The NRC believes that requiring certificate holders and applicants for a CoC to notify the NRC in advance of fabricating a packaging(s) would allow the NRC adequate opportunity to inspect these activities. This change is similar to the current requirement in §72.232(d) for Part 72 certificate holders or applicants for a CoC to notify the

NRC 45 days before starting the fabrication of the first storage cask under a Part 72 CoC. This action improves the harmonization between these two regulations in Parts 71 and 72.

Section 71.95 Reports

The existing introductory text and paragraphs (a), (b), and (c) have been combined into a new paragraph (a) which requires a licensee, after requesting the certificate holder's input, to submit a written report to the NRC in certain circumstances. The requirement for the licensee to request input from the certificate holder during development of the written event report will ensure that design deficiency issues have been thoroughly considered. The licensee will also be required to provide the certificate holder with a copy of the written event report, after the report is submitted to the NRC. This will permit the certificate holder to monitor and trend the package performance information, arising from package use by multiple licensees. Additionally, requirements on timing and submission location for the written reports have been relocated to new paragraph (c). Furthermore, the 30-day reporting requirement has been lengthened to a 60-day reporting requirement.

The existing paragraph (c) has been redesignated as paragraph (b) and revised for clarity.

New paragraphs (c) and (d) have been added to provide requirements on the timing, submission location, form, and content of the written reports.

Section 71.100 Criminal Penalties

Section 223 of the Atomic Energy Act of 1954, as amended, (the Act) provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. The Commission stated in a final rule on "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 55082; November, 24, 1992), that substantive rules under sections 161b, 161i, or 161o of the Act include those rules that create "duties, obligations, conditions, restrictions, limitations, and prohibitions." For the NRC to consider the possibility of criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any substantive regulations, the NRC must have clearly identified to affected parties which regulations in Part 71 are substantive rules. Accordingly, paragraph (b) of this section identifies those Part 71 regulations that the NRC does not consider as substantive regulations. Thus, willful violation of, attempted violation of, or conspiracy to violate any of the regulations listed in paragraph (b) is not subject to possible criminal sanctions.

Paragraph (b) of this section has been revised as a conforming change. The NRC has reviewed new §71.10 and considers that this regulation is not a substantive rule. Therefore, new §71.10 has been added to the list of sections in paragraph (b). The NRC reviewed new § 71.9, §71.18, and §71.23 and considers that these regulations are substantive rules. Therefore, these sections have not been added to paragraph (b). Additionally, the NRC has reviewed the existing §71.9, §71.10, and §71.53 and concluded these sections should be recharacterized as substantive rules. Therefore, new §71.13, §71.14, and §71.18 have not been included in paragraph (b). Additionally, existing §§ 71.52 and 71.53 have been removed from paragraph (b), because these section numbers have been removed from Part 71.

Subpart H—Quality Assurance

Section 71.101 Quality Assurance Requirements

Paragraph (a) has been revised by adding two new sentences to the end of the paragraph specifying responsibilities for certificate holders and applicants for a CoC.

Paragraph (b) has been revised to add the terms "certificate holder" and "applicant for a CoC." The second sentence has been revised to provide greater clarity and consistency within Subpart H by referring to "the QA requirement's importance to safety."

Paragraph (c) has been revised by redesignating the existing text as paragraph (c)(1), and new text has been added on submitting QA programs in accordance with the requirements of §71.1. New paragraph (c)(2) has been added to provide equivalent requirements on the submission of QA programs for certificate holders and applicants for a CoC.

Paragraph (f) has been revised to allow the use of existing NRC-approved Part 71 and Part 72 QA programs, in lieu of submitting a new QA program. Additionally, the terms "certificate holder" and "applicant for a CoC" have been added.

Paragraph (g) has been revised by making a minor change to clarify that §34.31(b) is located in chapter I of title 10 of the Code of Federal Regulations. Additionally, as a conforming change, §71.12(b) has been redesignated as §71.17(b).

Section 71.103 Quality Assurance Organization

Paragraph (a) has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.105 Quality Assurance Program

Paragraphs (a) through (d) have been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.107 Package Design Control

Paragraph (a) has been revised by adding the terms "certificate holder" and "applicant for a CoC." Further, the last sentence has been revised to improve clarity and consistency within Subpart H by referring to "processes that are essential to the functions of the materials, parts, and components that are important to safety."

Paragraph (b) has been revised by adding the terms "certificate holder" and "applicant for a CoC." Additionally, the last sentence of paragraph (c) has been revised by replacing the text "changes in the conditions specified in the package approval require NRC approval * * *." with "changes in the conditions specified in the CoC require NRC prior approval * * *."

Section 71.109 Procurement Document Control

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.111 Instructions, Procedures, and Drawings

This section has been revised by adding the terms "certificate holder" and "applicant for a CoC."

Section 71.113 Document Control

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.115 Control of Purchased Material, Equipment, and Services

Paragraphs (a) through (c) have been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.117 Identification and Control of Materials, Parts, and Components

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.119 Control of Special Processes

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.121 Internal Inspection

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.123 Test Control

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.125 Control of Measuring and Test Equipment

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.127 Handling, Storage, and Shipping Control

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.129 Inspection, Test, and Operating Status

Paragraph (a) has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.131 Nonconforming Materials, Parts, or Components

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.133 Corrective Action

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.135 Quality Assurance Records

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Section 71.137 Audits

This section has been revised by adding the terms “certificate holder” and “applicant for a CoC.”

Appendix A to Part 71—Determination of A_1 and A_2

No changes have been made in paragraphs I, III, and V; however, these paragraphs have been included due to revising Appendix A, in its entirety.

Paragraph II has been revised to use plain language and has been redesignated as subparagraph II(a). The intent of existing paragraph II has not been changed; however, the reference to existing Table A-2 has been revised as a conforming change to the new Table A-3. New paragraph II(b) has been added to provide direction on determining exempt material activity concentration and exempt consignment activity values when a radionuclide has been identified as a constituent of a proposed shipment, but the individual radionuclide is not listed in Table A-2. Consequently, the structure of paragraphs II(a) and II(b) is the same. New paragraph II(c) has been added to provide direction to licensees on how to submit requests for Commission prior approval of either A_1 and A_2 values or exempt material activity concentration and exempt consignment activity values, for radionuclides that are not listed in Tables A-1 and A-2, respectively.

Paragraph IV has been revised by adding new paragraphs (e) and (f) to provide equations to use in determining a consolidated exempt material activity concentration and exempt consignment activity value when a shipment contains multiple radionuclides. The existing text describing an alternative method for calculating the A_1 or A_2 value of a mixture has been re-designated as paragraphs (c) and (d). No changes have been made from the existing equations.

Appendix A, Table A-1—A_1 and A_2 Values for Radionuclides

This Table has been revised to reflect the values from TS-R-1.

Appendix A, Table A-2—Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides

A new Table A-2 has been added to Appendix A of Part 71. This table contains the values of Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for selected radionuclides. Table A-2 is referenced in new §71.14(a)(2) and is used in §71.14 to determine when concentrations of material are not considered radioactive material, for the purposes of transportation.

Appendix A, Table A-3—General Values for A_1 and A_2

The existing Table A-2 has been re-designated as new Table A-3, and the values have been revised to reflect the changes from TS-R-1.

Appendix A, Table A-4—Activity Mass Relationships for Uranium

The existing Table A-3 has been re-designated as new Table A-4. No changes have been made to the values contained in new Table A-4.

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APPENDIX D
MATERIALS AND FABRICATION

Issues related to package materials and fabrication are interlaced among all chapters in the Safety Analysis Report for Packaging (SARP). Although some aspects of the review are relatively straightforward (e.g., thermal properties of materials should be discussed in the Thermal Evaluation chapter), other issues may not be clearly aligned with the nine chapters of the SARP format. Consequently, the review of material and fabrication should address all SARP chapters to ensure that these areas have been properly evaluated.

Tables D.1 and D.2 provide a summary of typical issues that should be reviewed for materials and fabrication, respectively. The reviewer is cautioned not to use these tables as a simple "yes or no" checklist, but to consider each package and its specific issues on a case-by-case basis.

As noted in Chapter 1 of this PRG, information on materials and fabrication which is indicated on engineering drawings may be described in additional detail in a separate fabrication specification.

Table D.1 Review of Materials

Identification of Packaging Components	• Is each packaging component depicted on the drawings and identified in the parts list or by other appropriate means? • Is each packaging component not identified on the drawings properly justified as not important to safety?
Material Specifications of Packaging Components	• Is the material of construction of each packaging component specified on the drawings? • Is a material specification (e.g., ASME, ASTM, commercial equivalent) designated on the drawings for each material? Is the material specification appropriate for the code or standard applicable to the packaging? • For materials without an applicable specification, are material properties to be controlled properly specified on the drawings? Examples include minimum/maximum densities of foam, fiberboard, and similar materials, and minimum density neutron absorbing nuclides. Are these properties consistent with those used in the package evaluation? • Are appropriate examination requirements for each material specified on the drawings?
Material Properties	• Are material properties relevant to the SARP evaluation specified where appropriate? • Are the material properties appropriate for the temperatures and pressures under normal conditions of transport and hypothetical accident conditions? • Have appropriate test requirements for materials been established?
Brittle Fracture	• Is any packaging material subject to brittle fracture by cold or other mechanisms (e.g., hydrogen embrittlement)? • Are the criteria of RG 7.11 or 7.12 satisfied? • Has embrittlement by other mechanisms (e.g., fabrication processes) been properly addressed?
Chemical, Galvanic, and Other Reactions	• Is any material subject to chemical, galvanic, or other reaction (e.g., radiolysis) with each other or with the contents? If so, have these issues been properly addressed in the package evaluation? • Is any material subject to radiation damage? If so, has this issue been properly addressed?

Table D.1 Review of Materials (cont.)

Package Operations	• Should any material or component be inspected and/or replaced prior to fabrication or each use? • Are appropriate types of inspections and acceptance criteria specified?
Acceptance Testing and Maintenance Program	• Should any material or component be subject to acceptance testing prior to first use? • Should any material or component be inspected, maintained, and/or replaced as part of a periodic maintenance program? Is the period and type of inspection appropriate? Is the maintenance or replacement schedule appropriate? • Are the requirements for acceptance testing and maintenance specified?
Quality Assurance	• Has each component been properly categorized as to its importance to safety? • Have appropriate controls been established in the Quality Assurance chapter to assure that quality requirements are met? • Has appropriate documentation been specified to document that quality requirements are met?

Table D.2 Review of Fabrication

Identification of Packaging Components	• Is each packaging component depicted on the drawings and identified in the parts list or by other appropriate means? • Is each packaging component not identified on the drawings properly justified as not important to safety? • Have all safety-related fabrication features been well-characterized on the drawings, with regard to the appropriate code requirements?
Welds	• Is the location, type, size, thermal cycle/metallurgy (if applicable), and method of examination (with acceptance criteria) for each weld specified on the drawings or in the text? • Is a code or standard requirement for each weld, welding procedure, and welder qualification specified on the drawings? Is all of the weld information consistent with this code or standard? • Is the code or standard for the weld appropriate (see NUREG/CR-3019 and -3854)?
Codes and Standards for Other Fabrication Processes	• Is an appropriate code or standard for fabrication of each packaging component specified on the drawings? • For components without an applicable specification (e.g., lead shielding), is the fabrication process sufficiently described, controlled, and specified on the drawings? • Are appropriate examination requirements for each fabrication process specified on the drawings? • Is the package evaluation consistent with its fabrication specifications?
Package Operations	• Should components or features be inspected prior to each fabrication or use? • Are appropriate types of inspections and acceptance criteria specified?
Acceptance Testing and Maintenance Program	• Are appropriate acceptance tests and documentation specified to address fabrication issues (e.g., uniformity of lead, nondestructive evaluation of materials prior to fabrication, etc.)? • Should any component or feature be inspected, maintained, and/or replaced as part of a periodic maintenance program? Is the period and type of inspection appropriate? Is the maintenance or replacement schedule appropriate? • Are the requirements for acceptance testing and maintenance specified?

Table D.2 Review of Fabrication (cont.)

Quality Assurance	• Has each component been properly categorized as to its importance to safety? • Are training and qualification requirements for fabrication personnel properly specified? • Have appropriate controls been established in the Quality Assurance chapter to assure that quality requirements are met? • Has appropriate documentation been specified to document that quality requirements are met?

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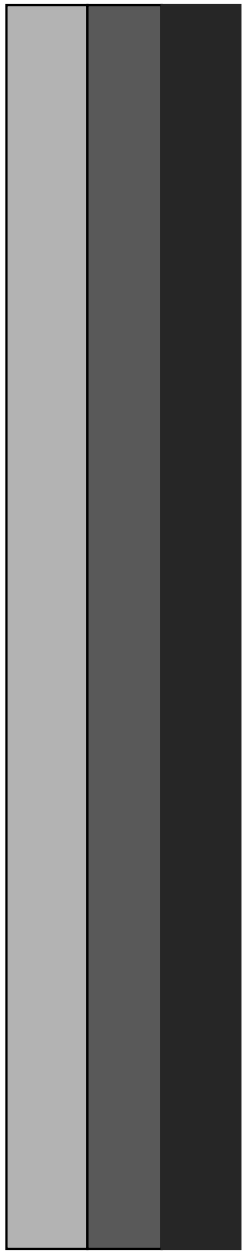


EM Environmental Management

safety ✤ performance ✤ cleanup ✤ closure

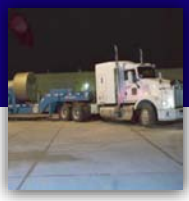
Standard Review Plan (SRP)

Site Transition (Post Cleanup) Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

September 30, 2008

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

Department of Energy
Washington, DC 20585

February 15, 2005

MEMORANDUM FOR FIELD DISTRIBUTION

FROM: MICHAEL W. OWEN
DIRECTOR, OFFICE OF LEGACY MANAGEMENT

PAUL M. GOLAN
ACTING ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT

SUBJECT: Development of Site Transition Plan, Use of the Site Transition Framework, and Terms and Conditions for Site Transition

On June 16, 2004, Michael W. Owen, Director, Office of Legacy Management (LM) and Jessie H. Roberson, Assistant Secretary, Office of Environmental Management (EM) co-signed a memorandum titled "*Transition of Sites from Environmental Management.*" The memorandum described EM's and LM's expectations on site transition process and requirements. The memorandum stressed the importance of two documents: the Site Transition Plan (STP) and the Critical Decision-4 (CD-4) package. This memorandum provides additional guidance on preparation of the STP. The specific requirements for the CD-4 package are outlined in *DOE O. 413.3 Program and Project Management for Acquisition of Capital Assets* and in an EM guidance memorandum dated July 13, 2004. It is important to note that the CD-4 package documenting the end of EM's mission at the closure sites should be prepared for closure of the site and not be limited to completion of the cleanup project.

The STP represents EM and LM's joint expectations up to and including the point of programmatic transfer. This will normally be the start of the fiscal year following EM physical completion. The STP should be developed through a collaborative effort by EM and LM staff and be guided by the *Terms and Conditions for Site Transition* provided in Attachment A. Each site's plan should describe the key transition activities, including schedule, milestones, and required resources. Additional guidance on the STP is provided in Attachment B.

The *Site Transition Framework* (STF), provided in Attachment C, should be used in the development of the STP. The STF represents requirements or conditions that must be addressed before a site can be transferred from EM to LM. The STF serves as the primary tool to evaluate whether all relevant transition activities and end-point criteria have been identified.

It should be noted that the STP and the STF are living documents that will be updated periodically as EM and LM work toward the successful transition of sites. The organization of the STP is expected to mirror the STF and the full scope of the STF is to be addressed in the CD-4 package.

Questions regarding this memorandum should be directed to Dr. Robert Goldsmith, Director, Office of Core Technical Group (EM-23) at 301/903-4954 or Dave Geiser, Director of Policy and Site Transition (LM-40) at (202) 586-8324.

3 Attachments:
Attachment A – Terms and Conditions for Site Transition
Attachment B – Site Transition Plan Guidance
Attachment C – Site Transition Framework

ATTACHMENT A

Terms and Conditions for Site Transition – February 2005

This document outlines proposed terms and conditions for managing and funding site transition activities between the Office of Environmental Management (EM) and the Office of Legacy Management (LM).

Planning/Process

- EM and LM will conduct the site transition process in accordance with the applicable regulations and DOE Orders (mainly *DOE O. 430.1B Real Property Asset Management* and *DOE O. 413.3 Program and Project Management for Acquisition of Capital Assets*).

- EM-1 and LM-1 will meet quarterly to discuss the status of site transition.

- EM and LM will work together to develop planning documents and estimates for the management of post-closure activities at the sites. EM and LM will develop and implement a process for resolving differences in estimates.

- The EM Site Manager, in coordination with the LM Site Transition Coordinator and the EM Site Transition Coordinator, will submit a quarterly progress report on transition activities to EM-1 and LM-1 starting April 1, 2005.

- The EM Site Manager will submit a final comprehensive Transition Lessons Learned document for the site to EM and LM

- EM and LM will jointly develop the Site Transition Plan.

- EM will lead development of the Critical Decision-4 (CD-4) Package with support from LM for those portions of CD-4 Package that address LM activities.

- LM will lead development of the Long-Term Surveillance and Maintenance Plan (LTS&M Plan) with support (i.e., providing site maps, data, engineering drawings, etc.) from EM.

- LM will conduct Readiness Reviews and provide findings to EM for inclusion in the CD-4 Package. EM will provide appropriate level of staff support to the review teams.

Budget Responsibility

- The budget responsibility for a site remains with EM until the beginning of the fiscal year following site cleanup completion[1]. LM will assume budget responsibility for site activities and contractor pensions and benefits in the fiscal year following EM physical completion.

- Where appropriate and beneficial to both organizations, EM and LM will work together to provide EM funds to LM's contractors in advance of programmatic transfer. This would enable EM to shift some functions from the closure contractor to LM's surveillance and maintenance contractor prior to programmatic transfer.

- EM will develop and provide a validated baseline and supporting basis of cost estimates for the first five years of post-closure management, two years prior to the planned date of transfer. This baseline will be the basis for the 5 year funds transfer in the PBD.

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[1] EM completion occurs when: short-term response activities are complete; long-term response measures are established and determined to be operational and functional; institutional controls are in place; and the necessary documentation is in place.

- EM will develop the DOE environmental liability estimate in accordance with Departmental policies and procedures. Responsibility for developing the environmental liability estimates will transfer to LM upon programmatic transfer.

- EM will prepare the formal transfer memo proposing the transfer of programmatic responsibility and budget for LM concurrence.

- EM will capture and include all post-closure work scope (e.g., expected surveillance and maintenance, public outreach, state funding, contractor benefits, etc.) in EM outyear planned estimates until the out year funding for the site is formally transferred.

- Funding for and management of the following activities will be the responsibility of EM until they are completed:

    - EM is responsible for NRDA settlements until two years after the programmatic transfer of the site. (Future NRDA claims based on failure to maintain the remedy are LM's responsibility);
    - Litigation regarding EM cleanup or other EM activity;
    - The closeout of all contracts associated with cleanup and closure of the site; and
    - Records of Decision and other regulatory drivers.

Work Force

- EM's existing Closure Contracts will be used as the mechanism to administer and pay pensions and post retirement benefits, until such time that a new contract vehicle can be put in place by LM.

- Until transfer occurs, EM will continue to fund contractor pension plans to satisfy all applicable requirements.

- EM will retain responsibility for open worker compensation claims under the state Workers Compensation System.

Records Management/IT

EM will:

- Plan, budget, and provide qualified resources to manage federal and contractor record inventories and information technology systems in accordance with all Federal, National Archives and Records Administration (NARA), and DOE Orders (Draft *DOE O. 243.X Records Management Program, DOE O 200.1 Information Management Program, 36 CFR, and 44 USC*) through programmatic transfer.

- Ensure, for both Federal and Closure Contractor staff, that standard practices and procedures for the transition of records and information systems are consistent with requirements established by the *Legacy Management Information and Records Management Transition Guidance* (March 2004), and *Site Transition Framework* (September 2004).

- Ensure that each STP includes an Information and Records Management Transition Plan (IRMTP). The IRMTP will assist both organizations in organizing records and information transfer tasks; establishing a timetable and milestones for their completion; and identifying manpower, funding and other resources that will be needed to complete the ownership transfer.

- Transfer all remaining records inventories, both federally- and contractor-held, to LM approved record storage facilities prior to site transfer. Prior to disposition in approved records storage facilities, all records inventories shall meet NARA storage requirements.

- Ensure that agreements are in place to disposition records, prior to actual site transfer, that do not transfer to LM (e.g., current contract close-out records, ongoing litigation and FOIA/Privacy Act requests, transuranic (TRU) waste-related records, and classified records).

- Disposition all classified records to authorized facilities and identify long-term custodian prior to programmatic transfer.

- Plan, budget, and execute the work necessary to digitize, in approved electronic format, the CERCLA Administrative Record for all EM Closure Sites under CERCLA requirements.

- Provide User and System Documentation for all IT systems/applications that are necessary to execute LM missions. Particular focus should be applied to IT applications currently used to support and manage, records and information management systems, employee compensation claims (i.e., EEOICPA), and environmental data necessary for long-term surveillance and maintenance activities.

- Transfer to LM all IT system/application licenses that are required to meet LM mission objectives.

- Provide electronic conversion of environmental and record data for post-closure management and support services in accordance with the specifications and conditions defined by LM.

- Provide consultation services by IT and data subject management experts to assist LM in understanding the operation, maintenance, data structures and contents, and systems configuration requirements for the applications necessary to conduct stewardship activities.

- Provide exports of databases and program source code for Information Systems being migrated to LM for stewardship operations and services.

LM will:

- Define the records, data, and format (electronic and hard copies) that are needed for post-closure management of the site.

- Provide, when requested by EM during site transition, records management services for frequently accessed, short-term records that are agreed to be transferred prior to physical site transfer. EM will reimburse LM for these services.

- Provide renewals of all IT system/application licenses that are required to meet LM mission objectives.

- Identify IT applications needed for post-closure management of and support services for the site. EM is responsible for disposition of all IT applications/systems not needed by LM.

- Specify the system and data content and format requirements for the IT applications needed for post-closure management and support. EM is responsible for minor formatting associated with IT applications/systems in order to transition data to LM.

Contracts and Grants

- For contracts and/or grants that are transferring to LM, EM will provide copies of procurement documents to LM and work with LM to identify points of contact in appropriate business centers.

Real Property

- For real property transferring to LM, EM will develop and provide: real property records, including access agreements for off-site wells or land parcels required for LTSM.

- The EM Site Manager will ensure that the FIMS is maintained and current prior to site transfer.

- EM will initiate the documentation to transfer real property from EM to LM and coordinate the finalization with LM and ME.

Contingency

- EM will provide funding to LM for any unfunded activities (e.g., an EM post-closure regulatory decision) that result from EM decisions. This includes, but is not limited to, funding for any remedy modification (e.g., installation of additional monitoring wells) for sites that do not have a final Record of Decision or equivalent. Funds transfer will be limited to the period covered by the PBD.

- Significant remedy failures which require modification of the remedies outside of the capabilities of the LM will be coordinated with EM. EM and LM will raise the issue to the Under Secretary for resolution.

ATTACHMENT B

Site Transition Plan Guidance

Goal: The Site Transition Plan (STP) is the primary tool intended to assist in successful closeout or transition of the Office of Environmental Management (EM) site responsibilities to the Office of Legacy Management (LM) for post-closure management. Within this framework, the STP is intended to achieve several specific objectives:

- Ensure efficient transfer of EM activities that remain after physical site completion to the EM Consolidated Business Center (CBC) or other appropriate organization.
- Provide requirements for, and support the preparation of, the Critical Decision-4 (CD-4) documentation for project closeout.
- Establish a common understanding of EM and LM financial, programmatic, and legal responsibilities throughout the transition period.
- Ensure the requirements of the Site Transition Framework (STF) are met.
- Establish requirements for LM post-closure responsibilities.
- Describe the approach to disposition real property, records, and data by EM and LM where appropriate.

It should be noted that the STP should include all work scope that will transition (i.e., to LM, EM, or some other entity) upon completion of EM work at the site.

Explanation of Terms: Transition is viewed as a process. Thus, for EM and LM the transition is the passage from the phase during which engineered, near-term actions are taken to mitigate environmental and human health risks to the next phase where residual risks are maintained in a sustainable safe condition to allow beneficial use. Transfer is the handoff of programmatic and financial responsibility from one program to another. Thus, upon completion, EM closure sites go through *transition* (a process) to achieve *transfer* (a milestone). The transition period ends on September 30th of the fiscal year in which EM completes its mission at the site. This date coincides with the projected transfer of programmatic responsibility for the site to LM.

DOE Order 430.1B Real Property and Asset Management Requirements: EM and LM intend to use two primary documents to achieve transition and comply with the requirements of *DOE Order 430.1B Real Property and Asset Management.* The STP will meet the requirement for a disposition plan and the long-term surveillance and maintenance plan (LTS&M Plan) will meet the Ten Year Site Plan requirement. A site specific STP should include:

- The projected date and end-point criteria for programmatic transfer.
- A summary of transition cost, scope, and schedule including organizational responsibility for major actions.
- Major milestones and deliverables that will be placed under configuration control administered by LM-1 and EM-1.
- A records turnover or retention plan, including the management of FIMS data and information.
- The information necessary to meet the requirements identified in *DOE O. 430.1B* for transfer of real property.

Development Process: The STP is developed using a joint EM-LM team. LM has the lead role in developing the STP with extensive support from EM staff. The STP should be developed two years prior to the planned transfer date. The STP also serves as the formal document for the transfer scope, date, and level of responsibilities, funding and control and custody for the property conveyed. The STP is approved by EM-1 and LM-1.

Use and Update of the STP: After the STP is approved, the critical milestones are placed under configuration control, and STP activities are executed by EM and LM staff. The site

manager, in coordination with the LM Site Transition Coordinator reports progress to EM-1 and LM-1 on a quarterly basis. The STP should be updated periodically by assessing transition progress against the STF requirements. The STP should reflect the latest activities and/or management decisions.

Relationship between the STP and the STF: The STF is the framework for developing the STP and includes a set of requirements that must be met before programmatic transfer of a closure site (see Box 1). The STF serves as the primary tool to evaluate whether all relevant transition activities and end-point criteria have been identified. It should be noted that the STP and the STF will be updated periodically as EM and LM work toward the successful site transition.

Box 1. The Site Transition Framework Establishes Requirements for 10 Areas

1. Authority and Accountability
2. Site Conditions
3. Engineered Controls, Operation & Maintenance Requirements, and Emergency/Contingency Planning
4. Institutional Controls and Enforcement Authorities (Real Property)
5. Regulatory Requirements and Authority
6. Long-Term Surveillance and Maintenance
7. Information and Records Management
8. Public Education, Outreach, Information and Notice
9. Natural, Cultural, and Historical Resource Management
10. Business Functions including Contractor Pensions and Benefits

Organization of the STP: The STP should be structured to address the STF's ten functional areas. Each functional area should include:

- The status of relevant site characteristics at the time the STP is submitted.
- A schedule of key activities and milestones associated with the functional area.
- Key assumptions associated with the transition and/or transfer.
- Risk management activities to address the major transition uncertainties.

Other Characteristics: A typical STP is expected to be 20-30 pages in length; a shorter length may be appropriate for smaller or less complex sites. The STP should address the full transition period. The STP is a management tool and not a regulatory document; it is not enforceable by external parties. However, DOE will provide the STPs to regulators and stakeholders for information upon request. The following items are considered standard for all STPs unless specifically waived:

- Disposition of the EM responsibilities or "Sunset Project."
- Development and approval of the LTS&M Plan.
- The approach to complete regulatory documentation and description of the post-closure regulatory framework.
- Schedule for known or anticipated real property transfer.

The STP and Critical Decision-4: As the site approaches closure, a CD-4 package must be developed in accordance with the *DOE O. 413.3 Program and Project Management for Acquisition of Capital Asset.* A CD-4 package documents the completion of the EM mission at the site and validates the successful execution of the STP to the transfer point. Thus the CD-4 package represents agreement between EM and LM on the status of the site and associated remaining activities at the time of transfer. Actions in the STP that remain at transfer are documented in the CD-4 package. The CD-4 package is signed by the Under Secretary for Energy, Science and Environment.

For additional information, please contact:

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Office of Environmental Management
301/903-4954

ATTACHMENT C

Site Transition Framework for Long-Term Surveillance and Maintenance

This Site Transition Framework (STF) provides a framework for all U.S. Department of Energy (DOE) facilities and sites where DOE may have anticipated long-term surveillance and maintenance (LTS&M) responsibilities. It is a tool to help facilitate a smooth transition from remediation to LTS&M, providing a systematic process for affected parties to utilize in analyzing the baseline, and to understand and manage actions from completion of the Environmental Management (EM) mission through site transition into LTS&M.

The STF is not intended to provide an exhaustive list of the specific requirements and information. Sites will have unique considerations that may not be adequately addressed by this tool, and it is anticipated that a team consisting of the transferring and receiving organizations will use judgment in utilizing these requirements and augmenting them with other DOE guidance. However, the STF should be followed to the extent possible at each site and adapted to accommodate unique site-specific requirements, needs, and documents.

Ideally, this STF should be used as early in the remediation process as possible. Subsequent applications of the STF to the site should be conducted periodically and used to verify that all appropriate steps have been or will be taken to close out the site and that actions by both organization to transfer the site to LTS&M are identified. The requirements are provided in the following sections and attachments of this document:

- Section I. Authorities and Accountabilities Are Assigned and Documented
- Section II. Site Conditions Are Accurately and Comprehensively Documented
- Section III. Engineered Controls, Operation and Maintenance Requirements, and Emergency/Contingency Planning Are Documented
- Section IV. Institutional Controls, Real and Personal Property, and Enforcement Authorities Are Identified
- Section V. Regulatory Requirements and Authorities Are Identified
- Section VI. Long-Term Surveillance and Maintenance Budget, Funding, and Personnel Requirements Are Identified
- Section VII. Information and Records Management Requirements Are Satisfied
- Section VIII. Public Education, Outreach, Information, and Notice Requirements Are Documented and Satisfied
- Section IX. Natural, Cultural, and Historical Resource Management Requirements Are Satisfied
- Section X. Business Closure Functions, Pension and Benefits, Contract Closeout or Transfer, and Other Administrative Requirements Are Satisfied
- Attachment 1, Real Property Requirements
- Attachment 2, Post-Closure Benefit Information and Data Needs

I. Authorities and Accountabilities Are Assigned and Documented

All interested parties' assignments of accountabilities and authorities for LTS&M have been identified and documented.

A. All documents allocating the roles and responsibilities of interested parties have been approved and signed (e.g., Memorandum of Agreement, Memorandum of Understanding, Interagency Agreement, Cooperative Agreement).

B. Each federal or non-federal entity that will be responsible for LTS&M activities listed in Section I-A has been identified. Funding sources for each activity have been identified and documented in Section VI.

C. Appropriate governmental requirements, policies, and procedures for managing resources have been incorporated into the LTS&M Plan and agreements.

D. The legal authority under which LTS&M will be conducted has been identified and documented or a "reservation of rights" has been indicated.

E. Section IV presents a discussion of authorities related to institutional controls.

II. Site Conditions Are Accurately and Comprehensively Documented

All documentation identifying site historical uses characterization, and remedial action, including the Preliminary and Final Closeout Reports, has been completed and made available to the public. Where available, the information identified in this section should be of survey quality and have Geographical Information Systems (GIS) references.

A. The site at the time of closure, including all remedies and remaining hazards, has been described. Examples include, but are not limited to, the following components:

   1. Physical features of the site, including, site topography, geology, hydrogeology, geomorphology, seismicity, site and area boundaries, and other features relevant to the long-term performance of the site.
   2. Locations of active, inactive, and decommissioned buildings, structures, and surface and subsurface infrastructure (e.g., utilities).
   3. Locations of residual hazards and associated engineered and institutional control systems.
   4. Locations of groundwater wells, wastewater outfalls, and air quality monitoring stations. Information has been depicted on site maps.
   5. For those sites undergoing closure, locations of off-site buildings and structures, important ecological resources, and associated potential receptors in the vicinity of the site.
   6. Characteristics of the remaining contaminants (e.g., radioisotope, activity, and physical and chemical form).
   7. Descriptions of the initial risk at the site and the risk remaining at the site following remediation. This information will be used to provide a reference baseline.
   8. The existence of and basis for decisions on cleanup levels for the end state, such as a "No Further Action," should be indicated.

B. For those sites undergoing closure, a conceptual site model for LTS&M has been completed (if deemed applicable) that shows the relationships between existing residual hazards, environmental transport mechanisms, exposure pathways, and human/ ecological receptors.

C. All remedial action(s) and associated documentation have been completed and approved by regulators.

D. Results of any Natural Resource Damage Assessment claims, where applicable, with associated documentation have been identified. This assessment should discuss the Department's potential environmental liability at the site.

III. Engineered Controls, Operation and Maintenance Requirements, and Emergency/Contingency Planning Are Documented

A. Engineered controls have been identified and documented. The information should include, but not be limited to, the following elements:

1. Design and construction drawings, specifications, and completion report.
2. Site physical and geotechnical data.
3. Locations of engineered controls accurately identified and depicted on site maps.
4. Identification of ongoing remediation and related waste management activities.
5. Performance history assessments indicating successful operation.

B. A life-cycle cost estimate, including basis and assumptions. The life-cycle cost estimate should be based on best available data but should also include a reasonable and prudent amount for future contingencies, recognizing that in most cases LTS&M activities may be ongoing until such a time that no hazards remain to human health and the environment. The results of the life-cycle cost should be documented in Section VI-B.

C. A master schedule of ongoing activities has been made available.

D. The risk-based end state, including exit criteria outlining if and/or when engineered controls will no longer be necessary, should be identified along with the supporting information. If exit criteria will be implemented while hazards to human health and the environment remain, a Probabilistic Risk Assessment over several half-lives should be provided to justify the exit strategy and the discontinuance of the engineered controls.

E. Operation and maintenance (O&M) activities have been documented, funding is in place, and a party has been selected to perform the necessary activities.

1. Surveillance and monitoring requirements have been documented (e.g., scope frequency, reporting, process descriptions, and analytical parameters and methods). This document should allow for optimization that is consistent with the selected remedy.
2. The cost, including basis and assumptions, of operations, maintenance, and surveillance activities has been estimated, documented, and revised periodically as experience dictates. The request for funding should be in accordance with applicable budget appropriations procedures.
3. An agreement and/or contract is in place for performance of all O&M activities during LTS&M if an outside party will be performing these activities.

III. Engineered Controls, Operation and Maintenance Requirements, and Emergency/Contingency Planning Are Documented (continued)

F. Emergency/contingency planning and the authority and responsibilities to implement have been identified.

1. Uncertainties associated with residual hazards, fate-and-transport mechanisms, exposure pathways, and the effectiveness of LTS&M activities have been identified.
2. Scenarios related to each uncertainty have been identified (e.g., failure scenarios).
3. Roles, responsibilities, and procedures to respond to each scenario have been established.
4. The conceptual site model developed in support of the remedial action or closure decision should be routinely reviewed, updated, and re-evaluated based on new technical information and on monitoring data collected during stewardship of the site.
5. Emergency and catastrophic planning for events such as fires, floods, etc., shall be documented.

IV. Institutional Controls, Real and Personal Property, and Enforcement Authorities Are Identified

A. Land use/institutional controls have been identified, approved by the regulator(s) (if applicable) and implemented. All institutional control components of each implemented remedy are described (e.g., future land-use assumptions upon which each implemented remedy is based, associated land-use restrictions). If engineered barriers will be relied upon as part of the remedy requiring institutional controls, assumptions regarding the longevity and performance of these barriers should be identified.

1. On-site and off-site land uses for each area (property) and its associated land-use assumptions have been identified.
2. Procedures for managing, assessing potential changes in, and enforcing on-site and off-site (as appropriate) land uses have been documented and are being conducted.
3. Institutional controls established as part of an implemented remedy have been identified, and a process is in place to monitor and document these institutional controls.
4. Roles and responsibilities that have been outlined for responding to requests to change existing land uses are consistent with the land use assumed during implementation of the selected remedy.
5. Procedures have been put in place for periodic review of land uses and institutional controls to ensure that they are being maintained and remain protective. Performance history indicating successful operation has been documented.
6. Procedures for management and periodic reassessment of institutional control restrictions are in place.
7. Off-site easements implemented to ensure the protectiveness of the remedy have been documented, and a process is in place to enforce/maintain these easements.
8. Exit criteria outlining when engineered controls/institutional controls will no longer be necessary have been documented, if not previously documented, in the Record of Decision (ROD) or other appropriate document.

B. Property records (as required by applicable regulations and/or guidance) are complete. Examples of property records follow; Attachment 1 provides a more complete list of property records.

1. The site's real estate history has been documented, including identification of former property owners, deed restrictions, or other land-use restrictions.
2. Site boundaries and site markers are easily identified and have been documented.
3. On-site and off-site easements, rights-of-way, and other property access rights have been established and documented. Preferably, this information should be depicted on site maps.
4. Water, mineral, and other natural resource rights have been identified.
5. Tribal treaty rights and other U.S. Government obligations have been identified.
6. Areas where LTS&M activities will be conducted have been documented in the property records.

IV. Institutional Controls, Real and Personal Property, and Enforcement Authorities Are Identified (continued)

C. Personal Property Transfer Requirements

The personal property transfers are completed in accordance with Title 41 *Code of Federal Regulations* (CFR) Part 101, Federal Management Regulations, and DOE Property Management Regulations (PMR).

V. Regulatory Requirements and Authorities Are Identified

Regulatory requirements regarding residual contamination have been identified. Pertinent regulatory documents are maintained and available to the public (e.g., RODS, Resource Conservation and Recovery Act (RCRA) permits and Corrective Action Decisions, Consent Orders, Interagency Agreements, and Federal Facility Agreements).

A. All regulatory decision documents and associated site characterizations have been identified and are either complete or scheduled for completion (e.g., all remedial action activities regarding the soil have been completed, but the impacted groundwater is in the process of being resolved) and are maintained in accordance with regulatory requirements.

B. The implemented remedy and associated LTS&M activities are verified to be in compliance with all regulatory requirements [e.g., appropriate agreements have been entered into with appropriate regulator(s)].

C. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Five-Year Review or other review results are available. Future periodic reviews (not to exceed 5 years), including supplemental analysis of site-wide Environmental Impact Statements (if applicable and/or required), should be planned and consistent with existing guidance.

D. The U S. Environmental Protection Agency (EPA) National Priority List (NPL) status and/or RCRA permit status or state requirements and the basis for these requirements have been clearly indicated (e.g., delisting, partial delisting, and non-NPL).

E. U.S. Nuclear Regulatory Commission (NRC) license status has been established. This status information should identify the license holder and the development of license transfer plans.

F. Locations of documents have been identified, and the documents are accessible. A process should be in place to ensure that the documents are maintained and kept current (e.g., new technology updates for records management).

VI. Long-Term Surveillance and Maintenance Budget, Funding, and Personnel Requirements Are Identified

Sites should be consistent with and follow their prescribed guidance in determining budget, funding, and personnel requirements. Some of the elements in this section may not apply.

A. A technical baseline document for LTS&M programs and activities at the site has been developed. The LTS&M baseline includes activities to be conducted by the receiving organization.

B. Funding (consistent with technical baseline) and supported by cost-estimates (Section VI).

1. Any funds for LTS&M have been identified and are available.
2. Estimates for the annual funding requirements for LTS&M activities, associated oversight, and information management requirements have been derived and have been included in the Annual Budget Request to Congress.
3. Funding assurances have been made based on those estimates.
4. Mechanisms to transfer funds required for LTS&M have been established.
5. Funding mechanisms for LTS&M activities and regulatory oversight activities conducted by other federal and non-federal entities have been established (e.g., documentation of financial assurance agreements for long-term monitoring and surveillance funding).
6. Estimates required for financial assurance payments have been determined.
7. Authority has been granted to the steward to use, or have access to, funds related to LTS&M.

C. Personnel requirements have been identified (for activities not previously addressed within this set of criteria).

1. All personnel functions and qualifications necessary for the technical implementation and administration of LTS&M activities have been identified.
2. A determination for the need of other on-site personnel has been made and the specific duties that may be required have been identified.
3. A closeout plan for the disposition of excess federal full-time equivalents has been developed.

D. A business closeout process has been developed (see Section X).

VII. Information and Records Management Requirements Are Satisfied

Records and information for LTS&M turnover or retention plans are reflected in post-closure or disposition plans.

A. Transfer of information and records.

1. Agreements are in place that identify the disposition of records transfer to the site custodian and records that transfer to other organizations (i.e., contract closeout records, ongoing litigation records and FOIA/Privacy Act requests, transuranic waste-related records, classified information).
2. Information and records needed for LTS&M, property management, contractor personnel benefits other than pensions, worker compensation, and Energy Employees Occupational Illness Compensation Program Act (EEOICPA) have been identified.
3. Practices and procedures for the transition of information systems and records have been established. Guidance is provided in the document *Legacy Management Information and Records Management Transition Guidance (March 2004).*
4. The guidance and operations information for information systems transferring to the site custodian, including metadata, have been identified and transferred along with the information systems.
5. A Site Information and Records Transition Plan has been developed and approved that establishes a framework to address site-specific records and information requirements, including storage locations, special handling needs, geospatial data, and access and retrieval requirements.
6. The location(s) for storage and maintenance of site records and information systems has been identified and approved.
7. A records tracking system has been implemented, and standards for data formats, finding aids, and indices have been provided to the transfer site.
8. Information from the transfer site's records tracking systems has been migrated to the tracking system, along with locator guides and indices.
9. Records and record locations specified in agreements (Section V) are identified along with points of contact.

B. Information and records management planning has been performed and is acceptable to the stakeholders, as required under regulatory requirements for stakeholder involvement and public availability.

1. Systems and procedures for the archival of LTS&M information in one or more on-site or off-site repositories have been developed.
2. Retention schedules that are appropriate for the management of records for LTS&M and for continuity of benefits, worker compensation, and EEOICPA claims have been developed.
3. Systems and procedures to establish and facilitate public access to and retrieval of records and information critical to LTS&M are in place. Examples could include, but are not limited to, Internet access, local library, and on-site information center (e.g., Interpretive Center, museum).

VII. Information and Records Management Requirements Are Satisfied (continued)

B. Information and records management planning has been performed and is acceptable to the stakeholders, as required under regulatory requirements for stakeholder involvement and public availability (continued).

4. The National Archives and Records Administration (NARA) has been engaged, through the DOE Office of Chief Information Officer, to approve any transfer of records past their retention dates or the loan of current records to organizations outside of DOE.
5. The DOE Librarian and DOE Historian should be consulted regarding the transfer of non-record materials, such as library materials and other items that may have historic value, before agreements are made regarding their transfer to non-DOE entities.
6. Classes of LTS&M information users and their access requirements have been identified and solutions have been implemented.
7. Information in DOE-approved information systems, such as those identified in DOE Order 430.1B, *Real Property Asset Management*, required for LTS&M has been identified.

VIII. Public Education, Outreach, Information, and Notice Requirements Are Documented and Satisfied

Any community involvement and associated Community Relations Plans should be governed by existing participation standards and systems.

A. List of site stakeholders with associated address information has been developed and a process is in place for updating this list.

B. Annual or more frequent updates of the Administrative Record and on-site information repository are available to interested parties. Community involvement tools have been developed (e.g., fact sheets, newsletters, email notifications, public meetings, etc.).

C. Costs associated with public involvement have been estimated (e.g., oversight committees, meeting locations). Funds sufficient for public involvement should be included in the funding requests.

IX. Natural, Cultural, and Historical Resource Management Requirements Are Satisfied

A. A discrete system or process is in place to protect information about sensitive and natural resources from inappropriate or unauthorized use or access.

B. Biological resources, threatened and endangered species, archaeological and cultural resources, Native American treaty rights, and/or other natural and cultural resources requirements have been identified and satisfied.

C. Precise locations and characteristics of natural and cultural resources that require LTS&M have been identified. A management system is in place and operating successfully.

X. Business Closure Functions, Pension and Benefits, Contract Closeout or Transfer, and Other Administrative Requirements Are Satisfied

Actions required by the completing organization and the receiving organizations related to business closeout functions are identified and reflected in requirements, policies and procedures (Section I-C), schedules and cost estimates (Sections III-B and III-C), and budget (Section VI)

A. Responsibilities have been determined for the administration and funding of

1. Retiree benefits and pension fund(s)
2. Workforce transition services (e.g., outplacement assistance)
3. National Defense Authorization Act for Fiscal Year 1993, Section 3161 Tuition Reimbursement Program and Relocation and Entrepreneurial Resource Program
4. Worker compensation claims
5. EEOICPA claims

B. Current contractor pensions and benefits needs are identified and planned (see Attachment 2 for more details):

1. Information about current pensions and benefit plans has been obtained.
2. Post-closure benefits administrator and providers have been identified and appointed.
3. Employment dates, salary, and security clearances have been verified.
4. Personnel-related databases (including manual systems) and records responsibility have been identified:
   a. Employment history and personnel files
   b. Historical radiological dose records
   c. Medical records
   d. Retiree pension and benefit records
   e. Security clearance history files
   f. Training records

C. Status of pending litigation and liabilities identified (Generally, these actions should be completed by the transferring organization.):

1. Pollution liability policy
2. Auto liability policy
3. General liability policy
4. Fiduciary/crime/medical malpractice liability policy
5. Government rating plan for workers compensation
6. Non-government rating plan workers compensation claims
7. Equal Employment Opportunity (EEO) and discrimination cases
8. Unresolved hourly employee claims
9. Beryllium liability claims
10. State or community litigation or claims

X. Business Closure Functions, Pension and Benefits, Contract Closeout or Transfer, and Other Administrative Requirements Are Satisfied (continued)

C. Status of pending litigation and liabilities identified (generally, these actions should be completed by the transferring organization) (continued)

11. Pending citizen action suits
12. Department of Labor, Administrative Review Board cases, and/or Federal court litigation relating to Labor Standards (e.g., Service Contract Act, Davis-Bacon Act)

D. Contract termination actions (These actions will normally be completed by the transferring organization unless contracts are required for LTS&M.):

1. Contract closeout actions for closure of restoration contracts shall be identified.
2. Contracts and financial agreements required for LTS&M identified (see Section I-B).

E. Requirements of DOE orders satisfied.

1. Facility Authorization Basis terminated
2. Price Anderson Authorities oversight
3. Reporting to International Atomic Energy Association (IAEA) terminated
4. Disposition of personal property items

Attachment 1, Real Property Requirements

I. Real Property Information Requirements

All real property information requirements must be identified and documentation must be obtained prior to the transfer of any site to the Office of Legacy Management (LM). Real property assets are defined as any interest in land, together with the improvements, facilities, structures, and fixtures located thereon, including prefabricated movable structures and appurtenances thereto, under the control of DOE. Real property assets are further defined in the *Federal Management Regulations*, Sections 101-476.103-12. Consider the following elements, as applicable:

- Determine what interests will remain at closure both on site and off site, including land, easements, minerals, water rights, well permits, licenses, and permits.
- Determine any other in grants or out grants proposed for transfer to LM.
- Determine future land use for property.
- Obtain as-built drawings for any remaining improvements and utilities.
- Obtain existing maintenance/operations plans and procedures.
- Perform a physical inspection of facility.
- Complete information on any ongoing acquisition/disposal efforts.

Where applicable, the following real property information requirements must be met prior to transfer of a property to LM.

II. General Information Needed

All the following information should be documented, stored, and available for LM use:

- Identification of authority used to acquire the interests
- Identification of all jurisdictions that exist
- Identification of proprietary, exclusive, or other federal interests, including off-site interests such as easements, licenses, and permits
- Identification of each grantor
- Indemnification granted

III. Budget and Accounting Data

- The budget authority for any area, such as leases, operation and maintenance of improvements, and infrastructures, that will be transferred to LM.
- PILT money
- Integrated facility infrastructure documentation
- MARS record
- Quarterly maintenance

Attachment 1, Real Property Requirements (continued)

IV. Land

All the following information should be documented, stored, and available for LM use:

- Identification of the type of title and the holder of the title (the agency or the United States).
- Request U.S. Army Corps of Engineers or other agency real estate records.
- Identification of where original real estate records are located and whether the real estate record is complete, including acquisition instrument and deeds, withdrawal records and *Federal Register* Notices, title plats, legal descriptions and plats, surveys, and maps
- Identification of outstanding interests, such as out leases or easements, deed restrictions, or non-federal controls or other burdens on the property (such as highway and utility rights-of-way).
- Identification, if applicable, of any federally funded off-site improvements (e.g., roads, traffic lights).
- All unneeded real property in grants and out grants must be terminated prior to transfer.
- Identification of any RCRA/CERCLA transfer restrictions.
- Identification of local government with jurisdiction for the property.
- Realty instruments have been recorded and any zoning or tax issues have been identified.
- Real Property Asset Management (RPAM)-required, 10-Year Plan has been completed.
- Identification of existing land uses, zoning, and proposed land use if available.
- Identification of any subsurface (mineral, oil, gas) rights.
- Identification of any water rights and well permits.
- PILT requests granted or pending.
- FIMS is complete and up to date.

V. Maps, Plats, and Exhibits

All the following information should be documented, stored, and available for LM use:

- Official land surveys, monumentation records, and cadastral surveys records stored and available for use.
- Official site maps, mineral rights maps, water rights maps, well permit maps, easement maps and legal descriptions, oil and gas lease maps, and tribal trust land properly geo-referenced in accordance with state or latitude/longitude coordinates and standards.
- Master title plats, title plats, and county title plats.
- Legal descriptions and recorded data.
- Existing and abandoned utility improvement easements maps.
- Locations of monuments.

Attachment 1, Real Property Requirements (continued)

VI. Mineral Rights

All the following information should be documented, stored, and available for LM use:

- Identification of mineral interests owned by the United States
- Locations of minerals severed from the surface estate
- Locations of any permitted mining operations

VII. Water Rights

All the following information should be documented, stored, and available for LM use:

- Identification of water rights owned by the United States.
- Location of water rights retained by the former owner of the property.
- Location of outstanding water conveyances on the property and information on the easement holders; provide copies of the easements.
- Description of surface water rights.
- Description of the surface water impoundments.

VIII. Well Permits

All the following information should be documented, stored, and available for LM use:

- Identification of well permits that exist for the United States.
- Identification of any state abandonment requirements.
- Identification of the state regulatory authority and point of contact.
- Identification of any off-site permits and access agreements; provide copies of the records and instruments to LM
- Data for FIMS are complete and up to date.

IX. Leasehold Interests:

All the following information should be documented, stored, and available for LM use:

- Identification of any existing leases and expected expiration dates; provide copies of the contracts to LM.
- Identification of any granted leaseholds to others (out grants).
- Data for FIMS are complete and up to date.

Attachment 1, Real Property Requirements (continued)

X. Other Real Property Interests

All the following information should be documented, stored, and available for LM use:

- Identification of any real estate institutional controls, such as deed restrictions, covenants, zoning agreements, or easements.
- Identification of any restrictions on the use of airspace over the site and point of contact if there are any restrictions
- Subordinated rights of others

XI. Infrastructure

All the following information should be documented, stored, and available for LM use:

- Identification of buildings or other structures that will remain.
- Identification of any leasehold interests associated with any buildings and other structures that will remain; if so, provide addresses of the leaseholders and copies of the contract.
- Identification of the costs, restoration requirements, cancellation or termination costs, and time frame for notices.
- Identification of any dam safety requirements or required annual inspections and reports:
  - Power generation systems
  - Treatment systems
  - Fencing
  - Disposal facilities
  - Electrical distribution stations
  - Extraction wells
  - Injection systems
  - Surface water structures (e.g., drainage channels, streams, dams, ponds flow controls, flow diversions)
- Identification of existing utilities that will remain.
- Identification of types and names of service providers (e.g., transmission or service, electric, natural gas, domestic water, sewage).
- FIMS requirements must be met, and applicable fields must be populated, complete, and up to date
- Identification of the FIMS administrator for the property
- Identification of security requirements that will remain or will be needed with the transition.
- Identification of maintenance management system used.

Attachment 2, Post-Closure Benefit Information and Data Needs

I. Pension Plans

Provide a list of current defined benefit plans. The following information is needed for each plan.

A. Financial/Custodian Data

1. Statement of assets
2. Reconciliation of market value of assets from period to period
3. List of benefits paid

B. Actuarial Information

1. Complete table of disability rates
2. Complete table of withdrawal rates
3. Actuarial valuation for each plan
4. Any assumption studies that have been performed in the past 5 years
5. Any other assumptions not explicitly detailed in the actuarial reports
6. The census data used for the actuarial valuations for the most recent plan year

C. Employer Plan Documents

1. With all updated amendments and Summary Plan descriptions for all plans
2. Most recent 5500 filings

II. Health and Welfare Benefit Plans

The following information is needed for each health and welfare plan (such as medical, dental, life insurance, vision and prescription drug) that is currently extended to or continues post-employment and is likely to continue for retirees and/or for other selected former employees post-closure (if different). The types of financial data required will vary based on the plan's funding arrangement, as outlined in the following subsections:

A. Financial Data

1. Fully Insured Plans
   a. Current rates
   b. Rates for the prior 2 plan years
   c. Copies of renewal letters
   d. Claims experience and participation history for the past 2 years (separated by plan)
   e. Premium history for the past 2 years

Attachment 2, Post-Closure Benefit Information and Data Need (continued)

II. Health and Welfare Benefit Plans (continued)

A. Financial Data (continued)

2. Self-Funded Plans
   a. Premium equivalent rates for the past 2 years
   b. Administrative rates for the past 2 years
   c. Reinsurance rates for the past t2 years
   d. Monthly participation history for the past 2 years
   e. Monthly incurred/paid claim data for the past 48 months (separated by plan, and by actives and retirees)

3. All Plans Regardless of Funding
   a. Employee and retiree contribution rates for the past 2 years
   b. Claim utilization reports for the past 2 years

B. Insurance Company Documents

1. Insurance contracts
2. Certificates of Insurance
3. Reinsurance contracts for self-funded plans

C. Employer Plan Documents(including Section 125 document, if applicable, and retiree health care document)

D. Employee Communication Materials

1. Summary Plan Descriptions
2. New hire orientation
3. New hire benefit enrollment (both health and welfare and retirement benefits)
4. Annual benefit enrollment materials and employee contributions
5. Employee newsletters and other regular communication
6. Retiree communications

E. Pension and Health and Welfare Benefit Plans Census Data Elements

1. Status [active, disabled, Consolidated Omnibus Budget Reconciliation Act (COBRA), terminated vested, retired]
2. Employee identification
3. Name
4. Date of birth
5. Sex
6. Date of hire
7. Zip code
8. Salary (base pay only)

Attachment 2, Post-Closure Benefit Information and Data Need (continued)

II. Health and Welfare Benefit Plans (continued)

E. Pension and Health and Welfare Benefit Plans Census Data Elements (continued)

9. Pension compensation [a description of the salary being provided (e.g., W-2 wages plus 401(k) deferrals)]
10. Prior plan year's hours
11. Job description (or title)
12. Employee classification (salaried or hourly)
13. Other employee classification (if applicable)
14. Prior pension plan accrued benefits (if applicable)
15. January 1, 1976, accrued benefit
16. Any supplemental benefits being paid (if applicable)
17. Date of disability, retirement, or COBRA qualifying event
18. Date of pension benefit commencement (if applicable)
19. Monthly pension benefit (if in pay status)
20. Form of benefit (if in pay status)
21. Beneficiary date of birth for pension (if applicable)
22. Medical plan election
23. Medical coverage tier (individual, family, etc.)
24. Dental coverage tier (individual, family, etc.)
25. Vision coverage tier (individual, family, etc.)
26. Amount of basic life insurance

In addition to the documents and data LM needs to collect, LM needs to develop an understanding about what is expected to happen to the plans and the workforce through site closure and beyond. The following questions include some of the questions LM has regarding pension and health and welfare benefit plans:

- Does the site anticipate changing the asset allocation in any of the pension plans from now until closure?
- What baseline date is the site using for site closure? What is the possibility that the actual site closure will be sooner or later?
- Does the site expect to hire any new employees (additional or replacement) from now until closure?
- What turnover pattern does the site expect for the site employees from now until closure (please provide separately for salaried and hourly employees)?
- What salary increases does the site expect from now until closure?
- Does the site expect to implement early retirement incentive programs or any changes to the site pension or health and welfare plans from now until closure ?
- Does the site expect any cost of living adjustments for retirees in the pension plans from now until closure?
- When do terminated vested participants generally start collecting benefits?

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

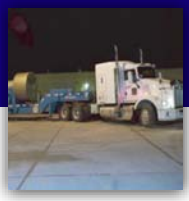
Standard Review Plan (SRP)

Review Plans and Final Reports Module










Technical Framework for EM Projects Critical Decision (CD) Milestone Review and Approval

Working Document

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OFFICE OF ENVIRONMENTAL MANAGEMENT

Review Plans and Final Reports

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REVIEW PLANS AND FINAL REPORTS

This section prescribes the general expectations for preparing a review plan to support planned projected reviews described in the SRP, as well as final reports that document the outcome of review activities. These documents establish a record of the approaches and criteria used in project reviews, provides management with a clear understanding of findings and observations resulting from project reviews, and establish a record for DOE and the contractor to track any necessary corrective actions.

I. REVIEW PLANS

The Review Plan guides the review team in the conduct of the review but it also provides the Project Managers with information necessary to prepare for and support the review process. The Review Plan discussion below provides instructions on how to develop such a Plan. It is intended as a general guide for a Review Team Leader and Team Members in planning and conducting various project reviews required by DOE O 413.3A. The main headers listed below are intended to form the structure of the review plan but each plan should be tailored to the project being reviewed and may not contain a particular section.

a. Introduction/Background

The Introduction/Background should briefly state the primary objectives of the review and describe the project and the facility status that is relevant to the review to be conducted. A brief and concise description of the project includes the planned facility mission, where it is located geographically, the intended processes and function(s) of the facility when complete, and any expected products to be generated by the facility. Facility process descriptions should also include sufficient information on material flows and waste streams. Decontamination and Decommissioning projects should include discussion of the anticipated facility end state and future use of the site.

Relevant project history should be presented to convey the proper context of the project and information that helps reviewers understand the facility being reviewed. This may include interfaces with other site operations and/or facilities being replaced by the new facility project. If the project involves the modification and use of existing buildings and structures, it is important to understand any prior operations and hazardous materials that were involved.

The Introduction/Background section should also describe the relationship of the review team to the project management organization. That is, whether the review is organized by a contractor using contractor resources; commissioned by the local DOE organization; or by a Headquarters sponsor.

b. Purpose

This section presents the reason for and objectives of the project review. This includes the regulations and DOE directives that identify the need for the review and the area(s) being reviewed.

c. Scope

The scope of the project review effort should be defined to provide a focus for review team activities and to aid in selection of review team members. The scope also helps the design or construction contractors prepare necessary materials and briefings that are appropriate to the review scope. This section of the Review Plan should be broken down to describe the topics covered by the review scope, any necessary assumptions or caveats considered by the review team, and project documents that are encompassed within the review (e,g., design documents, supporting safety documents, etc).

The performance objectives and criteria that apply to the review process will also be selected and presented in this section, or attached as an appendix to the Review Plan. These should be based on Appendix A individual Review Modules that are applicable based on specific project characteristics. The rationale for selection should be presented.

d. Review Schedule

The project review schedule should be supportive of the Critical Decision milestones and other reviews scheduled in accordance with DOE O 413.3A. The Review Plan should address the major review team activities supporting the project review and associated dates or durations for completion. At a minimum, the schedule should address the issuance of a review plan, the conduct of the onsite design review, issuance of a draft report for factual accuracy review, and the issuance of a final report.

e. Team Composition and Responsibilities

The members of the design review team and their assigned responsibilities should be identified in this section. The organizational affiliation should also be presented for each individual.

The number and composition of technical and safety disciplines assigned to the team will depend on the type of project being reviewed. The Review Team

Leader must ensure that each team member has the appropriate expertise. A short biography of each team member should be included as an appendix to the Review Plan.

f. Reporting Methods

The section of the review plan should disclose the methods used by the review team to communicate the results of the project review. This includes planned daily out-briefs or other meetings with the design contractor that are planned during the onsite review. It also includes the methods used to document results such as review checklists and the final report.

II. FINAL REPORT

The project review final report documents the approach taken by the review team, lists the strengths, findings, and observations identified during the review, and provides the review results. The report is the product of the review process. Individual team member write ups are provided to the Team Lead for incorporation into a Factual Accuracy Report which is provided to the project organization for review. Once review comments are reconciled, the Team Lead prepares a final report for approval by the official requesting the review.

The Report should include the following sections:

a. Executive Summary

The Executive Summary provides a concise synopsis of the activities conducted during the review, the number of findings, observations, and strengths identified, and a discussion of the most significant issues identified by the Review Team.

b. Introduction

The Introduction provides the Assessment purpose and drivers, organization(s), and the basic process followed during the Assessment.

c. Review Results

The Review Results section provides a summary stating whether the individual review criteria was met and a listing of strengths, findings, and observation identified for each area assessed.

d. Team Composition and Responsibilities

The Team Composition and Responsibilities section lists individual review team members and the area(s) they assessed.

e. Review Results

Upon completion of the project review, team members shall document their review results and determine if review criteria were met. The documentation shall list the records reviewed, personnel interviewed (by position title, not name), and activities observed during the project review. Team members shall provide a clear and concise write up for each Criterion stating what activities the member conducted while evaluating the Criterion and identifying any strengths, findings, and/or observations identified.

Finding – A noncompliance with a requirement. The requirement may be from a DOE Order, or Standard, or from a local DOE directive, or from a procedure or other site document.

Significant observations - Deviations from DOE Guides or Handbooks, EM HQ guidance documents, and other accepted industry practices for which corrective actions will be necessary.

Observation – A weakness or opportunity for improvement that cannot be tied directly to a requirement. Observations can be opinion based.

Strength – A practice that exceed assessor expectations.

In circumstances where a Team member disagrees with the Team's conclusion(s) or a Team Lead decision, the member may document this as a dissenting opinion. The dissenting opinion should include the member's basis for disagreement. If the dissenting opinion is due to a Team Lead decision, the Team Lead shall provide the basis for his/her decision.

Prior to issuing a final report, the Review Team Lead should provide a draft of the report to the assessed organization to review for factual accuracy. The assessed organization should provide written comments to the Team Lead for disposition. All comments should be resolved (e.g. accepted, rejected, etc.) prior to the final report being issued.

Once the factual accuracy comments have been resolved, the Team Lead shall provide the final report official requesting the review for approval and transmittal to assessed organization. Approved final reports shall be formally transmitted to the assessed organization via memorandum which includes the requirement for a corrective action plan (if necessary) within sixty days of report transmittal.