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DOE STANDARD

PLANNING AND CONDUCT OF OPERATIONAL READINESS REVIEWS (ORR)

U.S. Department of Energy
Washington, D.C. 20585

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PLANNING AND CONDUCT OF OPERATIONAL READINESS REVIEWS (ORR)

FOREWORD

1. DOE O 425.1B establishes the requirement to conduct Operational Readiness Reviews (ORRs) or Readiness Assessments (RAs) prior to restart of an existing nuclear facility or startup of a new nuclear facility. It also establishes the responsibilities and authorities of the responsible contractor and DOE elements in the process leading to a new start or restart.

2. This Standard has been updated and revised to reflect the revisions to the ORR Directives. The revisions generally provide increased discretion and clarify the intent of the ORR Directives. Also, the Standard discusses the role of the Readiness Review process in the Safety Management System process mandated by the Secretary of Energy.

3. DOE O 425.1B states, "DOE-STD-3006-2000 provides guidance on approaches and methods approved as acceptable for implementing the requirements of this Order." To achieve consistency, this Standard describes an approach to the conduct of Operational Readiness Reviews and Readiness Assessments for new starts and restarts of DOE nuclear facilities, and provides guidance for conducting the ORRs and developing Operations Office procedures to manage RAs.

4. Following the Foreword, there is a start/restart summary matrix chart outlining the requirements of DOE O 425.1B to conduct ORRs and RAs and defining who the startup authority should be.

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TABLE 1: STARTUP AND RESTART REQUIREMENTS SUMMARY

			Basis for Shutdown			
Hazard Category of Facility being started		New Facility	DOE MGT directed, unplanned shutdown	Extended Shutdown *	Significant Facility Modifications (f)	Shutdown caused by operations outside Safety Basis
HAZARD CATEGORY 1	Authorization Authority	S-1 (a)	Shutdown Official (c)	*6 months SO	SO	Authorization Authority (b)
	Review Type	ORR	ORR	ORR	ORR	ORR
HAZARD CATEGORY 2	Authorization Authority	S-1 (a)	Shutdown Official (c)	*12 months SO (a)	SO (a)	Authorization Authority (b)
	Review Type	ORR	ORR	ORR	ORR	ORR
HAZARD CATEGORY 3	Authorization Authority	SO (a)	Shutdown Official (c)	(e)* OPS Office MGR (a)	OPS Office MGR (a)	Authorization Authority (b)
	Review Type	ORR	ORR	RA (d)	RA (d)	ORR

(a) or Designee by indicated DOE Official.
(b) Official Designated to approve safety basis which was violated.
(c) Secretarial Officer (SO) may designate other Authorization Authority based on specific circumstances.
(d) RA as required by Operations Office procedures.
(e) Time as specified by Operations Office procedures.
(f) Significant as determined by the designed Authorization Authority.

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1.0 SCOPE

1.1 Scope. DOE O 425.1B specifies the conditions and circumstances when an Operational Readiness Review (ORR) or a Readiness Assessment (RA) is required as part of a new start or restart process. This standard provides guidance on the planning and conduct of the ORRs and RAs. This standard also provides guidance for requesting exemptions. The requirements for ORRs and RAs apply both to responsible contractors and to DOE. This standard addresses the requirements and suggests methods and approaches for both.

1.2 Purpose. The purpose of this standard is to describe acceptable methods and approaches to meet the readiness review requirements of DOE O 425.1B. Specifically, this standard describes methods and approaches to:

a. Determine the type of readiness review which is appropriate to the specific facility startup.

b. Develop the breadth and depth (scope) of the ORR or RA to be consistent with the history, hazards, and complexity of the facility starting up.

c. Develop the procedures and conduct an ORR or RA for a startup of a specific activity.

d. Confirm that the facility and /or programmatic activity is physically ready to startup.

e. Confirm that the managers and operators are prepared to manage and operate the facility in the phase in which it is about to startup.

f. Confirm that the necessary infrastructure (procedures, staffing, compliance with DOE Orders, rules, and other requirements, etc.) is in place.

g. Prepare requests for exemptions from the requirements of the DOE O 425.1B

The requirements in DOE O 425.1B are only applicable to startup or restart of nuclear facilities with Hazard Categories 1, 2, or 3. This standard provides acceptable methods and approaches for meeting the specific requirements of that order. DOE O 430.1A, *Life Cycle Asset Management*, also specifies that

prior to operations, operational readiness shall be verified. This standard may also be useful guidance to line managers when specifying methods and approaches for startup or restart of radiological facilities or non-nuclear facilities in accordance with requirements of DOE O 430.1A. DOE line managers are encouraged to consider the procedures in this standard when developing requirements and procedures for startup or restart of radiological or non-nuclear facilities.

1.3 Organization of the Standard. The standard is organized to be useful to both the managers who need a summary and an overview of the ORR and RA processes, methods, decisions, and products as well as the individuals who are responsible for the planning and conduct of the ORR or RA.

1.3.1 Scope. The section discusses the relationship of the Standard with the DOE O 425.1B which specifies the requirements for ORRs and RAs.

1.3.2 Applicable Documents. The section lists several references directly applicable to the methods and processes described in the standard.

1.3.3 Definitions. The section provides the meaning of the terms and statements used in the standard. The description or discussion of the terms may be expanded to be specific to the intended meaning in the standard. The usage in the standard is consistent with the usage in other DOE documents.

1.3.4 General Guidance. The section provides a sequential summary of the actions, responsibilities, decisions, and documents associated with the ORR and RA process. The section is organized in the sequence of the ORR process starting with the type of readiness review required, development of the readiness review plans, achieving readiness, and conduct and reporting of the readiness reviews. The section also contains general information helpful in gaining an understanding of the principles and the expectations of the ORR or RA processes.

1.3.5 Detailed Guidance. The section provides the detailed processes and methods to plan and conduct an ORR or an RA. The section is arranged by organizational responsibilities followed by a sub-section which provide detailed descriptions of each document required as a part of the ORR or RA process. Finally, sub-section 5.10 provides specific information about the RA requirements and expectations while sub-section 5.11 describes the requirements and expectations for alternative procedures which require an exemption from the requirements of DOE O 425.1B.

1.3.6 Appendices. The appendices contain detailed information useful to the individual team members or managers to assist in the preparation of individual documents required during the ORR or RA process:

- Appendix 1 contains a discussion of utilization of the graded approach to assist in defining the scope of the readiness review.

- Appendix 2 contains a listing of the Core Requirements including the relationship of the individual Core Requirements to the Principles of Integrated Safety Management.

- Appendix 3 contains additional information to clarify the intent of some of the Core Requirements.

- Appendix 4 is a writer's guide containing information and examples of required or recommended forms and document content. It is intended to assist team members in development of required documents and in documenting their activities and findings.

- Appendix 5 is a process flow diagram to show the sequence and responsibilities required at each point in the process. The process flow charts also indicate the section of the standard which describes the each step on the diagram.

2.0 APPLICABLE DOCUMENTS

2.1 Government Documents

2.1.1 DOE Orders

a. DOE Order 425.1B, *Startup and Restart of Nuclear Facilities*

b. DOE Order 251.1A, *Directives System Order*

c. DOE Policy 450.4, *Safety Management System Policy*

d. DOE Policy 450.5, *Line Environment, Safety and Health Oversight*

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

f. DOE Order 430.1A, *Life Cycle Asset Management*

2.1.2 DOE Manuals and Handbooks

a. DOE Manual 251.1-1

b. DOE Handbook, DOE-HDBK-3012-96, *Guide to Good Practices for Operational Readiness Reviews (ORR), Team Leader's Guide*.

2.2 Order of Precedence. In the event of conflict between the text of the document and a DOE Order or Rule, the DOE Order or Rule takes precedence. This document does not supersede applicable laws and regulations unless a specified exemption has been approved by the appropriate authority.

3.0 DEFINITIONS

This section provides the meaning intended for the terms and statements used in DOE O 425.1B and this standard. The description or discussion concerning the terms may be expanded or more specific than definitions found in other DOE documents. However, use of the terms and statements in this standard are consistent with definitions provided in other DOE documents.

3.1 Authorization Agreement. A documented basis between the Department of Energy (DOE) and the contractor for high-hazard facilities (Categories 1 and 2), incorporating the results of DOE's review of the contractor's proposed authorization basis for a defined scope of work. The Authorization Agreement contains key terms and conditions (controls and commitments) under which the contractor is authorized to perform work. Any changes to these terms and conditions would require DOE approval.

3.2 Authorization Basis. Safety documentation supporting the decision to allow a process or facility to operate. Included are corporate operational environmental requirements as found in regulations and specific permits, and, for specific activities, work packages or job safety analyses (see safety basis also).

3.3 Breadth. The set of core requirements evaluated by the ORR or RA team during conduct of the readiness review.

3.4 Conclusion. A discussion of the final judgement of readiness and adequacy for a review area, which considers the positive (strengths) and negative (findings) elements.

3.5 Core Requirement: A fundamental area or topic of review evaluated during an ORR or RA to assess whether a facility can be operated safely.

3.6 Corrective Action Plan. A defined and documented strategy for the correction of findings (which defines the deficiency), describes the actions that are be taken, assigns responsibility for the actions, discusses how the actions address and correct the finding, and indicates the dates when the actions will be complete.

3.7 Criteria. Rules and tests against which the quality of performance for a core requirement can be measured. Fundamental criteria are based on DOE Orders, policies, and on other statutory requirements included in contract List A and List B standards or requirements.

3.8 Declaration of Readiness to Operate. See Readiness to Proceed Memorandum.

3.9 Depth. The depth of review relates to the level of analysis, documentation or action by which a particular review objective is assessed. The depth to which different review objectives assessed may vary within an individual readiness review. Depth could vary from a simple records review to a detailed assessment including review of all records, all references, and all involved individuals and physical spaces. The depth is defined in the Implementation Plan prepared by the ORR or RA team.

3.10 Directed Shutdown. An unscheduled termination of program operations or activities directed by contractor management, local DOE officials, or by DOE Headquarters.

3.11 Evaluation/Evaluate. The process to determine the significance or worth of something by careful appraisal or study.

3.12 Facility Shutdown. (1) The situation in which a reactor is taken subcritical either manually or automatically to a safe shutdown condition, or (2) the condition in which a non-reactor nuclear facility ceases program work, or (3) the condition in which a programmatic nuclear explosive or nuclear experimental activity ceases (structure containing the activity may remain operational, i.e., not shut down). In a shutdown condition, a facility must still meet all applicable technical safety requirements and environmental, safety, and health requirements.

3.13 Final Report. A document prepared by the ORR/RA team at the completion of the ORR/RA which describes the results of the ORR/RA. The Final Report contains the methodology used to conduct the review, the conclusions drawn by the team, the findings identified, and a recommendation as to the readiness of the facility being reviewed to start program work. Section 5.9.3 provides additional details concerning the preparation and content of the Final Report.

3.14 Finding. An identified deficiency. Findings may be classified by the ORR team as either prestart or post-start, as defined below.

a. Prestart Finding - A finding that must be resolved before an activity can be started.

b. Post-start Finding - A finding that must be resolved, but may be corrected after the start of the activity. Post-start findings are addressed by a corrective action plan which includes any compensatory measures taken.

3.15 Functional Areas. Discrete groups of related safety and support programs.

3.16 Graded Approach. The process used to determine the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with: (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; (6) the complexity of the weapons-related or research activity; and (7) any other relevant factor.

3.17 Hazard. A source of danger (e.g., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

3.17.1 Hazard Categories. The consequences of unmitigated releases of radioactive and/or hazardous material are evaluated as required by DOE 5480.23 and classified by the following Hazard Categories:

a. Category 1. The hazard analysis shows the potential for significant offsite consequences.
b. Category 2. The hazard analysis shows the potential for significant onsite consequences.
c. Category 3. The hazard analysis shows the potential for only significant localized consequences.

DOE-STD-1027-92, Change Notice 1, and DOE-EM-STD-5502-94 contain additional information on methods and criteria for determination of Hazard Categories.

3.17.2 Hazard Classes. Non-nuclear facilities are categorized as high, moderate, or low hazards based on the following:

a. High - hazards with a potential for onsite and offsite impacts to large numbers of persons or for major impacts to the environment;
b. Moderate - hazards which present considerable potential onsite impacts to people or the environment, but at most only minor offsite impacts, and;
c. Low - hazards which present minor onsite and negligible offsite impacts to people and the environment. Requirements of DOE O 430.1A may apply.

3.18 Integrated Safety Management System. A Safety Management System (SMS) that systematically integrates safety into management and work practices at all levels as required by DOE P 450.4, *Safety Management System Policy*, and other related policies (DOE P 450.5 and DOE P 450.6).

3.19 Non-reactor Nuclear Facility. Those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Included are activities or operations that: (1) produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium; (2) conduct separations operations; (3) conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations; (4) conduct fuel enrichment operations; (5) perform environmental remediation or waste management activities involving radioactive materials; (6) conduct nuclear explosives activities; or (7) perform nuclear experimental activities. Incidental use and generation of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Accelerators and reactors and their operations are not included. The application of any rule to a non-reactor nuclear facility shall be applied using a graded approach.

3.20 Nuclear Facility. Nuclear facility means reactor and non-reactor nuclear facilities.

3.21 Objective Evidence. Any documented statement of fact, other physical condition information, or record (either quantitative or qualitative) pertaining to the quality of an item or activity based on observations, measurements, or tests which can be independently verified.

3.22 Objectives and Sub-objectives. Aims or goals for the readiness of a facility to start and continue to operate safely.

3.23 Operational Readiness Review. A disciplined, systematic, documented, performance-based examination of facilities, equipment, personnel, procedures, and management control systems to ensure that a facility will be operated safely within its approved safety envelope as defined by the facility safety basis. The Operational Readiness Review scope is defined based on the specifics of the facility and/or the reason for the shutdown as related to a minimum set of core requirements. A graded approach is used in defining the depth of the Operational Readiness Review based on these core requirements.

3.24 ORR Implementation Plan. The procedural document by which the ORR is conducted. This document implements the scope and direction approved in the ORR plan-of-action and define the depth of the review. Sections 5.4 and 5.9.2 describe the contents, preparation, and use of the ORR Implementation Plan.

3.25 ORR Plan-of-Action. The document prepared by line management which describes the breadth of the ORR and the prerequisites which must be met to start the ORR. It is the document by which line management defines what will be evaluated by the ORR. Both the Contractor and DOE prepare a plan-of-action. These are submitted to the authorization authority for approval.

3.26 Planned Shutdown. A facility shutdown required to perform scheduled activities (such as programmatic or equipment adjustments, reactor refueling, maintenance, surveillance, tests, inspections, and/or safety upgrades) or for programmatic reasons unrelated to the facility's ability to operate, such as a funding shortfall, is a planned shutdown. Local procedures should define the review requirements for shutdowns of this type. In all cases, if a review is required, the ORR or RA process will be used.

3.27 Prerequisites: A set of specific, measurable actions or conditions identified in the contractor and DOE Plans-of-action that are to be completed prior to the start of the respective ORR or RA. At a minimum, prerequisites are identified for each of the applicable core requirements of DOE O 425.1B.

Additional prerequisites may be established by line management. The prerequisites, when completed by line management, should be expected to bring the activity/operation into a state of readiness.

3.28 Process. A series of actions that achieves an end or result.

3.29 Program Manager. The Headquarters individual, or designee, appointed by and under the direction of a Secretarial Officer, who is directly involved in the operation of a facility under his or her cognizance and who holds signature authority to provide technical direction through the field element to DOE contractors for these facilities.

3.30 Program Work. Work in a reactor or non-reactor nuclear facility that is accomplished to further the goals of the facility mission and/or the program for which the facility is operated. Program work is not accomplished when a facility is shutdown. Program work does not include work that would be required to maintain the facility in a safe shutdown condition, minimize radioactive material storage, or accomplish modifications and correct deficiencies required before program work can recommence.

3.31 Reactor. Unless modified by words such as containment, vessel, or core, reactor means the entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores. Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies, and research, test, and power reactors, is defined as a reactor. All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors. Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions. Critical assemblies may be subject to frequent core and lattice configuration change and may be used frequently as mockups of reactor configurations.

3.32 Readiness Assessment. A review that is conducted to determine a facility's readiness to startup or restart when an Operational Readiness Review is not required or when contractor's standard procedures for startup are not judged by contractor or DOE management to provide an adequate verification of readiness. The scope of the RA is defined on a case-by-case basis in accordance with local contractor and DOE procedures.

3.33 Readiness To Proceed Memorandum (Declaration of Readiness to Operate). The formal document submitted by the contractor which certifies the conclusion that the facility is prepared to start or resume operations. The memorandum may include specific items requiring completion or resolution prior to resumption of program work. Submitting the memorandum is a prerequisite to starting the DOE ORR. Upon completion of the DOE ORR and correction of identified deficiencies, the memorandum is forwarded to the startup authorization authority with recommendation that startup be authorized.

3.34 Restart. The recommencement of program work. Restarts requiring an ORR can occur in operating facilities if the process to be resumed meets the requirements for an Operational Readiness Review. This can be true even if the same program work is on-going in some other portion of the operating facility.

3.35 Review Approach. A description of what the technical experts (team members) will examine and how the examination will be conducted to gather objective evidence that the criteria have been met. The review approach consists of a sampling of documents, hardware, people, and performance. These are alternatively termed Criteria and Review Approaches (CRAs) or Criteria and Review Approach Documents (CRADs).

3.36 Safety Analysis. A documented process to: (1) provide systematic identification of hazards within a given DOE operation; (2) describe and analyze the adequacy of the measures (systems, procedures, and administrative controls) taken to eliminate, control, or mitigate identified hazards; and (3) analyze and evaluate potential accidents and their associated risks.

3.37 Safety Analysis Report. The report that documents the safety analysis for a nuclear facility to ensure that the facility can be constructed, operated, maintained, shut down, and decommissioned safely and in compliance with applicable laws and regulations.

3.38 Safety Basis. The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the Department depends for its conclusion that activities at the facility can be conducted safely. Safety Basis includes hazard classification documents, Safety Analysis Reports (SAR), Technical Safety Requirements (TSRs), and DOE-issued safety evaluation reports (SER), and facility specific commitments made to comply with DOE nuclear safety requirements.

3.39 Safety Evaluation Report. A DOE document that describes the extent and detail of DOE review of a Safety Evaluation Report (SAR) or equivalent analysis report, the bases for approving the SAR (or equivalent), and any conditions of SAR (or equivalent) approval. Approval signifies that DOE has accepted the analysis as appropriately documenting the safety basis of a facility basis for operational controls necessary to maintain an acceptable operating safety envelope.

3.40 Safety Class Structure, Systems, and Components. Nuclear safety structures, systems, and components (SSCs) that are relied upon to protect the safety and health of off-site public as identified by safety analyses.

3.41 Safety Programs. Programs, required by DOE or other regulatory authority or committed to in the contractor's SMS description, that will be adhered to for a scope of work by a facility or site in support of the work.

3.42 Safety Significant Structures, Systems, and Components. Structures, systems, and components (SSCs) that are not designated as safety class SSCs, but whose preventative or mitigative function is a major contributor to defense in depth (i.e., prevention of uncontrolled material release) and/or worker safety as determined from hazard analyses.

3.43 Safety Structures, Systems, and Components. Both safety significant SSCs and safety class SSCs.

3.44 Scope. The overall magnitude of the ORR as defined by the breadth of core requirements selected and depth of evaluation of these core requirements during conduct of the ORR.

3.45 Secretarial Officer. The senior manager within a DOE organization such as Defense Programs (DP), Environmental Restoration and Waste Management (EM), Office of Science (SC), or Office of Nuclear Energy, Science and Technology (NE) who may be an Assistant Secretary of Energy or an Office Director. The Secretarial Officer normally has a designation of "1" (DP-1, EM-1, NE-1).

3.46 Senior Advisor (sometimes identified as Senior Safety Advisors or Senior Nuclear Safety Experts). Senior individuals with significant experience in determination of operational readiness and specific technical expertise who serve as technical assistants and advisors to the ORR Team Leader.

3.47 Senior Operational Readiness Review Team Members. Members of the Operational Readiness Review team which include as a minimum, the Operational Readiness Review Team leader, senior nuclear safety experts, and other supervisory or advisory personnel who draft the Operational Readiness Review Implementation Plan, oversee and review the activities of other team members or materially assist the Operational Readiness Review Team Leader in developing the final Operational Readiness Review report.

3.48 Startup. The initial operation of a facility or process to perform program work.

3.49 Startup Notification Report. A periodic report by each responsible contractor to identify future nuclear facility new starts and restarts—usually those scheduled in the next year. The report identifies the facility and based on the criteria of DOE O 425.1B specifies whether an ORR or a RA is required. For those startups or restarts where neither an ORR or a RA is appropriate by the contractor line management, routine operating procedures should be used for the startup or restart. For facilities requiring an ORR, or RA, the authorization authority is identified. The report is submitted to the authorization authority for approval. The report should receive periodic updates in accordance with Operations Office procedures.

3.50 Startup or Restart Plan. The management plan developed by the responsible contractor that describes the process of deliberate, controlled operations the contractor will follow after authorization to start nuclear operations following an ORR or RA. Appendix C contains additional information on the suggested content of a startup plan.

3.51 Unplanned Shutdown. The termination of program work at a facility for any cause, such as equipment malfunction, personal error, or on shift operator response to indications or a situation that would have had unsafe consequences without shutdown.

3.52 Unreviewed Safety Questions. This is a determination made by examining the following circumstances: (1) temporary or permanent changes in the facility as described in existing safety analyses; (2) temporary or permanent changes in the procedures as derived from existing safety analyses; and, (3) tests or experiments not described in existing safety analyses. On identification of any of the above circumstances, an Unreviewed Safety Question exists if one or more of the following conditions result: (1) the probability of occurrence or the consequences of an accident or malfunction of equipment

important to safety as previously evaluated in the facility safety analyses could be increased; (2) the possibility for an accident or malfunction of a different type than any evaluated previously in the facility safety analyses could be created; and, (3) any margin of safety as defined in the bases of the Technical Safety Requirements could be reduced.

4.0 GENERAL GUIDANCE

4.1 Purpose and Coverage. It is the Department's policy that program work shall not be started or resumed in nuclear facilities until the facility has been brought to a state of readiness to safely conduct that program work and that the state of readiness to operate has been verified (DOE O 425.1B). In some circumstances, the Order requires that an Operational Readiness Review (ORR) be conducted by both DOE and the responsible contractor to provide the verification. Procedures and requirements for the ORR are described in this technical standard. This standard also provides procedures and guidance for conduct of alternative readiness reviews such as Readiness Assessments.

The Operational Readiness Review is an activity to confirm that management has brought the facility to a state of readiness to commence or resume program work. The management effort may include management self-assessment activities in preparation for the ORRs. Once management concludes that readiness has been achieved, this state of readiness is independently verified by the contractor ORR and confirmed by the DOE ORR. Only then will the nuclear facility be authorized to resume program work.

There are two types of ORR, a contractor ORR and a DOE ORR. The DOE ORR is different from a properly executed contractor ORR. The DOE ORR should start with an assessment of the adequacy and accuracy of the contractor ORR. Because the contractor ORR provides the substantial basis for acceptance of readiness, the DOE ORR should include an assessment of the scope of the contractor ORR, and it should include actual verification by a sampling of contractor ORR results (e.g., verification of the conduct of operations by walk-down of procedures, observation of normal and off-normal operations or training evaluations, quizzing of personnel on training material, etc.). The DOE ORR should place significant emphasis on the effectiveness of the contractor's preparations through actual demonstrations of normal operations, abnormal events, emergency drills, etc. Additionally, the DOE ORR should assess the readiness of the responsible DOE line organization(s) to safely manage operations, and the effectiveness of coordination among organizations.

The ORR is intended to confirm that (1) the facility is in a state of readiness to safely conduct operations in accordance with the safety basis; and (2) the management control programs are in place to ensure safe operations can be sustained. At many sites, this equates to mature implementation of the Integrated Safety Management System (ISMS) in conjunction with implementation of the individual facility Authorization Basis. The ORR must be structured to verify both the readiness to safely start operations as well as assess the maturity of the site and facility's programs to sustain and improve these operations.

A foundation for readiness of the nuclear facility is an approved safety basis as defined in approved facility safety documentation, approved environmental documentation, a satisfactory safe working environment, and compliance with DOE Orders and requirements. In many instances, a key element of readiness is an effective ISMS. The ORR team must verify that the necessary approved requirements documentation is in place and that procedures, personnel, and equipment and systems support the approved requirements. It is not the responsibility of the ORR team to approve the foundation documentation—only verify that it is approved and that it has been implemented. Critical to a determination of the facility's compliance with DOE Orders and requirements is verification that a review of the facility's conformance to applicable DOE Orders and requirements has been performed and non-conformance issues addressed.

The breadth of the ORR includes the minimum core requirements provided in DOE O 425.1B. The depth of the evaluation of core requirements is determined according to the situations associated with the shutdown and subsequent outage, magnitude of hazard, and level of complexity associated with the proposed facility operating mode through use of the graded approach. The discussion in the approved plan-of-action will guide the ORR team in the definition of the depth of the evaluation described in the Implementation Plan.

This standard also contains procedures and guidance for Readiness Assessments as well as conditions and expectations for situations where exemption from Order requirements may be appropriate. Sections 5.10 and 5.11 contain specific discussions on these alternative methods for verifying readiness to commence program work.

4.2 Requirements. The following describes the sequence of events and decisions when an ORR is required as part of the startup of new nuclear facilities or restart of an existing nuclear facility. The

criteria in DOE O 425.1B define when an ORR is required as well as the authorization authority for a new start or restart activity.

4.2.1 Determination of ORR Requirements. Periodically (quarterly or as required by Operations Office procedures) each responsible contractor is required to identify all facility new start and restart activities planned for the future. The contractor should recommend an appropriate startup or restart ranging from an ORR to a routine startup or restart. The responsible contractor also proposes the authorizing authority for each new start and restart action. Contractor management should provide justification for the proposed course of action provided. The report from the responsible contractor is the startup notification report.

The DOE Operations Office reviews the responsible contractor's proposal and recommends approval or modification to Headquarters who then approves or, modifies and approves, the contractor's proposal. In those cases when restart authority rests with the DOE Operations Office, the contractor’s proposal should be dispositioned at that level and forwarded to Headquarters for information. Once approved by the appropriate DOE Headquarters authority, the contractor's proposal is provided to the contractor for action and to appropriate internal and external oversight agencies for their information.

4.2.2 Responsible Contractor's ORR Plan-of-Action. Four to six months before the projected date for the contractor's ORR, the contractor prepares and submits for approval the ORR plan-of-action. In the event the requirement for an ORR is identified less than four months before the estimated start, the ORR plans-of-action must be expeditiously developed, reviewed, and approved so that the ORR schedule is maintained. The plan-of-action provides the proposed ORR breadth (Sections 5.1.7 and 5.9.1 discuss methods for breadth definition), the prerequisites for starting the ORR (Sections 4.5a and 5.9.1.2.4 provide details), ORR schedule including estimated start date and duration, the proposed ORR Team Leader, and any other information required by DOE O 425.1B and information unique to the proposed ORR. The responsible contractor's submitted ORR plan-of-action is reviewed by the Operations Office manager or designee and approved or forwarded to the designated authorization authority with a recommendation for approval. A copy is sent to the Office of Environment, Safety and Health (EH-2) for review and comment as well. The designated authorization authority approves the contractor's plan-of-action and returns it for execution with copies to appropriate internal and external oversight organizations.

4.2.3 DOE ORR Plan-of-Action. Following receipt of the responsible contractor's plan-of-action, the Operations Office management organization prepares the DOE ORR plan-of-action. The DOE ORR plan-of-action includes in the breadth all areas appropriate to the responsible contractor plan-of-action plus a thorough review of the DOE management organization for capability to oversee the facility operations to be started. The DOE ORR plan-of-action includes prerequisites (Sections 4.5a and 5.9.1.2.4 provide details), team leader designation, breadth of the DOE ORR (Section 5.4 and Appendices 1 and 2 provide additional details on determination of the breadth), estimated schedule and duration, and additional information required by DOE O 425.1B. The DOE ORR plan-of-action is formally transmitted via management to the appropriate authorization authority with a copy to EH-2 for review and comment. Once approved, the DOE ORR plan-of-action is provided to appropriate oversight organizations.

4.2.4 ORR Implementation Plan (DOE and responsible contractor). The approved plan-of-action is provided to the designated ORR Team Leader. The Team Leader identifies the necessary team membership to conduct the ORR. The Team Leader, with the assistance of the team, develops the Implementation Plan. The Implementation Plan is the plan for conduct of the ORR. It includes the checklists, evaluation criteria, review methodology, qualification requirements for team members, reporting expectations, etc., as necessary, to efficiently execute and report the results of the ORR. Section 5.9.2 describes the Implementation Plan in more detail.

4.2.5 Achieving Readiness. The responsible contractor line management takes action to bring the facility into a condition of readiness to start or resume operations. As a part of that activity, management self-assessment (MSA) activities may be appropriate. The responsible contractor effort to achieve readiness may be conducted in accordance with a project management plan, startup plan, or other project management document. Similarly, DOE line management also achieves readiness to oversee contractor operation. A management self assessment of DOE line management, including management programs to oversee contractor operations, may be appropriate.

4.2.6 Responsible Contractor ORR. Once contractor line management has determined that readiness has been achieved by meeting all of the prerequisites specified in the approved responsible contractor ORR plan-of-action, the contractor ORR is conducted and reported in accordance with the responsible contractor ORR Implementation Plan. When prestart findings from the contractor ORR have been

resolved as described in Section 5.9.4.1, the contractor prepares and forwards to the Operations Office the Readiness to Proceed Memorandum described in Section 5.9.4.

4.2.7 DOE ORR. Following receipt of the responsible contractor's Readiness to Proceed Memorandum, the Operations Office manager or designee concurs in the contractor's readiness, verifies DOE management readiness including meeting the DOE prerequisites in the DOE POA, and recommends to the authorization authority that the DOE ORR be conducted. At the direction of the authorization authority, the DOE ORR is conducted and reported in accordance with the DOE ORR Implementation Plan. The DOE ORR includes a detailed review of the contractor's ORR plus other performance assessments in accordance with the approved scope. Following completion of the DOE ORR and resolution of prestart findings, DOE management recommends to the authorization authority that startup approval be granted.

4.3 Readiness Assessments. DOE O 425.1B requires that a Readiness Assessment (RA) may be required whenever an ORR is not required to verify readiness to resume program work. The Order requires the RA be conducted in accordance with Operations Office and contractor procedures which should also specify when an RA is required. The Order further states that guidance in this standard provides accepted methods and approaches for use in preparation of the Operations Office and responsible contractor's procedures. Section 5.10 discusses Readiness Assessments including provisions which should be included in the local procedures. Many principles of the ORR process apply to the RA. A well defined graded approach is important to ensure the effort is adequate to verify readiness without being excessive in terms of time or resources. It is particularly important that the individual circumstances concerning each restart be carefully considered when defining the number and details of the RA.

4.4 ORR Oversight. Throughout the ORR process various Headquarters, Operations Office, DOE organizations and external oversight organizations may become involved in the process. To ensure that proper liaison occurs, documentation from each step in the process must be provided to the appropriate internal and external oversight groups for information and comment. In most cases, the documentation is provided after approval by the appropriate management official. It must be stressed, however, that all information must be provided in a timely manner if all organizations are to be able to execute their responsibility without delaying critical steps in the process. Frequent liaison must occur between management at each level and oversight organizations at each level, both internal and external, to ensure

that all responsibilities and commitments are fulfilled. Transmittal of DOE documents to agencies outside of DOE must follow established procedures.

4.5 General Comments.

a. The prerequisites for starting a specific ORR must be specified in the DOE and responsible contractor plans-of-action as required by DOE O 425.1B. The specifics vary with each ORR, as discussed in Section 5.9.1.2.4, but the basic principle is that the responsible contractor ORR shall not commence until management has determined the facility is ready to operate. The DOE ORR shall not commence until the responsible contractor has reported in writing its readiness to commence operations and until DOE management is ready to oversee the operations. The specific prerequisites identified in the plans-of-action may refer to phases of the startup process, conditions of the project management plan, specific consent or Compliance Agreements or Implementation Plan status, etc., in order to quantify the method to meet the basic principle of readiness. Prerequisites should be specific and verifiable. The DOE plan-of-action should contain specific prerequisites that, when completed, provide confidence that DOE is ready to oversee contractor operations that are about to be started.

b. The responsible contractor and DOE shall conduct their respective ORRs only when the approved prerequisites have been achieved. However, there may be circumstances or events, such as periodic Emergency Preparedness drills or complex system testing, when the review team may monitor the event rather than cause a similar event to occur during the period of the review. This early review is appropriate. The activity must be documented in the report of the ORR. It is also appropriate for the ORR teams to conduct pre-ORR activities necessary to gain a familiarization, understanding, and qualification necessary to prepare the ORR Implementation Plan and conduct the ORR prior to prerequisites being met.

c. ORRs shall be conducted by personnel qualified in the technical matters involved. The number of ORR team members varies with the scope of the ORR and the size and complexity of the facility. The senior members of an ORR shall not be from offices assigned direct line management responsibility for the work being reviewed by the startup or restart authority: any exceptions require approval of the startup or restart authority. All ORR team members must have demonstrated

assessment expertise in addition to technical expertise. No ORR team member shall review his or her own work or that for which they are responsible.

d. As a minimum, the DOE and responsible contractor ORR reports shall be maintained in auditable form. This should include the ORR finding closure records.

e. The contractor and DOE readiness review process must have a provision to record and retain lessons learned for future use. Lessons learned should be documented in the ORR report.

f. The process flow diagram in Appendix 5 depicts the sequence of requirements to achieve startup authorization. The diagram includes a reference to the Section(s) of the ORR standard that describe the requirements of each step or element.

4.6 Exemptions. DOE O 425.1B specifies that the exemption provisions of DOE O 251.1 and DOE M 251.1-1 are applicable. Obtaining an exemption to ORR requirements might be appropriate in those situations when a short duration, one-time activity is to be conducted for which the requirements for an ORR are not warranted. Examples of this situation include one-time, unique operations to clean out systems or components incident to deactivation and decommissioning (D&D) or short duration actions necessary to support national commitments in unusual circumstances. The justification for exemption should be prepared by the responsible contractor and reviewed or approved on a case-by-case basis in accordance with DOE M 251.1-1. The exemption request should define the process to confirm readiness to safely start the operations and to ensure that the operation will be conducted with the degree of safety warranted by the hazards and risks of the process being conducted. The exemption request should define compensatory measures such as continual supervisory or DOE presence during operations to be taken to assure safety. The exemption request should identify the activities to be taken to assure readiness of personnel, procedures, and structures, systems, and components to safely conduct the operation. The exemption request should also specify the methods of review to verify readiness has been achieved. The justification to conduct operations under these specified conditions is provided to EH for their independent review. When the exemption is to extend beyond the time requirements of DOE O 425.1, section 4.a (1), the exemption request to authorize an RA in lieu of an ORR should provide justification for approval and describe the scope of the proposed Readiness Assessment to be conducted.

5.0 DETAILED GUIDANCE

5.1 Roles and Requirements for Contractor Operational Readiness Review. Most responsible contractors have developed procedures to manage the readiness process. This section is intended to describe the recommended content and attributes of an ORR program and organization. It is anticipated that most contractors will require only minimum modifications to their procedures to achieve the intent of this standard and meet the requirements of DOE O 425.1B, Attachment 1, "Contractor Requirements Document."

5.1.1 Summary of Contractor Operational Readiness Review (ORR) Process. The contractor ORR shall focus on the readiness of all hardware, personnel, procedures, and compliance with the applicable requirements.

a. The purpose of the contractor's ORR is to confirm that nuclear facilities being started up or restarted:
   - Are constructed in accordance with the approved design;
   - Can be operated safely;
   - Will be or are operated, maintained, and supported by trained and competent personnel;
   - Are designed and operated in conformance with applicable DOE Orders and regulatory requirements;
   - Will be or are operated so that no undue risk to employees, the public, or the environment results; and
   - All of the above items are properly and adequately documented.

b. The foundation for readiness of the nuclear facility is a DOE approved safety basis, approved environmental documentation, a satisfactory safe working environment, and compliance with DOE Orders and requirements. The Authorization Agreement may be an effective compilation of necessary documents. The ORR must confirm that necessary, approved, requirements documentation is in place and that procedures, personnel, equipment, and systems support the approved requirements. It is not the responsibility of the ORR to approve the foundation documentation—only to verify that it is complete, approved, and implemented as required by core requirements of DOE O 425.1B. Critical to a determination of compliance with DOE Orders and other contractual standards is a robust standards management process at the site and facility. Under most circumstances, the

Integrated Safety Management System includes a standards flowdown and implementation element that will be evaluated during the ORR.

c. The contractor's ORR should provide a structured and independent appraisal of the facility's readiness to startup/restart. The ORR is a confirmation that line management responsible for the facility has successfully achieved a state of readiness to commence facility operations. The ORR should not be used as a management technique to achieve a state of readiness to commence facility operations.

An effective ORR process provides assurance that these objectives are accomplished and documented. The confirmation of these objectives is accomplished by performance-based evaluations, which include (but are not limited to) review of documentation, field observations, interviews, observation of training evolutions, integrated system checkouts or cold run demonstrations, walkdowns of procedures, etc.

5.1.2 Responsible Contractor Startup Notification Report. Periodically as specified by Operations Office procedures (recommended to be quarterly), the responsible contractor should develop a startup notification report or change to an existing report that identifies all known facility new starts and restarts. The report identifies the facility, specifies whether an ORR or a readiness assessment is required to verifies readiness to commence or resume operations. The remarks should describe the basis for the recommended actions based on the requirements in DOE O 425.1B. For the Startup Notification Report (SNR) to be an effective tool for managing the startup and restart process and assuring agreement in the process between the contractor and the DOE, procedures governing these reports should contain the following elements:

- An SNR is submitted periodically by the contractor that updates information from a previous period for startups/restarts that have not yet occurred and adds information for each startup/restart that has been identified since the last report. The SNR should project startups/restarts at least one year ahead. The purpose is to establish early and at the appropriate level (the authorization authority) the appropriate review methodology for the startup/restart. Changes late in the process routinely lead to delays and additional problems.

- Minimum information to be included in the SNR for each startup/restart should include a description of the facility or program work; reason for non-operation (e.g. maintenance or modification outage, no program work, new facility, shutdown for safety concerns, etc.); the approximate date operations

were last conducted (for restarts) and the projected date for the startup; proposed type of readiness review; basis or justification for proposed type of readiness review; proposed startup/restart authority. This information allows for an informed decision to be made by DOE, as well as a confirmation that the requirements are understood and implemented.

- Each periodic SNR should be reviewed and approved by the DOE field element manager. In those cases when the startup authority resides with the Program Secretarial Officer (PSO), the field element manager should comment and make a recommendation regarding approval. This assures agreement at the appropriate level for the startup decision, thus reducing the possibility of last minute changes of direction, which are quite costly.

- Each periodic SNR, including the field element comments and actions, should be forwarded to the cognizant PSO, site Lead Program Secretarial Officer (LPSO), and EH-2. This provides the information necessary for the PSO, LPSO, and EH-2 to execute their respective oversight functions.

- Contractor readiness review action to start or restart operations should not commence until the DOE startup or restart authority has approved the proposed readiness review process. Every startup or restart of a nuclear operation, other than routine resumption of operations after short, planned interruption, should be included in the SNR. These startups/restarts, requiring review, should be started/restarted using an ORR or properly scoped RA as appropriate. Other routine resumptions of operations can be conducted without a readiness review using normal contractor procedures for the facility or activity. Contractor routine procedures should not be developed for the purpose of avoiding a properly scoped Readiness Assessment. The RA process is flexible, yet assures the minimum attributes needed to provide assurance to the DOE that work will be conducted safely.

- In those cases when a startup or restart is identified that will occur within less than the period of the latest SNR, a separate (or addendum) SNR should be provided to ensure timely agreement on the details of the readiness review process for that restart.

5.1.3 Responsible Contractor Operational Readiness Review Plan-of-Action. For new starts and restarts requiring an ORR, the responsible contractor management should provide an ORR plan-of-action that specifies the intent to conduct an ORR and briefly describe the proposed ORR process to the DOE.

The plan-of-action should clearly delineate management responsibilities, authority, and accountability for the ORR (as specified in the DOE O 425.1B) and include the following:

- Notice of the intent to conduct an ORR;
- Identification and description of the facility;
- Team leader;
- Prerequisites;
- Define the breadth of the review;
- Estimated start date(s) of the review; and,
- Estimated time needed to conduct the review.

5.1.4 Responsible Contractor ORR Implementation Plan. Consistent with the breadth defined in the ORR plan-of-action and the specific facility involved, a structured review plan should be prepared and implemented that identifies all of the necessary criteria and review approaches required for the determination of readiness to safely startup and operate the specified facility. The Implementation Plan defines the ORR depth to be consistent with the breadth and conditions of the restart. If a previous ORR has been completed for the facility being reviewed, the ORR Implementation Plan and subsequent review should stress the operations that have changed since the last review as well as the effectiveness of corrective actions for any findings. The ORR Implementation Plan is described in Section 5.9.2.

5.1.5 Contractor Operational Readiness Review Team. The overall responsibility of the ORR team is to examine the aspects of the activity under review and assure themselves, management, and the DOE that the equipment, procedures, and personnel associated with the activity are ready for startup and safe operation. To ensure independence, the ORR teams shall not include as senior members (including team leader) individuals who are from offices assigned direct line management responsibility for the work being reviewed by the startup or restart authority: any exceptions require approval of the startup or restart authority. Additionally, no ORR team member shall review his or her own work or work for which they are directly responsible.

5.1.5.1 Contractor ORR Team Leader. This is a senior individual with the necessary qualifications for managing and conducting the ORR. The basis of the qualifications should include:

- Technical familiarity with the activities and functional areas being reviewed;
- Previous performance-based review experience or training;

- Demonstrated leadership and managerial skills; and
- Operational Readiness Review experience, or formal training.

The ORR Team Leader is responsible for overseeing the ORR process, including:

- Defining ORR team membership;
- Preparing and approving the ORR Implementation Plan;
- Planning, coordinating and conducting the ORR;
- Preparing and approving the ORR Final Report;
- Estimating the level of effort and schedule requirements;
- Establishing ORR objectives and milestones;
- Compiling or acquiring access to all necessary background information (e.g., description of process equipment and control measures); and,
- Acting as the team interface with management.

A key responsibility of the Team Leader is selection and qualification of the team members. Each team member should have the following qualifications, as defined and verified by the Team Leader:

- Technical knowledge of the area assigned for evaluation. The knowledge should include experience working in the technical area.
- Knowledge of performance-based assessment processes and methods. This knowledge may be gained through experience as an auditor or inspector or it may be gained through training and evaluated as acceptable by the Team Leader.
- Facility specific information which may be gained through a combination of required reading and facility tours and presentations.
- Independence in that no team member may review his/her own work or work for which he/she was the responsible manager.

The Team Leader shall ensure that the ORR records contain sufficient information to certify the qualification of team members. This information would normally be provided through individual resumes, required reading, and training records. Appendix 4 includes an example form for use to consolidate the required information.

The extent of the Team Leader's responsibilities may require the individual to be formally released from other duties. The ORR Team Leader should be responsible for keeping management informed of the team's progress and findings.

The *Guide to Good Practices for Operational Readiness Reviews, Team Leader's Guide*, DOE-HDBK-3012-96, has been developed to provide information useful to an ORR Team Leader in preparation and conduct of an ORR or Readiness Assessment. The handbook contains a discussion of the process for preparation and conduct of the review. It also contains a lessons learned section which is a compilation of the lessons learned from the first several years of conducting ORRs. The handbook is a useful guide for both experienced team leaders as well as those with less experience. In addition, the DOE Internet ORR Home Page contains many examples and lessons learned that may be of assistance to an ORR Team Leader. This page can be accessed at http://www.dp.doe.gov/CTG/RESOURCE/orr/default.htm.

5.1.5.2 ORR Team Members. The overall responsibility of the ORR team is to examine the aspects of the activity under review and to assure themselves, management, and the DOE that the equipment, procedures, and personnel associated with the activity are ready for startup and safe operation.

The ORR team may consist of plant personnel or external experts (company or contractor) who have been assembled at the request of the ORR Team Leader. The size and expertise of the ORR team depends upon a number of factors including the complexity of the activity being reviewed, schedule requirements, and the scope of the review. The ORR review team shall include at least one member with qualifications (as defined in section 5.1.5.1) to assess each core requirement identified in the ORR plan-of-action.

Representatives from operations, environment and regulatory compliance, safety, engineering, technical, and quality assurance organizations associated with the activity but not directly responsible for it may be selected as team members. An individual's knowledge of the particular systems, processes, safety documentation, or facility, as well as knowledge of the ORR process should be considered.

Team members are required to conduct a broad range of tasks including (but not limited to):

- Assisting, as requested, the Team Leader and senior members in preparation of the Implementation Plan;
- Developing acceptance criteria/performance objectives and related lines of inquiry for each review objective;
- Reviewing "as-built" drawings and other applicable procedures and documents;
- Compiling supporting documentation;
- Providing a determination that the activity complies with applicable environmental requirements and federal and state laws and regulations;
- Conducting the ORR in accordance with ORR criteria/performance objectives as assigned in the ORR Implementation plan or by the ORR team leadership;
- Conducting and reflecting the evaluation within the context of the principles and functions of Integrated Safety Management;
- Concurring with the determination of operational readiness and the conclusions presented in the ORR report in the team members area of assessment;
- Submitting completed certification documentation for review and approval;
- Preparing supporting or special reports;
- Working with other ORR team personnel to ensure timely resolution of the checklist items; and,
- Assisting, as requested, the Team Leader and senior members in preparation of the ORR Report.

5.1.6 Responsible Contractor Oversight Organizations. The level of participation of the responsible contractor's Oversight Organizations (e.g., Safety, Quality Assurance, Environment) in the ORR process depends on the individual contractor's organization and the scope of ORR being performed. It is recommended that members from the contractor's Oversight Organizations participate in the readiness review process as ORR team members. If other internal reviews are essential to achieving readiness of the facility, the reviews should be completed as a prerequisite to the contractor's ORR. For example, if security is an element of concern, the ORR should confirm that the operation can be safely conducted in the presence of the appropriate security force and that the security force is trained to function in the presence of the hazards associated with the operation. All confirmation of readiness of the security plans and personnel should be prerequisite to the ORR.

5.1.7 Contractor's Determining the Scope of the ORR. The scope (breadth and depth) of the ORR should include the identification of the processes and systems, documentation, and management controls

(including procedures, personnel, and programmatic functions). The functional areas to be assessed during the ORR should be identified. A graded approach can be used as part of the process to determine the depth to which each core requirement will be reviewed. Appendix 1 of this standard contains a discussion of the graded approach.

A unique, first-of-a-kind, or complex activity should involve a review with a more extensive scope than a routine restart of an existing activity. This scope will be affected by the facility's size, complexity and degree of independence from site support. Attention should be given to the interface between new activities and existing functions.

The contractor ORR plan-of-action described in Section 5.9.1 specifies the breadth of the ORR. The ORR Implementation Plan should specify the scope including the breadth and depth.

5.1.8 Achieving Readiness. The responsibility for achieving a state of readiness to conduct safe operations resides solely with the line management of the facility or programmatic line management for weapons or nuclear material programs. The Core Requirements described in DOE O 425.1B provide a summary of the critical issues that should be considered in preparation for operations. In general terms, readiness must be established in the areas of personnel (training, proficiency, numbers, etc), equipment (safety and process systems operational), and programs (safety basis implementation, operational formality, maintenance, ISM, quality, etc). Preparations have a great possibility for success when specific prerequisite actions are established associated with these areas. The requirements to spell out these prerequisites are contained in DOE O 425.1B. Establishment of these prerequisites and verification of their completion both guide the process of achieving readiness as well as contribute greatly to its success. A critical ORR success factor is the rigor with which line management determines that the prerequisites have been met and readiness has been achieved. A robust line MSA program, while not a required action, has been a key element in the ability of line management to achieve readiness. Frequently, when an MSA is not conducted, the ORR is not successful the first time.

5.1.9 Certification of Readiness: The contractor ORR procedures (also applicable to RAs) should include a provision that prior to starting the independent Readiness Review (ORR or RA), line management must certify that all prerequisites specified in the plan of action have been met. (A manageable list of open items may exist, as discussed in section 5.9.4.1 at the time the contractor readiness review starts).

5.1.10 ORR Evaluations. The ORR team should conduct performance-based assessments that include observing and documenting the responses of operating and support program personnel to normal and off-normal events as demonstrated by drills, preoperational tests and exercises. In addition, field assessments should be conducted to verify that field configurations match the applicable supporting documentation. The ORR team should also conduct interviews with personnel, including management, to evaluate their readiness to conduct operations. The ORR Implementation Plan guides the evaluations.

The ORR evaluations should place particular emphasis on structures, systems, and components that are safety related (relevant to public and worker safety and health) or of particular importance to the safety of the planned operation of the activity. The results of these evaluations shall be included in the ORR report.

DOE Operations Office or Area/Site Office personnel should observe and evaluate the responsible contractor ORR process. It is therefore important that the ORR process be open and defined to permit the DOE oversight. Team meetings should be informative both for the benefit of the team as well as DOE oversight. Interviews and record reviews as well as evolutions and drills should be scheduled in a manner to support openness. The ORR Team Leader should coordinate with DOE oversight personnel to facilitate their responsibility to observe and evaluate the contractor ORR.

Documentation of the methodology, criteria, and results of the responsible contractor ORR assessment is important to the credibility of the review and the foundation for the follow-on DOE ORR. The value of the review depends in large part on the record of the ORR to be persuasive that it was thorough in execution as well as adequate in scope (breadth and depth). Section 5.5 and Appendix 4 of this standard provide additional information on recording the results of the ORR.

5.1.11 ORR Final Report. An ORR Final Report shall be prepared. The Report should contain a brief summary of the review activities, the conclusions reached, the basis for those conclusions, and the findings identified. The ORR Final Report may also identify observations that would not impact startup, restart or shutdown but, if corrected, could lead to excellence in operations. The ORR Final Report shall make a conclusion as to whether startup or restart of the facility can proceed safely. In addition, there shall be a statement in the ORR Final Report as to whether all identified non-compliances or schedules for gaining compliance with applicable DOE Orders, directives, and Standards/Requirements Identification Documents as listed in the contract List A/List B have been identified in writing; have been

formally approved; and, in the opinion of the Operational Readiness Review team maintain adequate protection of the public health and safety, worker safety, or the environment.

The ORR Final Report should include a section describing the lessons learned during the ORR, including a discussion of both the process and the technical issues identified. Section 5.8 of this standard further discusses lessons learned.

The ORR Final Report should include a section that provides the ORR team members the opportunity to discuss differing professional opinions, non-judgmental general comments, and observations. The ORR Final Report is described in more detail in Section 5.9.3.

5.1.12 Contractor Declaration of Readiness to Proceed. Once the contractor ORR process has been completed, the contractor should develop an action plan which provides the methodology and the schedule for resolution of the findings from the ORR. Prior to forwarding the Readiness to Proceed Memorandum to DOE, the prestart findings shall be resolved and the action plan, including schedule of completion for the remaining findings, should be prepared. DOE will not begin the DOE ORR until the contractor's Readiness to Proceed Memorandum has been received and accepted. Once the DOE ORR process has been completed and all DOE findings and comments are satisfactorily resolved, formal approval to start the facility is granted in accordance with the requirements approved in the ORR plan-of-action. The Readiness to Proceed Memorandum is described in more detail in Section 5.9.4.

5.2 Roles and responsibilities for the DOE Field Activities including Area Offices and Operations Offices. The following items are a compilation of the responsibilities of the Operations and Area Offices in the execution of the new start and the restart readiness review process. Each action or responsibility is described in more detail elsewhere in this standard or in DOE O 425.1B. The purpose of this section is to collect the applicable requirements in one place. The unique circumstances of the individual situation determine the specific applicability of any individual requirement.

5.2.1 DOE Prepares Implementing Procedures. Prepare implementing procedures as necessary to carry out the requirements of the readiness review process (both ORR and RA) in accordance with the requirements of DOE O 425.1B and the guidance of this standard. In those cases where the Operations Office manager intends to delegate the decision authority for specific actions or individual

circumstances, that delegation should be specified in the implementing procedures to be provided by formal letter or memorandum.

5.2.2 DOE Response to Contractor's ORR Startup Notification Report. DOE Operations Office management should review and forward the report to the Secretarial Officer via Headquarters management. The forwarding endorsement should recommend approval or changes to be included prior to approval.

- Each periodic SNR should be reviewed and approved by DOE Field Office Management. In those cases when the startup authority resides with the PSO, the Field Office Management should comment and make a recommendation regarding approval. This assures agreement at the appropriate level for the startup decision, thus reducing the possibility of last minute changes of direction, which are quite costly.

- Each periodic SNR, including the Field Office comments and actions, should be forwarded to the cognizant PSO and site LPSO. This provides the information necessary for the PSO, LPSO, and EH-2 to execute their respective oversight functions.

- Contractor readiness review action to start or restart operations should not commence until the DOE startup or restart authority has approved the proposed readiness review process.

5.2.3 DOE Review and Approval of Contractor's ORR Plan-of-Action. Review and approve, or review and forward for approval, the responsible contractor's ORR plan-of-action.

5.2.4 DOE Prepares the ORR Plan-of-Action. Prepare the ORR plan-of-action for each nuclear facility new start and restart for which an ORR is required. The responsible contractor's ORR plan-of-action or the approved restart plan (when utilized) should provide the starting point for the DOE ORR plan-of-action. The DOE plan-of-action should include prerequisites that assure readiness of DOE programs and personnel to oversee contractor operation. When a DOE RA is required, DOE must also prepare a properly scoped plan-of-action.

5.2.5 DOE ORR Preparation Support. Support preparation of the DOE ORR in accordance with the provisions of the ORR plan-of-action. If the ORR Team Leader is from the Operations or Area Office,

support the preparation and planning for the ORR including preparation of the DOE's ORR Implementation Plan. Provide support for conduct of DOE ORRs.

5.2.6 DOE Oversight of Contractor Activities. Provide day-to-day oversight of the responsible contractor's activities to achieve and verify readiness to conduct operations including review of the contractor ORR report and prestart finding closure plans and closure documentation. Through this day-to-day oversight, the Operations Office management is able to provide knowledgeable recommendations concerning responsible contractor's actions and proposals.

5.2.7 DOE ORR Preparation. Support the preparation and self assessment of the DOE Operations Office and Area Office programs and personnel as required by the approved DOE ORR plan-of-action and DOE ORR Implementation Plan. Achieving readiness for DOE to oversee contractor operations is an important action necessary to support contractor startup.

5.2.8 DOE Review of Contractor's Readiness to Proceed Memorandum. Review and take appropriate action on the responsible contractor's Readiness to Proceed Memorandum. If the Operations Office manager is the authorization authority, he or she grants authority to conduct the DOE ORR. For other new starts and restart, when satisfied of the readiness of the facility and the readiness of the Operations Office management personnel and procedures to oversee contractor activity, the Readiness to Proceed Memorandum is forwarded to Headquarters recommending the DOE ORR be started.

5.2.9 DOE Endorsement Expectations. DOE line management responsible for oversight of contractor operations should prepare an endorsement to the Readiness to Proceed Memorandum as a part of forwarding it to the restart authority. The DOE line management endorsement should discuss two important elements:

- DOE line management assessment of the readiness of the contractor to commence operations. This assessment should be based on the day-to-day observation of contractor activities and an assessment of the adequacy of the contractor ORR and corrective actions.
- Readiness of DOE line management to oversee contractor operations following startup including meeting prerequisites and core requirements in the DOE POA. The basis for the conclusion, including the results of any DOE line management self-assessments conducted in anticipation of startup should be included in the endorsement.

5.2.10 Conduct DOE ORR. The DOE ORR team conducts and prepares the report of the DOE ORR in accordance with the Implementation Plan.

5.2.11 DOE Concurrence Process. When the DOE ORR is complete and all prestart findings are closed, concur in the status of prestart findings and recommend to the appropriate decision official that start of operations be authorized. In the cases when the Operations Office manager has been designated as the authorization authority, he or she will authorize restart and inform the Secretarial Officer.

5.2.12 DOE Prestart Findings Closure Process. Evaluate the responsible contractor's prestart finding closure process and verify closure of DOE ORR prestart findings as designated by the startup or restart authority. To verify closure, support may be requested from the DOE ORR Team Leader or members but remains a line management responsibility. DOE line management verify adequacy of corrective action plans for all findings from the DOE ORR.

5.2.13 DOE Informs the Contractor of Authorization to Start Operations. Inform the responsible contractor when authorization to start operations has been granted by the authorization authority designated in the ORR plan-of-action.

5.3 Roles and responsibilities for DOE Headquarters. This section is divided into two parts. The first (5.3.1) describes the roles and responsibilities of DOE Headquarters Line Management personnel. The second part (5.3.2) describes the roles and responsibilities of the DOE Headquarters Independent Oversight personnel (Office of Environment, Safety, and Health). Many of the requirements discussed below are also included in the Functions, Responsibilities, and Authorities Manual (FRAM).

5.3.1 Headquarters DOE Management. The following items are a summary of the responsibilities of the Secretarial Officer. The specific items are further defined in other sections of this standard or in DOE O 425.1B. The summary provides a listing that responsible managers can use to verify that all necessary steps and decisions have been considered.

5.3.1.1 Obtain Secretary of Energy Approval. The Secretarial Officer must gain S-1 approval for startup or restarts of nuclear facilities when S-1 is the authorization authority.

5.3.1.2 Implementing Procedures. Prepare implementing procedures as necessary to carry out the requirements of the readiness review process in accordance with the requirements of DOE O 425.1B and the principles of this standard. Where the Secretarial Officer intends to delegate the approval responsibility for specific actions or individual circumstances, the delegation should be specified in the implementing procedures to be provided by formal letter or memorandum. These implementing procedures may be included in the FRAM.

5.3.1.3 Approve Responsible Contractors Startup Notification Report. This report should be received periodically from each responsible contractor with recommended actions by the Operations Office manager. DOE Headquarters management should receive and approve it, or approve with modifications. Copies of the approved report are returned to the responsible contractor via the Operations Office with additional copies sent to all interested internal and external oversight organizations. When restart authority is delegated to the field, responsible headquarters line managers should review the SNR for information. This review is one element of headquarters oversight.

5.3.1.4 Approve the ORR Plan-of-Action. Each new start or restart requires both a contractor and DOE ORR plan-of-action. Since each new start or restart is unique, the plan-of-action specifies the details of the new start or restart process based on the specific circumstances and in accordance with DOE O 425.1B. The authorization authority is designated in the SNR.

5.3.1.5 Distribute ORR Plan-of-Action. The approved ORR plans-of-action are the basis for ORR activity in the restart or startup process. It must therefore be distributed to all interested individuals and organizations.

5.3.1.6 DOE ORR Preparation Support. Support preparation of the DOE ORR in accordance with the provisions of the ORR plan-of-action. If the ORR Team Leader is from Headquarters, support the preparation and planning for the ORR including preparation of the DOE ORR Implementation Plan. Provide support for conduct of the DOE ORR. Observation of the ORR process in the field as well as review of the ORR reports should be one element of headquarters oversight.

5.3.1.7 Authorize Start of DOE ORR. The designated authorization authority reviews the responsible contractor's Readiness to Proceed Memorandum and contractor ORR report, including the Operations Office endorsements and if acceptable, grant approval to commence the DOE ORR.

5.3.1.8 DOE ORR Support. Support the DOE ORR evaluation of Headquarter's programs and personnel as required by the approved DOE ORR plan-of-action and DOE ORR Implementation Plan.

5.3.1.9 Grant Approval to Start or Restart Operations. The designated authorization authority reviews the results of the responsible contractor's and DOE ORRs and when satisfied that all prestart findings have been resolved, grant permission to start or resume operations.

5.3.1.10 Keep Responsible Parties and Organizations Informed. Throughout the process, it may be necessary to provide copies of plans and reports or briefings to appropriate organizations. The Secretarial Officer planning for each specific restart or startup must evaluate these needs and requirements and ensure they are properly executed.

5.3.1.11 Management Self-Assessment. Conduct an MSA of the ORR process as required by DOE 414.1/ P 450.5/M411.1-1A (FRAM).

5.3.2 Independent Oversight Organizations. DOE O 425.1B, Section 5.c specifically indicates that DOE independent oversight of the Operational Readiness Review and Readiness Assessment process is the responsibility of the Office of Environment, Safety and Health. To assure that the startups and restarts of DOE nuclear facilities proceed in a timely fashion it is incumbent upon the contractors, Operations Office Managers, and Secretarial Officers to assure that the Office of Environment, Safety and Health is provided with appropriate documentation to review throughout the process. It is also incumbent upon the Office of Environment, Safety and Health to provide comments to these organizations in a timely fashion to assure that their concerns are addressed with minimal impact on the startup and restart schedule.

5.3.2.1 Assistant Secretary for Environment, Safety and Health (EH-1). In addition to the general Departmental responsibilities specified in DOE M 411.1, Manual of Functions, Responsibilities, and Authorities (FRAM), EH-1 assigns EH-2 to exercise independent oversight of the startup and restart process for nuclear facilities. This responsibility specifically entails the following:

(1) In coordination with the Cognizant Secretarial Officer (CSO), perform independent reviews of startup and restart activities as appropriate and provide results of these reviews to DOE

Operational Readiness Review Team Leaders, cognizant Operations Office Managers, and CSOs for resolution.

(2) Assess the CSO, Operations Office, and contractor procedures for startup or restart of nuclear facilities and provide periodic reports to the Secretary on their effectiveness. This periodicity should be governed by the perceived health of the processes at the various organizations. Organizations with noted deficiencies should receive additional assistance. Lessons learned from these evaluations should be shared throughout the department.

(3) In coordination with PSO and Field Office, perform independent review of contractor start up notification reports and provide results of these reviews to Cognizant Operations Office Managers and Cognizant Secretarial Officers for resolution.

(4) Review and comment on contractor and DOE plans-of-action and Operational Readiness Review Implementation Plans for startup or restart of nuclear facilities for both Readiness Assessments and Operational Readiness Reviews, including the specification of the involvement in the startup or restart activities proposed by the Office of Oversight (EH-2).

(5) Review and comment on the Operational Readiness Review Final Report recommendations regarding startup or restart to the DOE startup or restart approving official. These comments should be focused on the objective of ensuring correction of the identified issues and the prevention of a similar occurrence, particularly with respect to programmatic deficiencies.

(6) Provide any dissenting opinion on the readiness of a facility to startup or restart to the DOE ORR team, DOE line management, or the Secretary if a significant safety concern is not being properly corrected.

(7) If requested by the Secretary, concur in the final decision to startup or restart a nuclear facility.

5.3.2.2 EH Concerns. Any environmental, safety, or health concerns discovered by the Office of Environment, Safety and Health during their oversight of DOE's ORR will be brought to the immediate attention of the DOE ORR Team Leader for resolution.

5.4 Organizing for and Conducting the Department of Energy ORR.

5.4.1 Purpose. To provide guidance on the actions to be taken to form a DOE ORR team, develop the Implementation Plan, conduct and report the results of the review.

5.4.2 Formation of the Team. Each ORR is conducted by a multi-disciplined team of experts, including individuals knowledgeable in public and worker safety and health, and environmental protection. Team members are individually chosen by the ORR Team Leader to ensure that collectively their backgrounds will include the important facets of operations to be reviewed. The experts are also chosen to ensure the ORR team covers all functional areas/core requirements defined in the ORR plan-of-action. The number of members is determined by the scope of the ORR and the size and complexity of the facility.

Each team member must have the following qualifications verified by the Team Leader:

- Technical knowledge of the area assigned to evaluate. The knowledge should include experience working in the technical area.
- Knowledge of evaluation processes and methods. This knowledge may be gained through experience as an auditor or inspector or it may be gained through training evaluated as acceptable to the Team Leader.
- Facility specific information which may be gained through a combination of required reading and facility tours and presentations.
- Independence in that no team member may review his/her own work or work for which he/she was responsible.

The Team Leader must ensure the ORR records contain the information to certify the qualification of team members. This information would nominally be obtained through individual resumes, required reading records, and training records. Appendix 4 includes an example form for use to consolidate the required information.

5.4.3 Responsibilities.

a. As one element of the DOE ORR plan-of-action, the responsible DOE line manager nominates a qualified team leader who should be a senior DOE employee with adequate experience and knowledge to

effectively lead the evaluation of the facility. The appointment of the team leader is approved as part of the DOE ORR plan-of-action.

b. The Team Leader is responsible for the independent management and execution of all aspects of the DOE ORR. Section 5.4.4 discusses specific requirements.

c. Senior Members/Advisors - The ORR senior members/advisors, when required, are responsible for: providing assistance to the Team Leader in the exercise of his/her responsibilities; providing guidance to the team members; identifying the issues to be addressed during the ORR; approving the criteria and review approaches to be used by the team members; and assisting the ORR Team Leader in writing the Final Report. Senior advisors are Senior members of the ORR team and therefore must meet the requisite independence criterion for senior members. Requirements for senior advisors should be included in the ORR plan-of-action. Not all ORRs require senior advisors.

d. Operational Readiness Review Team Members - The team members are responsible for assessing the adequacy of readiness by conducting reviews in selected areas important to the safe resumption of operations. The team members assist the Team Leader and senior members in defining the depth of review in their assigned areas; documenting the criteria and review approach for their assigned area, subject to approval by the senior advisors and the Team Leader; attending team meetings to coordinate activities with other team members; documenting their own activities, findings, and conclusions in a manner to be specified by the Team Leader and the senior advisors; and concurring in ORR Final Report (any differing opinions are attached to the report in writing).

5.4.4 Team Leader Responsibilities. Key team leader actions are summarized as follows:

a. Select ORR team members to conduct the ORR. The information in the ORR plan-of-action guides the Team Leader in defining the areas requiring inclusion and the number of team members needed. Team member qualifications must be evaluated and verified by the Team Leader.

b. Prepare the ORR Implementation Plan in accordance with the scope (breadth and depth) defined in the ORR plan-of-action. Section 5.9.2 and Appendices 1 through 3 provide additional information on the development of the Implementation Plan. ORR team members and senior members assist in developing the Implementation Plan.

c. Prepare for conduct of DOE ORR. DOE Handbook, DOE-HDBK-3012-96, *Guide to Good Practices for Operational Readiness Reviews (ORR), Team Leader's Guide*, has been developed to provide information useful to an ORR Team Leader in preparation and conduct of an ORR or RA. The handbook contains discussion on process for preparation and conduct of the review. It also contains a lessons learned section which is a compilation of the lessons learned from the first several years of conducting ORRs. The handbook is a useful guide for both experienced team leaders as well as those with less experience. Additional information that helps the Team Leader prepare for the ORR is available on the DOE ORR Internet Home Page at http://www.dp.doe.gov/CTG/RESOURCE/orr/default.htm.

d. Manage the ORR in accordance with the Implementation Plan and information in DOE O 425.1B and this standard.

e. Manage the preparation and promulgation of the ORR Final Report. Section 5.9.3 discusses this report.

f. Remain available to participate, as required, by management in the closure verification of the ORR findings.

5.4.5 Criteria and Review Approaches. The reviews conducted by each ORR team are guided by CRADs defined in the ORR Implementation Plan. The CRADs should be grouped into functional areas. The selection of functional areas and the specific groupings is decided at the discretion of the ORR Team Leader. The selections should be based on the scope of the ORR and the expertise of the team members.

Appendix 4 provides examples which can be used in developing the specific CRADs for the specific ORR. The ORR plan-of-action breadth determination will have provided the required core requirements. The ORR Implementation Plan CRADs defines the evaluation process of the core requirements.

5.4.6 Conduct of the DOE Operational Readiness Review. After receiving and accepting a Readiness to Proceed Memorandum and when authorized by the authorization authority, the ORR will begin. The ORR team uses the criteria and review approaches defined in the ORR Implementation Plan. The ORR team members assess whether the criteria assigned to them for review have been met. The senior members actively participate in the reviews performed by the team members and assist the Team Leader in providing oversight of the ORR.

Each DOE ORR consists of systematic reviews of readiness activities as defined by the criteria and review approaches to assess whether operations could be conducted safely if allowed to start or resume. In most cases, the systematic review should start with the record of the contractor ORR. In addition, the ORR team evaluates the operators' performance in conducting ongoing activities, such as equipment operability checks and dry runs, and the simulated operations requested by the Team Leader. In many cases, it is appropriate to observe an exercise of the operational personnel in unusual or upset conditions and the related abnormal or emergency responses.

The foundation for readiness of the nuclear facility is an approved safety basis as defined in approved facility safety documentation, approved environmental documentation, satisfactory safe working environment, and compliance with DOE Orders and requirements. The ORR must verify that the necessary approved requirements documentation is in place and that procedures, personnel, and equipment and systems support the approved requirements. It is not a requirement that the ORR process approve the foundation documentation—only to verify that it is complete, approved, and implemented as required by the core requirements of DOE O 425.1B. Critical to the establishment of operational requirements are formal agreements between the operating contractor and DOE delineating these requirements (e.g., S/RIDs, WSS, List of DOE Orders). These are generally in the form of a contract standards, which are required by the DOE Acquisition Regulations (DEAR) for nuclear facilities, listing. The content includes requirements that govern the safe operations of the facility. A systematic review of the facility’s conformance to these requirements should be performed. In many situations, a recent verification of implementation of the contracts standards into site manuals of practice will be available. In those situations, it is only necessary for the ORR team to verify implementation of the site manuals of practice in facility or activity being evaluated by the ORR. These requirements should be verified by the operating entity to have been implemented in the facility, or DOE approved compensatory measures put in place during the period of implementation. DOE should approve the compensatory measures and the implementation period if needed.

The DOE ORR should include assessment of the technical and managerial qualifications of those in the DOE field organization who have been assigned responsibilities for direction and guidance to the contractor, including the Facility Representative. A similar review should be made of the qualifications of contractor personnel responsible for facility operations.

In most cases, a key element of the DOE ORR is a detailed review of the methods and results of the contractor's ORR. The results, including corrective actions, should be assessed for adequacy and effectiveness. The DOE ORR should conduct additional selected detailed assessments to verify the findings of the contractor ORR as well as review areas that the record of the contractor ORR indicates had not received adequate review in either breadth or depth.

During the DOE ORR, the documentation of review findings and the assembly of objective evidence of operational readiness is the responsibility of individual team members in accordance with specific direction given by the Team Leader and the senior members. Each team member's review activity, as well as findings, should be documented on standard ORR Assessment and ORR Deficiency Forms (see Forms 1 and 2 in Appendix 4).

During the course of the DOE ORR, it is important that a close dialogue between the facility management and the ORR team leadership be maintained. As part of the dialogue, preliminary or draft deficiency identifications may be provided to management to ensure a full understanding of all issues, and to permit presentation of additional information. A daily meeting between facility management and ORR leadership is suggested for this dialogue. Such identification of deficiencies to facility management is only to be done to ensure full understanding of pertinent issues and information. Deficiencies resulting in findings identified at any point in the ORR are to be included in the ORR Final Report and formally addressed for resolution and closure regardless of any interim actions which may be taken by line management to address such deficiencies.

At the end of the DOE ORR, the team members complete their evaluation of the operational readiness of the facility and submit their findings to the Team Leader and senior members. The senior members review the team members' findings and assist the Team Leader in developing a recommendation regarding the readiness to safely start or resume program work in the facility. A report is prepared by the ORR team to document the results of the ORR and provide justification for the team's conclusion as to whether startup or restart of the facility can proceed safely. The report also identifies any open findings including those that must be resolved prior to resumption of operations.

There shall be a statement in each ORR Final Report as to whether the facility has established an agreed upon set of requirements to govern safe operations of the facility. This set of requirements, generally in the form of an Authorization Agreement, should be formalized with DOE through the contract or other

enforceable mechanism. These requirements should be appropriately implemented in the facility, or appropriate compensatory measures, formally approved, have been put in place during the period prior to full implementation. The ORR team should provide their assessment as to whether or not this set of requirements is adequate to maintain protection of the public health and safety, worker safety, and the environment.

This conclusion shall be based on:

(1) Review of the program to document conformance with the agreed upon set of requirements, including a process to address new requirements; and

(2) Extensive use of references to the established requirements in the ORR documentation.

Team members are asked to concur in the DOE ORR Final Report. Any dissenting opinions are documented and attached to the report. The ORR Final Report is transmitted by the team leader to the authorization authority as designated in the ORR plans-of-action. In most instances, the ORR Final Report is forwarded in support of the Readiness to Proceed Memorandum.

The team also prepares a lessons learned report concerning the ORR and the ORR process. The lessons learned may be part of the ORR Final Report but must be in a format to stand alone for use by other ORR teams and team leaders. Through these lessons learned continuous improvement of the ORR process is achieved.

5.5 Documentation of the ORR Results (Both Responsible Contractor and DOE). The validity of, and the ability to defend, the results of an ORR depends in large part on the thoroughness with which the process and the observations are documented. The record of the ORR must be clear as to what was evaluated and the methodology used during the evaluation. The criteria in the Implementation Plan are the “what.” The record must clearly record the “how” that leads to the conclusions reached concerning the particular criteria. The Implementation Plan specifies a standardized method to record the assessment process for each criteria including what was inspected, what records were reviewed, who was interviewed, and what procedures were observed. Form 1 (see Appendix 4) is a sample Assessment Form which can be utilized to describe the steps in the criteria evaluation process.

During the ORR, it is expected that the team will identify individual deficient conditions. Frequently, the deficient conditions, when evaluated in aggregate, reflect a programmatic or implementation weakness

that is of concern and requires correction to ensure operations are conducted safely when started (prestart finding), or requires correction to mitigate longer term concerns or programmatic deterioration (post-start finding). The “roll-up” or systemic conclusion drawn from the individual deficient conditions are identified as findings. One of the important tasks of the team is to identify the significant findings that impact on adequacy of programmatic support or indicate inadequate implementation of important operational conditions. It will always be possible to identify individual deficiencies. The challenge is to determine when a group of seemingly minor individual issues are indicative of a more systemic issue that should be identified as a finding.

The Implementation Plan also provides a standardized method to identify findings to the requirements identified within the criteria. Each finding must be clearly described including examples of the individual issues that are included in the finding. The finding must describe what is deficient, the reference to which it is deficient, and be written in a manner permitting correction. Prior to being published, each finding should be identified as to whether or not, in the opinion of the ORR team leadership, it must be resolved as a prerequisite to start of operations. Criteria for this judgement should be published in the Implementation Plan. It may also be appropriate to identify the level of management (i.e. contractor, DOE Field, or DOE HQ) at which the finding should be closed. While the ORR team may assist management in reviewing the action taken on a finding, responsibility for closure should reside with line management. The Implementation Plan should describe the closure process and include the form of the closure documentation. Form 2 (see Appendix 4) is a sample Deficiency Form which may be specified to identify findings. Form 3 (see Appendix 4) may be specified as the required documentation to describe corrective action and close the finding.

5.6 Final Report. The Final Report of the ORR should include as appendices or attachments the individual criteria assessment documentation as to how the criteria were evaluated, and findings documentation. Conclusions, a summary of the findings, and the process used is described in the body of the ORR report. See Section 5.9.3 for additional detailed information for development of the ORR Report.

The Final Report of the contractor's ORR should be an enclosure to the Readiness to Proceed Memorandum from the contractor. The Readiness to Proceed Memorandum indicates the status of resolution of prestart findings and a corrective action plan for post-start findings. The DOE ORR Final

Report should be part of the endorsement to the Readiness to Proceed Memorandum which indicates that the conclusions reached by the DOE ORR support the recommendation in the endorsement.

The core requirements, in aggregate, address many of the core functions and guiding principles of an ISMS. The final report should include a discussion regarding the Team Leader's assessment of the adequacy of the implementation of those functions and principles, which may have been addressed by the ORR at the facility undergoing the review. To more clearly show the relationship of ISM principles to the ORR expectations, the core requirements are listed as they relate to each of the principles of ISM. Therefore, through an evaluation of the results of the ORR in relation to the individual core requirements, it is reasonable to draw a conclusion as to the maturity and effectiveness of ISM implementation at the facilities or activities within the scope of the given ORR or RA. This is not either direction or inference that any additional review be added to the ORR/RA process to address ISM. Only to the extent that the ISM processes are visible in the established review should they be evaluated and commented on.

5.7 ORR Follow-Up. The completion of the ORR and the finalizing of the report are not the end of the ORR process, nor the team's involvement in that process. Several actions require the participation of the Team Leader, as well as team members. The Team Leader should notify all team members of future involvement concerning close-out briefings, interpretation (and possible justification) of findings, review of corrective action plans for adequacy, and review of final closure actions. Line management may request members of the team to assist in closing findings. That is a line management function. The team can make recommendations regarding who should close the findings (see section 5.7.3).

5.7.1 Post-ORR Presentations. The Team Leader must coordinate any follow-up meetings, which include closeout meetings with the affected facility and/or programmatic line management, debriefings of the team, and presentation of the report to upper management (responsible contractor and DOE). The Team Leader may be required by the Secretarial Officer (or other appointing authority) to present the team report to upper DOE management, and discuss the contractor corrective action plans. Presentations may be required to internal or external interested groups as well. In addition, it may be appropriate for the Team Leader to indicate a recommended organization to verify proper closure of individual prestart findings.

5.7.2 Corrective Action Plans. The contractor and DOE must prepare corrective action plans for the correction of all findings assigned to each element. Except as noted, these requirements apply to both the Contractor and DOE ORR findings. The action plan should contain the following elements:

a. The finding, as written in the report submitted by the ORR team, and whether the finding is a prestart or post-start finding.

b. A detailed proposed action plan for addressing the deficiencies identified in that finding. The proposed action plan should provide evaluation of any overall programmatic deficiencies or root causes related to a specific finding which may lead to further similar occurrences and include actions addressing such deficiencies or root causes. For findings in the DOE ORR, DOE must approve the contractor's proposed corrective action plan.

c. The proposed dates when the action elements will be completed. If the corrective actions for a finding are phased, then the dates for each phase should be detailed.

d. If it is a post-start finding, a description of the risks and mitigating actions, if any, to be taken during the interim that will reduce the risks associated with the finding to an acceptable level before final correction. DOE line management shall verify that the corrective action plan has been entered into the appropriate quality program issue management system.

5.7.3 Action Tracking/Closure Methodology. Monitoring and verification of satisfactory closure of prestart findings from both the Contractor and DOE ORRs is a line management responsibility. The ORR Team Leader and team members may be requested to assist in the verification or adequate resolution of prestart findings. DOE O 425.1B defines elements of the required process to close ORR prestart findings. This is accomplished by development of a closure package that is reviewed and certified by the facility management and further reviewed by DOE management for findings from the DOE ORR. These procedures should be documented either in a facility wide requirement or within the individual ORR Implementation Plan. Closure packages should contain the following information:

a. The finding, written verbatim from the original report, and identifying the finding as a prestart or post-start finding.

b. The actions proposed in the action plan developed, submitted, and approved with the original completion schedule.

c. A brief description of the actual corrective actions taken and reasons for concluding that closure has been achieved and how referenced documents support closure. The referenced documents or objective evidence from these documents illustrating the corrective actions, and the dates of the actions should also be included.

d. Signatures of appropriate line management, as defined by the site procedures or within the ORR Implementation Plan. A draft closure form is provided as Form 3, ORR Finding Resolution Form, in Appendix 4.

e. DOE Verification (DOE ORR findings as a minimum) of the adequacy and completion of the corrective actions.

5.8 Lessons Learned. All ORR reports must contain a section concerning lessons learned and should be used by both contractor and DOE to improve the ORR process. These lessons learned provide information concerning problems encountered by the review team, adequacies or inadequacies concerning the review, design and implementation, expertise, or any other relevant factors or information that may be used by future review teams.

A mechanism to ensure that these lessons are transmitted to future review teams and incorporated into the design and implementation of future reviews has been implemented. Lessons learned are available at the DOE ORR web site, http://www.dp.doe.gov/CTG/RESOURCE/orr/default.htm. In addition, many of the lessons learned have been included in DOE-HDBK-3012-96.

The ORR process may also identify lessons learned applicable to similar facilities. Lessons learned in areas such as operations, procedures, design or documentation may be identified. The ORR team should include these lessons learned in the report as well. Facility management or DOE management is then responsible for promulgation of these lessons learned in accordance with established procedures for lessons learned. The ORR Report may be issued prior to completion of the writing of the lessons learned section in order that distributing the report might not be delayed. However, each ORR report must ultimately contain a lessons learned section as required by DOE O 425.1B.

5.9 ORR Process Deliverables. The ORR process deliverables are the ORR plans-of-action, the ORR Implementation Plans, the ORR report, and the Readiness to Proceed Memorandum.

5.9.1 ORR Plan-of-Action.

5.9.1.1 General considerations. The responsible contractor and DOE each prepare an ORR plan-of-action. The ORR plan-of-action is prepared by line management and describes the breadth and the prerequisites of the ORR. The plan-of-action is the document in which line management describes what will be evaluated by the ORR, based on the extent of the activities involved in the resumption or startup. Through the process of the ORR plan-of-action, the proper authority within the Department of Energy concurs with or approves the planning for the ORR process. The ORR process is then conducted in accordance with the approved elements of the plan-of-action. Once approved, the ORR plans-of-action are distributed to responsible or interested groups within and outside the DOE. Distribution outside of DOE should be in accordance with Department procedures.

The ORR plans-of-action are forwarded via management to the designated authorization authority for the particular restart or new start. A copy of the proposed plan-of-action is provided to EH for review and comment in accordance with Section 5.3.2. The authorization authority approves the plans-of-action for the contractor and DOE ORRs.

The amount of detail in each ORR plan-of-action varies with the complexity of the facility and the situation. As a rule of thumb, the level of detail must be adequate to justify to a skeptical reviewer the decisions being proposed. The detail must be adequate for preparers, reviewers, and the Team Leader to defend the decisions being made.

The DOE ORR plan-of-action is prepared by the Area Office, Operations Office, or Headquarters line management. The responsible contractor recommended ORR plan-of-action provides a starting point for the DOE ORR plan-of-action.

5.9.1.2 Elements of the ORR Plan-of-Action. Each ORR plan-of-action contains the following elements. Except where noted otherwise, the following elements apply to both the contractor and DOE ORR plans-of-action. Where the information is identical, it is expected that the DOE plan-of-action will be identical to the contractor document.

5.9.1.2.1 Name of the Facility/Activity Being Started. The name must be specific to what is to be evaluated and started. For example, if a single process within a building is to be restarted, the facility name would be the process name. On the other hand if the process encompasses several buildings and an area, the name would be the encompassing process name.

5.9.1.2.1.1 Description of Facility/Activity. This includes buildings, systems, and processes included in the startup or restart. The description may be instrumental in defining the scope of the review. For example, if most support functions and procedures are outside the boundary of the facility being started up, the ORR scope would focus on interfaces with existing programs. This section of the plan-of-action defines the physical scope of the ORR. The physical scope may include systems, structures, and/or processes.

5.9.1.2.1.2 Identification of the Responsible Contractor. This is the contractor who certifies readiness of the facility to operate. It is normally the contractor who submits the responsible contractor ORR plan-of-action.

5.9.1.2.2 Designation of Action as a New Start or Restart. This is the identification as to whether the facility is being started for the first time or being restarted. It is reasonable that a new process within an existing building would be a new startup. Resumption of a process after an extended period of no operation would most reasonably be a restart.

5.9.1.2.2.1 New Start Discussion. The following elements or details of the facility should be included to support or create the basis for the recommended decisions:

- Hazard categorization for new facility and basis for the designation (criticality, explosive, chemical, environmental, etc); and
- Acquisition costs for new facility or process.

5.9.1.2.2.2 Restart Discussion. If the action is a restart of an existing facility or process, the following information should be provided to support the follow on decisions:

- Hazard categorization of the facility once restarted and basis for determination (criticality, explosive, chemical, environmental, etc.). In the event that no formal hazard categorization has been made, a discussion of the relative hazard is appropriate;

- Cause for shutdown;
- Duration of shutdown;
- Repairs accomplished during shutdown period;
- Modifications accomplished during shutdown period and affect on the approved safety basis; and,
- Any anticipated process changes following restart.

5.9.1.2.3 Proposed Breadth for the ORR. This is a key section in both the contractor and DOE plans-of-action. The breadth is the top tier core requirements. The breadth should be derived starting with the minimum core requirements listed in DOE O 425.1B and the physical scope in the facility description. The discussion should support the decision to eliminate any core requirements based on recent, independent appraisals in the excluded areas. The DOE ORR plan-of-action breadth considers the contractor ORR as well as DOE management and oversight programs.

The discussion of the breadth of the ORR in the plan-of-action supports the development in the ORR Implementation Plan of the depth of each aspect of the ORR. In support of this function of the plan-of-action, and to ensure maximum understanding regarding the intention of the restart authority as to what should be reviewed, care and attention to detail are important in the development of the breadth section of the plan-of-action. The breadth must start with a clear discussion of the physical or geographic scope of the ORR. A clear definition of the structures, systems, and components, as well as the individual processes or activities that are within the scope of the ORR should be provided. Experience indicates that clarity can be best achieved when each core requirement is discussed individually. The discussion should include justification for those core requirements that may not be included in the ORR. For those core requirements to be included, the discussion should clearly describe the detail or depth to which each is to be reviewed. In some cases, only the interface with site infrastructure programs needs to be included. In other cases, the entire site wide program must be evaluated. The discussions should include reference to site wide as well as facility specific reviews that provide a basis for the ORR. Evaluations such as previous ORRs, ISMS verifications, independent DOE or contractor reviews, or similar reviews may reduce the necessary depth of review for individual core requirements. Similarly, the recent history of the facility, site, or activity may be important in defining the level of detail or depth of individual portions of the review. Conditions such as recent occurrences, investigations, or systemic issues identified within the site may be the basis for an increase in the breadth or depth of the review of individual core requirements.

5.9.1.2.4 ORR Prerequisites. Defining the prerequisite conditions to be met by the facility management prior to the start of the ORR (appropriate for both the responsible contractor ORR as well as the DOE ORR) is an important element of a successful ORR. The process the contractor uses to separate gaining readiness through management actions and confirming readiness through the ORR process should be reflected in the prerequisite requirements. The contractor ORR plan-of-action prerequisites must address each core requirement of DOE O 425.1B. The DOE ORR plan-of-action prerequisites should include readiness of DOE management and Operations Office programs and assigned personnel who monitor facility operations. Adequate detail should be included to permit an understanding of exactly which programs and personnel are considered essential to adequate oversight of the facility or process for start or restart. The prerequisite section of both the contractor and DOE ORR plans-of-action should refer to specific items such as a project management plan, a readiness self-assessment plan, a compliance assessment program, safety documentation such as SAR, TSR, etc. or environmental assessments or impact studies. The prerequisites should be described in terms of specific measurable items.

5.9.1.2.5 Estimated ORR Start Date and Duration. The date is for planning purposes only and should be the best estimate. Identification of a date is not to infer that the ORR start is schedule driven rather than readiness driven. The DOE ORR estimated start dates, as well as the contractor ORR schedule, should be provided for information in the Contractor ORR plan-of-action to assist DOE management in planning for the DOE ORR.

5.9.1.2.6 Proposed ORR Team Leader. The individual must have the necessary independence with the required experience and technical background consistent with the complexity of the facility and the specific ORR. The individual must meet the criteria discussed in Section 5.1 for the responsible contractor ORR and Section 5.4 for the DOE ORR.

5.9.1.2.7 Requirement for Senior Advisors. Senior advisors are recommended for DOE ORRs of complex facilities. In many instances senior advisors may not be required, particularly if the Team Leader has significant ORR experience. On other occasions, a single senior advisor to assist the Team Leader may be appropriate or for particularly complex or controversial ORRs of high hazard facilities, as many as three senior advisors may be advisable.

5.9.1.2.8 Official to Approve Start of the ORR. In most circumstances for the DOE ORR, this is the authorization authority designated in the approved startup notification plans. Designation of the authorization authority is made in accordance with the requirements of DOE O 425.1B. For the contractor ORR, the official designated to approve the start of the ORR should be a line manager senior to the manager responsible for achieving overall readiness to start operations.

5.9.1.2.9 Official to Approve Startup or Restart of the Facility. This is the individual specified in DOE O 425.1B based on a new start or restart circumstances. The specific authorization authority is listed in the startup notification plan.

5.9.1.2.10 Reviewers' Approval. List the individuals by name and title who prepared and reviewed this document. The signature indicates that they have reviewed the document and recommend approval by the authorization authority listed.

5.9.1.2.11 Distribution. This is a listing of the individuals and organizations who receive copies of the ORR plan-of-action following approval. Individuals and organizations are listed who have either responsibilities or interests in the new start or restart process.

5.9.2 ORR Implementation Plans. The ORR Implementation Plan is developed by the team responsible for conducting the ORR. The Implementation Plan is approved by the Team Leader designated in the ORR plan-of-action. This ORR Implementation Plan documents not only the process the team uses to conduct the review, but also defines the rationale for that process. The documentation includes the selection of criteria and review approaches and the procedures the team uses to develop findings and conclusions, and the criteria to be applied to categorize findings as prestart and post-start. The ORR Implementation Plan is the document that provides for the depth of evaluation of the ORR breadth and execution of other details in the approved ORR plan-of-action.

The ORR Implementation Plan should provide sufficient detail to serve as both information to management and guidance to the ORR team members. The team preparing the ORR Implementation Plan requires a thorough understanding of the facility and its associated issues. Pre-development on-site facility visits and interviews may be required before the ORR Implementation Plan can be adequately developed.

The ORR Implementation Plan should be provided by the Team Leader to appropriate oversight and higher-level DOE management prior to commencement of the DOE ORR. EH responsibility and options are described in Section 5.3.2.

The following outline provides a suggested format for the ORR Implementation Plan.

1.0 Introduction/Background: Describes the activity that will be reviewed and the reason for shutdown (if a restart). This section provides background information concerning the basic process, hazards, and issues associated with the activity to be reviewed.

2.0 Purpose: Describes the reasons why the review will be conducted, and provides the basic insights for the defined scope of the review.

3.0 Scope: The scope defines the physical and administrative boundaries of the facility, and justifies those defined boundaries and support function review relative to each of the following:

- Plant and equipment (hardware) readiness;
- Management and personnel readiness; and,
- Management programs (procedures, plans, etc.) readiness.

The scope section of the ORR Implementation Plan describes the approved breadth from the approved ORR plan-of-action. Each breadth element required by the plan-of-action must be incorporated into the ORR Implementation Plan. The depth to which each scope element is evaluated is specified and quantified by the Implementation Plan criteria and review approaches to be consistent with the discussion in the approved plan-of-action.

The scope section should define the major objectives of the review. These objectives define the discipline or areas selected for review and define the approach and guidelines which must be implemented for an organization to achieve a state of operational readiness. This section also defines the physical scope including facilities, systems, and processes. In addition, it describes the level of review of the various site infrastructure programs that make up the site's Integrated Safety Management System.

4.0 ORR Prerequisites: The ORR Implementation Plan should summarize the prerequisites specified in the approved plan-of-action. It is not the responsibility of the ORR team to develop the prerequisites but

they must understand them and be prepared to verify that the prerequisites have been achieved at the start of the ORR.

5.0 Overall Approach: Defines the generic approach by which the review is conducted, and provides an introduction to the ORR process. The ORR Criteria and Review Approaches (CRAs) are defined by the processes described in this section. How findings are classified as prestart and post-start should be defined here, as should the method for report preparation, finding resolution and methods of closure.

6.0 ORR Preparations: Describes any preparations, including team pre-review site visits, document reviews, etc., that will be undertaken prior to the on-site review. A discussion of qualifications and training considerations for ORR team members could appear here.

7.0 ORR Process: Describes the actual Criteria and Review Approaches (CRAs) that will be used to review the defined core requirements of the review. These CRAs should be developed in a Criteria and Review Approach Document (CRAD) to include the following items:

A. Core Requirement – Identification of the requirement that will be verified as having been achieved by the readiness process;
B. Criteria – Specifically how the core requirements/core objectives will be measured, which may include regulatory requirements, etc. References for these requirements should be cited.
C. Review Approach – A definition of the combination of documentation review, personnel interviews, systems walkdowns , and exercises and/or drills observed that will be conducted to derive objective evidence the team will use to measure the defined criteria and assess the readiness of the particular objective or sub-objective;

8.0 Administration: Describes the mechanism for the ORR-related meetings, correspondence, communications, team structure, etc. of the review. The ORR team composition/organization, interface requirements, any oversight groups, and DOE organizations to be involved in the review should be discussed in this section.

9.0 Reporting and Resolutions: The section should detail the methods that the ORR team will use to report review results. Elements described in Sections 5.5, 5.8, and 5.9.3 of this standard should be included.

10.0 Schedule: A discussion of the proposed schedule for any preparation, pre-review site visits, on-site review, conduct of review, report preparation, and closeout.

11.0 Appendices: The appendices should include the specific CRADs to be utilized by the team members to conduct the individual assessments. The Appendices may also include reporting forms, writing guides, team resumes, and other sections appropriate to stand alone in an appendix. The appendices of this standard, as well as the Team Leader's Guide and ORR Home Page, contain information and examples which may be useful during development of the appendices for the ORR Implementation plan.

5.9.3 Operational Readiness Review Final Report. The final product of the Operational Readiness Review process is the ORR Final Report. This Final Report documents not only findings and conclusions, but the process by which these were developed. The ORR Final Report is the deliverable from the ORR. It is the basis for senior management decisions including startup or restart approval and must therefore accurately reflect the conditions found during the conduct of the ORR.

The ORR Final Report documents the logic of the review and conveys the results of the review. It provides a summary of review activities and confirmation that the criteria and review approaches detailed in the Implementation Plan were followed, with explanations for any deviations from the Plan. It also contains enough detail that the reader can follow the review logic of the ORR, traceable from the ORR Implementation Plan to the ORR findings.

The ORR Final Report forms the basis for conclusions as to the effectiveness of the facility's ORR preparation, the contractor ORR, and the readiness of the facility to proceed with startup or restart. The Final Report must also provide information concerning the readiness of the management system (both the contractor and DOE) to oversee and manage the activity. If deficiencies exist, the ORR Final Report defines those clearly as well as what inadequacies must be addressed before startup and after startup.

5.9.3.1 ORR Final Report Format. DOE O 425.1B (section 4.b.(8)) provides requirements and guidance for the content of the ORR report. It does not however, provide the format. The following is a suggested format derived from a composite of past DOE ORR Final Reports. A synopsis of each section is contained in the following paragraphs.

1. Title Page (Cover)
2. Signature Page
3. Executive Summary
4. Table of Contents
5. Introduction
6. ORR Evaluation
7. Status of ISMS Implementation
8. Lessons Learned
9. Appendices

1. Title Page (Cover) – The cover and title page state the subject, and the date of the review or evaluation. The report cover should be as clean as possible, and should not contain any extraneous information, data, graphics, or pictures.

2. Signature Page – A signature page should be provided. The signatures on the Final Report should include all team members. Signatures by individual team members signify their agreement as to the report content and conclusion in the areas to which they were assigned. In the event all team member signatures cannot be obtained due to logistical considerations, the Team Leader should gain their concurrence via fax or telcon and sign for them.

3. Executive Summary – An executive summary is recommended. This summary is a one to three page synopsis of the review, findings, and readiness determination. The executive summary should introduce information, and direct the reader to those portions of the report that provide more detail concerning the information. Some suggested points for the executive summary include:

a. A brief synopsis of the review activity, which provides information concerning the team's evaluation of readiness;
b. The readiness of the activity to proceed;
c. The management system adequacy to oversee the operation;
d. A summary evaluation of the adequacy of the ORR preparation (and possibly the ORR program); and
e. A synopsis of the significant problems and strengths.

4. Table of Contents – A Table of Contents should be provided to facilitate review of the report. The Table of Contents should identify, with page numbers, all sections and subsections of the report, illustrations, charts, and appendices.

5. Introduction – An introduction should provide information and background regarding the facility being reviewed, the reason(s) for shutdown (if a restart), the purpose of the review/evaluation, and the scope of the activity evaluation. Other information that should be provided include a brief discussion of:

a. The overall objectives of the evaluation;
b. The review process and methodologies used in the review;
c. The team composition; and
d. Definitions applicable to the review.

6. ORR Evaluation – For each functional area, the report should discuss the core requirement and provide conclusions as to the readiness of the functional area to safely support proposed operations. Conclusions as to the readiness of hardware, personnel, procedures, and the management system that controls each review area should be addressed, including key issues concerning the review area. The evaluation should discuss the prestart and post-start findings associated with the review and provide a conclusion as to the readiness of the facility to begin operation.

Any deviations from the Implementation Plan should be discussed, along with the reasons for the deviation(s), and what alternative actions were taken to compensate, if required. As the evaluation section provides the bases for the determination of readiness for each core requirement, it should discuss not only the deficiencies found during the review, but should also discuss those positive aspects that affected the determination. In addition, the ORR Final Report should also identify as "Observations" those items that are not findings, but if addressed, would lead to excellence in operations. The detailed documentation to support the conclusions may be included in an appendix which consists of the individual check lists with the accompanying appraisal and issue forms. See Appendix 4 for additional details.

7. Implementation of ISMS – The core requirements, in aggregate, address many of the core functions and guiding principles of Integrated Safety Management (ISM). The final report should include a statement regarding the Team Leader’s assessment of the adequacy of the implementation of those functions and principles which were addressed by the ORR at the facility undergoing the review. This is neither direction nor inference that any additional review be added to the ORR/RA process to address ISM. Only to the extent that the ISM processes are visible in the established review should they be evaluated and commented on.

8. Lessons Learned – The report should identify lessons learned that may be applied to design, construction, operation, and decommissioning of similar facilities and to future ORRs. The ORR Final Report should address the problems and the successes encountered in the review and evaluation process (what worked, what did not work). These activities should be documented to provide guidance on future ORRs. Lessons Learned associated with programmatic activities such as operations, procedures, design or documentation should also be included if applicable.

9. Appendices – Appendices should be provided for data that support the actual report. Data that should be considered for appendices include:

a. Implementation Plan;
b. Criteria and Review Approach Document;
c. ORR Activities Plan;
d. Team List and Resumes;
e. Evaluation of criteria (Form 1);
f. Prestart Findings summary (Form 2);
g. Post-start Findings summary (Form 2).

5.9.3.2 Status of Requirements. There shall be a statement in each ORR Final Report as to whether the facility has established the following: an agreed upon set of requirements to govern safe operations of the facility; this set of requirements has been formalized with DOE through the contract or other enforceable mechanism; these requirements have been appropriately implemented in the facility, or appropriate compensatory measures, formally approved, are in place during the period prior to full implementation; and in the opinion of the ORR team, maintain adequate protection of the health and safety of the public, the worker, and the environment. This conclusion shall be based on:

1. Review of the program to document conformance with the agreed upon set of requirements, including a process to address new requirements; and
2. Extensive use of references to the established requirements in the ORR documentation.

5.9.3.3 Recommendation as to Readiness to Operate. The Final Report documents the results of the ORR and make a conclusion as to whether startup or restart of the nuclear facility can proceed safely.

5.9.3.4 Differing Opinions. The ORR Final Report should provide opportunity for team members to include:

- Differing professional opinions;
- Non-judgmental general comments;
- Observations;
- Dissenting opinions, which should be documented, and attached to the report.

While the team should strive to reach a consensus concerning all aspects of the review, DOE recognizes that professional judgement does not always allow complete agreement. In cases of disagreement, the Team Leader must make the final decision concerning the disposition of the finding or concern. However, discussion of all aspects of the finding should be provided in the report to allow the authorization authority all relevant information on which to form an opinion.

If a team member feels that aspects of his/her opinions have not been adequately represented, that member should file a report of differing opinion. This report should be attached to the ORR Final Report, identified as an appendix, for review by the approving authority.

5.9.4 Readiness to Proceed Memorandum. The Readiness to Proceed Memorandum is the formal communication from the responsible contractor to DOE that the facility has been brought to a state of readiness to start operations. The memorandum is a prerequisite to the DOE ORR. The Operations Office uses the contents of the Readiness to Proceed Memorandum, coupled with its own routine management understanding of the status of the facility, as a basis for the recommendation or decision to commence the DOE ORR. A similar, formal documentation of readiness should be used by the contractor before start of the contractor ORR. A formal declaration of readiness to start the contractor ORR should be prepared by contractor line management only when readiness to start operations has been achieved and ORR prerequisites specified in the plan-of-action have been met.

5.9.4.1 Timing of the Readiness to Proceed Memorandum. The Readiness to Proceed Memorandum should not be submitted until all actions required for startup or restart have been completed, with the exception of a manageable list of open prestart items that have a well defined plan and schedule for closure. There should be no unresolved issues in the path towards closure of these prestart items.

The principle that management is responsible for bringing the facility to a condition of readiness to start operations and that the ORR verifies that readiness must not be disregarded. If there are an excessive

number of open items at the time the Readiness to Proceed Memorandum is submitted to DOE the initial conclusion is that the responsible contractor's management and ORR processes were not successful.

The following discussion concerning the acceptability of the open prestart items at the time the Readiness to Proceed Memorandum is provided:

a. Each open item prerequisite to commencing facility operations must be identified as a part of the Readiness to Proceed Memorandum.

b. The number of open items must be small. In determining how many open items is acceptable, one principle should be that every area to be evaluated by the DOE ORR must be sufficiently complete to permit evaluation. For example, a single finding or multiple findings that in aggregate mean that some key program has not yet been developed and put in place would not be acceptable since the DOE ORR would be unable to review the adequacy of the program. Only if that program were to be in place prior to the end of the ORR would a finding of this sort be acceptable as an open item in the Readiness to Proceed Memorandum.

c. Each open item must be defined with an explicit corrective action plan. Open items such as "the required environmental permits have not been requested or approved" would not be acceptable in that many additional facility procedures and activities are potentially dictated by the corrective actions to the identified open item.

d. Each open prestart item from the contractor ORR must have a reasonable plan of corrective action in place. The plan must be included with the identified open items in the Readiness to Proceed Memorandum. The schedule for completion of the corrective action plan must be consistent with the timing for the completion of the DOE ORR.

In summary, the open items should be few in number, well defined with a well defined corrective action plan, able to be completed on a schedule which is consistent with the DOE ORR schedule, and not of such a nature individually or in aggregate to preclude an adequate review by the DOE ORR of any specific area.

5.9.4.2 Contents of Readiness to Proceed Memorandum. The Readiness to Proceed Memorandum is a communication from an authorized individual of the responsible contractor to the DOE Startup Authority. The communication certifies that the facility is in a state of readiness to commence operations following completion of the identified open prestart items and the DOE ORR. For each open prestart item listed, a corrective action plan, including a schedule of completion, must be included. The communication should recommend a date for the DOE ORR to start. The DOE ORR completion schedule should be consistent with the final completion date for the identified open restart items. The Readiness to Proceed Memorandum should certify completion of the contractor's ORR as well as all items in the prestart management plan. A copy of the completed contractor ORR report should be included.

5.9.4.3 DOE Action Following Receipt of Readiness to Proceed Memorandum. The submitted Readiness to Proceed Memorandum, including the discussion of open items and action plans, is reviewed by DOE Operations Office management. The review includes verification of the accuracy of the included information, evaluation as to the completeness of the listing of open items, and whether the corrective action and time estimates are realistic. In addition, the Operations Office will verifies DOE's readiness to oversee facility operations as specified in DOE O 425.1B, which requires that DOE line management up to the authorization authority document in writing their readiness to oversee operations. With the review as a basis, DOE Operations Office management forwards the Readiness to Proceed Memorandum to the appropriate DOE line manager with a recommendation as to whether the memorandum should be accepted and the DOE ORR scheduled or whether additional information or action should be requested of the responsible contractor, or additional actions taken by DOE Operations Office management. Following DOE field review, the Readiness to Proceed Memorandum is either returned to the responsible contractor with identified comments or forwarded recommending approval to start the DOE ORR. Each DOE management endorsement should identify programs and personnel positions which have been verified as ready to support facility operations, as well as how the evaluation was accomplished and actions taken to achieve the state of readiness to oversee operations. The acceptable Readiness to Proceed Memorandum is ultimately forwarded via the appropriate management chain of authority to the individual designated in the ORR plan-of-action to approve starting the DOE ORR for final approval and action.

The Readiness to Proceed Memorandum, with enclosures and endorsements, is retained as a part of the facility restart record as well as the ORR report and associated documentation. Experiences and lessons

learned in managing the Readiness to Proceed Memorandum and process should be included in the ORR report lessons learned section.

5.10 Readiness Assessments. DOE O 425.1B requires that when an ORR is not required incident to a restart, an RA should be considered to verify readiness to start or resume program work. DOE O 425.1B in addition requires that Operations Offices develop procedures to gain approval to start or resume program work when an RA is required and that the procedures specify a graded approach in development of RA requirements.

The Operations Office and responsible contractor procedures should also specify when an RA is not required incident to restart following a short and routine shutdown. The procedures should also indicate what standard operating procedures (not review procedures) will be used when neither an ORR or an RA is required to verify readiness to resume program work.

The responsible contractor must execute the initial, and in some cases the only Readiness Assessment. Therefore, the responsible contractor's procedures should contain provisions and processes for RAs.

The procedures for RAs may be included in the Operations Office and responsible contractors startup or restart procedures. They should, however, be separate from the requirements for ORRs, and should be separate from procedures for Management Self Assessments incident to gaining readiness.

The following considerations are provided for use in development of the Operations Office procedures for Readiness Assessments (RAs).

5.10.1 Principles of ORRs relevant to RAs. Several principles relevant to ORRs are equally applicable to RAs:

(1) The RA is not a method to gain readiness to start or resume program work. It is however, a confirmation that management has achieved readiness to resume operations prior to the actual restart.

(2) The RA should be conducted utilizing a formal procedure. By using the graded approach, the procedure may be a simple checklist or a broad based assessment. In either case, the procedure should be formal, approved, and executed by a designated individual or team.

(3) The results of the RA should be audit able and retained in the records of the facility with a record that any findings during the RA were resolved.

(4) The scope (breadth and depth) of the RA must be a management decision utilizing the graded approach. For example, a routine resumption of operations following a short outage in which few minor repairs and/or modifications were conducted could require little in addition to a pre-approved check list. In the other extreme, a Hazard class 3 facility restart following an extended outage may require a contractor and DOE RA with a scope equivalent to an ORR of a Hazard Classification 2 facility following a similar outage. In both cases, a defensible management decision would be required to approve the scope. The decision and basis in each case shall be documented in writing and approved by the designated authorization authority prior to commencement of the Readiness Assessment. These decision documents are included as part of the record of the restart. In most cases, a plan-of-action that includes the necessary information should be utilized.

(5) The responsible contractor must inform the Operations Office of the startups which require RAs, as well as those requiring an ORR. This should be done in the Startup Notification Report. It might also be appropriate to recommend whether the Operations Office should conduct an independent RA or monitor and approve the results of the contractor RA.

(6) Specified prerequisite conditions for the conduct of the RA should be identified either in a contractor standing procedure for routine restarts or as part of the RA procedure for more complex restarts.

(7) Readiness Assessment team members require technical and assessment qualifications to ensure the credibility of the results of the RA. No RA team member should review work for which he or she is directly responsible.

(8) There is flexibility within the expectations for an RA. Therefore, it should not be necessary for the contractor to define any other readiness review processes. If a readiness review is need, the ORR/RA process should be used. If a readiness review is not required, the restart should be conducted using facility or activity operating procedures.

5.10.2 Acceptable Procedural Exceptions to ORRs for Conduct of RAs. In the following areas, the Operations Office may specify procedures that are different from those for the ORR process.

(1) In the case of routine restarts when little maintenance and few minor modifications have occurred, but an RA is required, it may be appropriate for the responsible contractor to use a pre-approved checklist and have the results monitored or reviewed by a member of the Operations Office. In these cases, a separate DOE RA might not be required; the responsible contractor could be the restart authority. However, any Operations Office review of the RA that is deemed necessary should be performed prior to resumption of operations.

(2) The sequence of the contractor and DOE RAs could be more flexible when authorized by the restart authority. Similarly, the contractor RA might be sequenced in parallel with final actions to gain readiness to resume operations. The principle that the RA verifies areas in which readiness has been gained remains critical to the process. Therefore, the relevant prerequisites must be met prior to start of individual parts of the RA.

(3) The independence of the team members from management could be less rigorous for the RA. The principle that no RA team member review his/her own work shall be retained.

(4) The requirement for formal, written notification of readiness to resume operations provided to the Operations Office could be modified. Notifications in accordance with DOE O 232.1A could be used if specified in Operations Office procedures.

(5) The formal RA record must be adequate to identify what was done, the results, and the recommendation concerning resumption of operations by the individual(s) who conducted the RA. Contractor and Operations Office procedures should specify the minimum record for various categories of RAs discussed in the procedure. For example, those RAs which use pre-approved checklists would have a less complex report than those RAs following an extended shutdown of a Hazard Category 3 facility with significant modifications.

(6) The RA plan or checklist may or may not contain all elements of an ORR Implementation plan.

Many of the policies and procedures described in this standard are relevant and appropriate for inclusion in procedures for Readiness Assessments. For example, the discussions concerning breadth and depth decisions are equally appropriate to RAs as well as ORRs. In situations where an ORR would be required except that the Hazard Categorization is 3 vice 2, ORR procedures from the standard would be

appropriate with only limited differences as discussed above. In particular, sections 5.1 and 5.4 which describe contractor and DOE ORRs should be reviewed and considered for inclusion when developing procedures for RAs. All appendices of this standard are also appropriate in the planning and execution of the RAs and should be referenced and/or used in the contractor and Operations Office procedures.

The Operations Office and responsible contractor procedures should include provisions appropriate to the unique circumstances and facilities at each site. The procedures require sufficient detail to adequately guide the process. Equally important, the procedures must have adequate flexibility to support unique situations while requiring adequate management review and oversight of the process to ensure a defensible, proper result.

Operations Office managers may require that the responsible contractor procedures, which include the detailed requirements for RAs, be submitted for review or approval. Similarly, Secretarial Officers may require Operations Office procedures be submitted for review or approval. The Operations Office and Headquarters managers should specify whether the procedures are to be submitted for review and/or approval.

5.11 Exemptions. DOE O 425.1B directs the requirements for exemptions to DOE Order 251.1, *DOE Directives System*. Examples of situations that warrant utilization of the exemption process include short duration, one-time activities such as unique activities to clean out or otherwise take a system or component out of service for purposes of D&D. An exemption might also be appropriate in the event of a national priority tasking at a facility which might not be in readiness to conduct the required operation or task as an unrestricted operation. Due to the finite duration and finite definition of the processes to be conducted, compensatory measures and interim or temporary actions might be appropriate. In order to assure that the exemptions do not lead to a reduction in safety or an unacceptable increase in risk, case-by-case review or approval by the CSO is required. An exemption may also be appropriate when the time limits in DOE O 425.1B, section 4.a (1), are exceeded. In those cases, the exemption request would justify approval and specify the scope of the Readiness Assessment. In all cases, the exemption request will address the essential elements required by DOE M 251.1-1, Chapter II, Section 4.C.

5.11.1 Expectations for Exempted Operations. Activities controlled under Order exemptions will be conducted in a manner to assure no reduction or compromise in safety of the public, the environment, or the workers. The exemption request describes the standards to be achieved to reach a condition of

readiness to conduct the activities and the method of verification that the required readiness conditions had been attained. When compensatory measures such as mentors, supervisory oversight, Facility Representative presence, or area evacuations are appropriate, they should be defined and verified prior to approval to commence the operations being given. In all cases, the activities are to be conducted within an approved safety basis. The systems, structures, and components important to assuring safe operations will be verified to be in a condition to assure an acceptable level of safety. Operational procedures should be identified and should be adequate to control the processes and assure the acceptable level of safety. Personnel should have an adequate level of knowledge, qualification, and experience such that when coupled with the specified compensatory measures, satisfactory formality of operations is assured. The methods to meet these principles should be defined and the record of meeting and verification of these principles should be retained.

5.11.2 Process for Exemptions. DOE M 251.1-1 establishes the procedures and authorization to request and approve exemptions to DOE Orders. The following steps describe the process to gain approval, plan, and carry out program work when an exemption to the requirements to DOE O 425.1B is appropriate.

(1) CSO review or approval of the exemption to the requirements of DOE O 425.1B for the specific activities will be obtained in accordance with DOE O 251.1. In most cases, the request will be initiated, described, and justified by the responsible contractor. The request will include the process to be utilized to develop, review, approve, and monitor the exempted operations. DOE line management will endorse the proposal, including statements of DOE line actions which will be in place to support the activity and assure a satisfactory level of safety is maintained. The exemption request must address the essential elements specified in DOE M 251.1-1, Chapter II, Section 4C.

(2) The responsible contractor develops the procedures for the operation and achieves readiness to startup or restart the program work in accordance with them. DOE line management oversees the contractor efforts including review and approval of the procedures and verification of readiness to startup or restart program work. DOE Independent oversight is provided copies of all procedures.

(3) The responsible contractor conducts the program work in accordance with the approved procedures.

(4) DOE line management monitor the satisfactory accomplishment of the program work in accordance with the approved procedures. Particular attention must be taken to ensuring all compensatory measures remain in place and continue to be effective.

(5) DOE independent oversight, when deemed appropriate by EH, monitors the preparation and conduct of these procedures as desired.

APPENDIX 1

APPLICATION OF THE GRADED APPROACH

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APPLICATION OF THE GRADED APPROACH IN ORR PLANNING

For the purposes of this appendix, the graded approach is defined as the process by which the readiness determination is adjusted in depth of detail required and magnitude of resources expended to be commensurate with the facility's potential impact on safety, environmental compliance, safeguards and security, and its programmatic importance, including present and future mission. The graded approach is commensurate with:

(1) The relative importance to safety, safeguards, and security;
(2) The magnitude of any hazard involved;
(3) The life cycle stage of a facility;
(4) The programmatic mission of a facility;
(5) The particular characteristics of a facility;
(6) The cause and circumstances of the facility shutdown;
(7) Complexity of the weapons-related or research activity; and
(8) Other relevant factors.

All ORR s address the minimum set of core requirements and any additional requirements as deemed necessary for adequate review (breadth). A recent review, equivalent to an ORR, may be used as justification for eliminating a core requirement from the breadth of the ORR. With respect to ORR planning, a graded approach is utilized to determine the level of detail, that is, the depth. The combination of breadth and depth forms the envelope (scope) within which the ORR is conducted. Proper utilization of the graded approach is essential to conducting a successful ORR. The supporting principle governing the use of the graded approach must be that knowledgeable personnel analyze the factors surrounding the restart, determine the depth of the review needed, and then document this determination. Precise documentation facilitates communication with knowledgeable outside officials that the proper level of review has been conducted and that readiness to operate has been accurately verified.

The depth of an ORR cannot be determined using a cookbook or formula approach. Depth requirements depend on knowledgeable people identifying relevant topics based on their experience, the facility's characteristics, the facility's operating environment, the operating and support organizations' capabilities, and the risks associated with the proposed startup or restart. The breadth discussion in the approved

plan-of-action should provide a basis for determination of the depth of the review of individual criteria or core requirements.

Criteria and review approaches are developed for each core requirement, which specify the level of detail that is appropriate for that issue. The following factors and their implications should be considered in developing the depth of the ORR and should be considered in preparation of the plan-of-action:

- Physical modifications to the facility: Any modification must be assessed for its potential effect on facility hazards and risks, on the facility safety basis as documented in the Safety Analysis Review (SAR) and associated Technical Safety Requirements (TSRs), on facility procedures, on the need for personnel to be trained on the reconfiguration, etc. In addition, the integrity of the facility design baseline may need to be verified.

- Procedural changes: Changed or new procedures must be reviewed to determine if they have been adequately verified and validated, if the operators have been adequately trained on the modified procedures, and if the procedures at the workstations clearly reflect the changes.

- Personnel changes: Continuity of the operations team must be assessed to determine if significant loss of experienced personnel has occurred and, if so, has been adequately mitigated. Training and qualification of new and reassigned personnel must be verified.

- Length of shutdown: There is a characteristic loss of operator familiarity with normal facility operations that increases with the length of the shutdown. If the shutdown is unusually long, a review and possibly requalification of the operators may be necessary. There are also physical processes (corrosion, radioactive decay, evaporation, etc.) that may become important following an extended outage. The longer the outage and the more complex the activity during the outage, the more rigorous should be the review to identify unanticipated changes.

- Overall hazard characteristics of the facility: The nature of the hazards to safety and the environment associated with a facility/process are a major component in determining the depth of the ORR. The depth of an ORR for a facility that handles small quantities of tritium gas would not be as complex as one that handles large quantities of plutonium.

- The complexity of the activity: The size and complexity of the facility and/or process being reviewed drives the size and complexity of the ORR. The depth of the review requires that reviewers be able to comprehend and accomplish the criteria provided them. The number of criteria developed is based on the size and complexity of the facility/process.

- A new process or facility versus the restart of an existing activity: A significantly new process would involve verification of training and qualification of workers and new procedures without any significant reference points available onsite. This would drive the ORR to be more thorough and comprehensive than the review for a process that has a significant experience base onsite.

- The programmatic significance of the subsequent operations: A facility/process that is intended for long-term programmatic operations would necessarily require a more comprehensive and thorough review in some specific area than would a temporary operation.

- Introduction of new hazards: The proposed facility evolution (startup or restart) must be evaluated for potential new hazards. While some new hazards will be obvious, a critical review is needed to identify subtle new hazards introduced by the startup of new facilities or modification of existing facilities. Modifications made to improve operations in one aspect may unexpectedly introduce hazards in a different area.

- Increase in existing hazards or risk: Modifications to the facility, personnel, or procedures must be evaluated for their potential to increase the hazard level (e.g., by increasing the inventories of hazardous materials) or the hazard potential (e.g., by introducing a new mechanism for the release of hazardous materials).

- Operating history of the facility: The record of operational reliability, e.g., reliability during most recent operation, may identify issues to be addressed in the proposed ORR. Additionally, the nature of the facility/process transition to standby or shutdown status needs to be considered. A shutdown resulting from systemic safety concerns may require greater ORR depth than would a shutdown in response to an individual safety concern.

- Confidence in site-wide issues: Even if the proposed startup or restart does not directly involve changes to site issues (e.g., emergency preparedness, site fire response, environmental monitoring), it

may be prudent to evaluate these in an ORR unless recent reviews have shown them to be acceptable. Startup or restart of a facility is problematic within a significantly flawed site infrastructure. Conversely, a strong record of implementing DOE requirements, e.g., Conduct of Operations, would allow for a justifiable reduction in depth in that area in the ORR.

- Issues raised through other internal or external reviews: The ORR may need to verify that previously raised issues have been adequately addressed. These issues may be facility-specific or may relate to the site infrastructure within which the facility operates. Technical Safety Appraisals and Tiger Team reports are important sources of these issues. The facility's experiences in implementing the corrective actions and lessons learned may also provide a valuable perspective for determining the depth of the ORR. Caution must be exercised in utilizing previous inspections as justification for eliminating a topic or limiting the breadth of review. The adequacy of any previous review to be used in this manner should be equivalent in all respects to the review that would have been conducted during the ORR.

- DOE O 425.1B requires that ORRs document lessons learned. Such lessons may assist in determining the depth of the ORR. Previous reviews may highlight issues to be considered or may provide the justification for doing a less detailed review if recent reviews and restart experience can be cited.

- Extent to which the facility/process has been evaluated or operated using the standards and level of excellence being used in the ORR: In applying the graded approach, the extent to which the facility has utilized or been evaluated against the current nuclear safety standards should be considered. A facility that has operated successfully using the DOE nuclear safety standards may require a less extensive ORR depth.

APPENDIX 2

GENERIC SAMPLES FOR DEVELOPING THE PLAN-OF-ACTION AND IMPLEMENTATION PLAN

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GENERIC SAMPLES FOR DEVELOPING THE PLAN-OF-ACTION AND IMPLEMENTATION PLAN

The following pages include the minimum ORR core requirements and several examples of evaluation objectives that permit a structured and orderly process in defining the scope of the ORR. The list of minimum core requirements are used to establish the breadth of the review. Any additional core requirements specific to the facility or ORR should also be included. A recent review, equivalent to an ORR may be used as justification for eliminating a core requirement from the breadth of the ORR. The examples of evaluation objectives are provided to assist in development of the depth of the review, which is specified in the CRADs. The lists are not all inclusive, however, they provide a starting point in the development of specific criteria for each core requirement of an ORR. The number of criteria and the level to which each of these criteria are assessed is specific to the ORR and governed by the graded approach as discussed in Appendix 1. These listings are not a part of the ORR or the ORR plan-of-action. They are included to provide an aid for managers in defining the breadth of the ORR and preparing the plan-of-action, and for team leaders in defining the depth of the ORR and developing implementation plans.

Each of the core requirements listed below, as a minimum, must be addressed when developing the breadth of an Operational Readiness Review (ORR). Justification shall be provided in the plan-of-action if it is determined that a particular core requirement will not be reviewed. The plan-of-action may reference a timely, independent review which addressed the requirements in a technically sound manner to justify not performing further evaluation of a core requirement during conduct of an ORR. A graded approach, defined in Appendix 1, will be used to determine the level of analysis, documentation, and/or actions necessary (depth) to evaluate the core requirements listed below or other core requirements in the defined breadth of the ORR.

Minimum Core Requirements. Each of the minimum core requirements listed below shall be addressed when developing the breadth of an Operational Readiness Review. Justification shall be provided in the plan-of-action, prepared in accordance with paragraphs 4b(2) and (3), above, if it is determined that a particular core requirement will not be reviewed. The plan-of-action may reference a timely, independent review that addressed the requirements in a technically sound manner to justify not performing further evaluation of a core requirement during an Operational Readiness Review. The purpose of these core requirements is to assess the readiness of facility personnel, programs, and

equipment to conduct work safely, hence these core requirements are directly related to the seven guiding principles of integrated safety management. The core requirements apply to both DOE and the contractor as appropriate, unless otherwise noted.

Core Requirements:

(1) Line management has established programs to assure safe accomplishment of work (the startup or restart authority should identify in the plan-of-action those specific infrastructure programs of interest for the startup or restart). Personnel exhibit an awareness of public and worker safety, health, and environmental protection requirements and, through their actions, demonstrate a high- priority commitment to comply with these requirements. *(CR #8) (CR #14)* [1]

(2) Functions, assignments, responsibilities, and reporting relationships (including those between the line operating organization and ES&H support organizations) are clearly defined, understood, and effectively implemented with line management responsibility for control of safety. *(CR #11)*

(3) The selection, training and qualification programs for operations and operations support personnel have been established, documented, and implemented. The selection process and applicable position-specific training for managers assures competence commensurate with responsibilities. (The training and qualification program encompasses the range of duties and activities required to be performed.) *(CR #2)(CR#19)*

(4) Level of knowledge of managers, operations, and operations support personnel is adequate based on reviews of examinations and examination results and selected interviews of managers, operating, and operations support personnel. *(CR #3) (CR #19)*

(5) Modifications to the facility have been reviewed for potential impacts on training and qualification. Training has been performed to incorporate all aspects of these changes. *(CR #18b)*

[1] The italicized numbers in parentheses following each core requirement [e.g., *(CR#3)*] are the numbers of the core requirements as they appeared in the previous version of this Order, DOE O 425.1A.

(6) There are sufficient numbers of qualified personnel to conduct and support operations. Adequate facilities and equipment are available to ensure operational support services (e.g., operations, training, maintenance, waste management, environmental protection, industrial safety and hygiene, radiological protection and health physics, emergency preparedness, fire protection, quality assurance, criticality safety, and engineering) are adequate for operations. *(CR #8) (CR #13)*

(7) Facility safety documentation is in place and has been implemented that describes the "safety envelope" of the facility. The safety documentation should characterize the hazards/risks associated with the facility and should identify preventive and mitigating measures (systems, procedures, administrative controls, etc.) that protect workers and the public from those hazards/risks. Safety structures, systems, and components (SSCs) are defined and a system to maintain control over their design and is established. *(CR #4)*

(8) A program is in place to confirm and periodically reconfirm the condition and operability of safety SSCs. This includes examinations of records of tests and calibration of these systems. The material condition of all safety, process, and utility systems will support the safe conduct of work. *(CR #5)*

(9) The facility systems and procedures, as affected by facility modifications, are consistent with the description of the facility, procedures, and accident analysis included in the safety basis. *(CR #15)*

(10) There are adequate and correct procedures and safety limits for operating the process systems and utility systems that include revisions for modifications that have been made to the facility. *(CR #1)(CR #18a)*

(11) A routine drill program and emergency operations drill program, including program records, have been established and implemented. *(CR #9)*

(12) An adequate startup or restart program has been developed that includes plans for graded operations and testing after startup or resumption to simultaneously confirm operability of equipment, the viability of procedures, and the performance and knowledge of the operators.

The plans should indicate validation processes for equipment, procedures, and operators after startup or resumption of operations including any required restrictions and additional oversight. *(CR #10)*

(13) The formality and discipline of operations is adequate to conduct work safely and programs are in place to maintain this formality and discipline. *(CR #12)*

(14) Formal agreements establishing requirements are in place between the operating contractor and DOE, via the contract or other enforceable mechanism, which govern the safe operations of the facility. A systematic review of the facility's conformance to these requirements has been performed. These requirements have been implemented in the facility, or compensatory measures are in place, and formally agreed to during the period of implementation. The compensatory measures and the implementation period are approved by DOE. *(CR #7)*

(15) A feedback and improvement process has been established to identify, evaluate, and resolve deficiencies and recommendations made by oversight groups, official review teams, audit organizations, and the operating contractor. *(CR #6)*

Additional Department of Energy Oversight Core Requirements –

(16) The technical and managerial qualifications of those personnel at the DOE Field organization and at DOE Headquarters who have been assigned responsibilities for providing direction and guidance to the contractor, including the Facility Representatives, are adequate (DOE Readiness Review only). *(CR #16)*

(17) The breadth, depth, and results of the responsible contractor Operational Readiness Review are adequate to verify the readiness of hardware, personnel, and management programs for operations (DOE Readiness Review only). *(CR #17)*

(18) DOE Operations Office Oversight Programs, such as Occurrence Reporting, Facility Representative, Corrective Action, and Quality Assurance Programs, are adequate (DOE Readiness Review only). *(CR #20)*

The following shows the relationship between ISMS Principles and the Core Requirements. Core requirements follow the allied Guiding Principles.

Guiding Principle #1 – Line Management is responsible for the protection of employees, the public, and the environment. Line management includes those contractor and subcontractor employees managing or supervising employees performing work.

(1) Line management has established programs to assure safe accomplishment of work (the startup or restart authority should identify in the plan-of-action those specific infrastructure programs of interest for the startup or restart). Personnel exhibit an awareness of public and worker safety, health, and environmental protection requirements and, through their actions, demonstrate a high- priority commitment to comply with these requirements. *(CR #8) (CR #14)*

Guiding Principle #2 – Clear and unambiguous lines of authority and responsibility for ensuring ES&H are established and maintained at all organizational levels.

(2) Functions, assignments, responsibilities, and reporting relationships (including those between the line operating organization and ES&H support organizations) are clearly defined, understood, and effectively implemented with line management responsibility for control of safety. *(CR #11)*

Guiding Principle #3 – Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.

(3) The selection, training and qualification programs for operations and operations support personnel have been established, documented, and implemented. The selection process and applicable position-specific training for managers assures competence commensurate with responsibilities. (The training and qualification program encompasses the range of duties and activities required to be performed.) *(CR #2)(CR#19)*

(4) Level of knowledge of managers, operations, and operations support personnel is adequate based on reviews of examinations and examination results and selected interviews of managers, operating, and operations support personnel. *(CR #3) (CR #19)*

(5) Modifications to the facility have been reviewed for potential impacts on training and qualification. Training has been performed to incorporate all aspects of these changes. *(CR #18b)*

Guiding Principle #4 – 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.*

(6) There are sufficient numbers of qualified personnel to conduct and support operations. Adequate facilities and equipment are available to ensure operational support services (e.g., operations, training, maintenance, waste management, environmental protection, industrial safety and hygiene, radiological protection and health physics, emergency preparedness, fire protection, quality assurance, criticality safety, and engineering) are adequate for operations. *(CR #8) (CR #13)*

Guiding Principle #5 – Before work is performed, the associated hazards are evaluated and an agreed upon set of standards and requirements are established which, if properly implemented, provide adequate assurance that employees, the public, and the environment are protected from adverse consequences.

(7) Facility safety documentation is in place and has been implemented that describes the "safety envelope" of the facility. The safety documentation should characterize the hazards/risks associated with the facility and should identify preventive and mitigating measures (systems, procedures, administrative controls, etc.) that protect workers and the public from those hazards/risks. Safety structures, systems, and components (SSCs) are defined and a system to maintain control over their design and is established. *(CR #4)*

(8) A program is in place to confirm and periodically reconfirm the condition and operability of safety SSCs. This includes examinations of records of tests and calibration of these systems. The material condition of all safety, process, and utility systems will support the safe conduct of work. *(CR #5)*

(9) The facility systems and procedures, as affected by facility modifications, are consistent with the description of the facility, procedures, and accident analysis included in the safety basis. *(CR #15)*

Guiding Principle #6 – 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.

(10) There are adequate and correct procedures and safety limits for operating the process systems and utility systems that include revisions for modifications that have been made to the facility. *(CR #1)(CR #18a)*

(11) A routine drill program and emergency operations drill program, including program records, have been established and implemented. *(CR #9)*

(12) An adequate startup or restart program has been developed that includes plans for graded operations and testing after startup or resumption to simultaneously confirm operability of equipment, the viability of procedures, and the performance and knowledge of the operators. The plans should indicate validation processes for equipment, procedures, and operators after startup or resumption of operations including any required restrictions and additional oversight. *(CR #10)*

(13) The formality and discipline of operations is adequate to conduct work safely and programs are in place to maintain this formality and discipline. *(CR #12)*

Guiding Principle #7 – 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 on 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.

(14) Formal agreements establishing requirements are in place between the operating contractor and DOE, via the contract or other enforceable mechanism, which govern the safe operations of the facility. A systematic review of the facility's conformance to these requirements has been performed. These requirements have been implemented in the facility, or compensatory measures are in place, and formally agreed to during the period of implementation. The compensatory measures and the implementation period are approved by DOE. *(CR #7)*

(15) A feedback and improvement process has been established to identify, evaluate, and resolve deficiencies and recommendations made by oversight groups, official review teams, audit organizations, and the operating contractor. *(CR #6)*

(16) The technical and managerial qualifications of those personnel at the DOE Field organization and at DOE Headquarters who have been assigned responsibilities for providing direction and guidance to the contractor, including the Facility Representatives, are adequate (DOE Readiness Review only). *(CR #16)*

(17) The breadth, depth, and results of the responsible contractor Operational Readiness Review are adequate to verify the readiness of hardware, personnel, and management programs for operations (DOE Readiness Review only). *(CR #17)*

(18) DOE Operations Office Oversight Programs, such as Occurrence Reporting, Facility Representative, Corrective Action, and Quality Assurance Programs, are adequate (DOE Readiness Review only). *(CR #20)*

APPENDIX 3

Clarification of Some Core Requirements Contained in Appendix 2

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Clarification of some of the Core Requirements contained in Appendix 2

Since the formal inception of the Operational Readiness Review (ORR) program, lessons learned have been generated. Through review of these lessons learned is has been noted that some of the Core Requirements need further explanation to properly communicate the expectations contained therein. Specifically Core Requirement 7 regarding implementation of established requirements has generated confusion from both a preparation and an evaluation perspective. Core Requirement 10 has generated confusion from a preparation standpoint. Further details regarding these core requirements are provided below.

Core Requirements 7 states, "Formal agreements establishing requirements are in place between the operating contractor and DOE, via the contract or other enforceable mechanism, which govern the safe operations of the facility. A systematic review of the facility's conformance to these requirements has been performed. These requirements have been implemented in the facility, or compensatory measures are in place, and formally agreed to during the period of implementation. The compensatory measures and the implementation period are approved by DOE." This requirement was established to drive implementation of various initiatives including S/RIDs and Work-Smart Standards. The requirement however, includes implementation of the established requirements at the facility. Organizations have misinterpreted this requirement to be fulfilled through the completion of the S/RID or Work-Smart Standards program. While the completion of the program elements is certainly prerequisite to the proper controls being established in the facility, the facility level implementation of the requirements is the issue of primary concern. The procedures and direction for "floor level" operations must implement the established requirements agreed to by DOE and the operating contractor through the S/RID, Work-Smart Standard, or other acceptable program. The existence and adequacy of these procedures and direction at the floor level must be verified by line management prior to startup/restart, and confirmed by the ORR or RA team during the startup/restart review.

Core Requirement 10 States, "An adequate startup or restart program has been developed that includes plans for graded operations and testing after startup or resumption to simultaneously confirm operability of equipment, the viability of procedures, and the performance and knowledge of the operators. The plans should indicate validation processes for equipment, procedures, and operators after startup or resumption of operations including any required restrictions and additional oversight." This requirement was established to provide direction for the period following the ORR or RA and the startup/restart of the facility. It is recognized here that, since operations are not authorized prior to and during the ORR or

RA, actual operations can not be validated by a line manager or evaluated by an ORR or RA team. Hence, to some degree (more for a more complex facility), operators will be operating equipment, using procedures, and handling the hazards for the first time. It is appropriate to establish additional controls, support, and oversight for critical period of the startup process, which is often called the "deliberate operations phase." Review of the plans for these deliberate operations give the ORR or RA an opportunity to judge the level of complexity of the remaining startup/restart activities, the control to be exercised, and provide an appropriate recommendation to the startup authority, without having actually seen these events. Likewise, the responsible line manager can gain confidence through the plan that operators, procedures, and equipment have gained the requisite readiness to conduct work safely.

Some sites have provided guidelines for the establishment of startup/restart controls that accomplish the objectives outlined above. An example of these guidelines is included here for informational purposes. It is appropriate to note that the detail and magnitude of this plan is largely dependent of the complexity of the activity which is being started or restarted and the degree to which operations can be demonstrated prior to the introduction of hazards. If the majority of operations can be conducted and demonstrated during preparation and review processes, the plan should include those operations which could not be demonstrated, or will be conducted for the first time with the hazard present. Alternatively, an operation where the majority of the preparation must be done through walkthrough and table top, the plan would necessarily be more extensive.

Guidelines for Startup Plan Development

The plan should provide for a controlled, deliberate approach to achieving safe, hot operations. Other plans and schedules affecting startup should be summarized in the startup or restart plan such that the startup or restart plan is a complete, stand-alone document which clearly delineates the graded and systematic approach to full operations. The plan should detail implementation of management and facility activities necessary to achieve full operations not merely describe established programs.

A key element involves the participation of qualified management personnel in the evaluation initial operations testing. As such, the plan should include specific management observer responsibilities associated with each aspect of the plan. The following paragraphs provide further guidance on the plan.

A. Identification of facility management observers necessary for initial operations oversight.

(1) List the management personnel assigned for initial operational evaluations of the graded operations testing, including summary level duties, responsibilities, and shift staffing requirements. (Specific duties and responsibilities should be listed in the remaining sections of the plan). Include the specific duration of the initial operational evaluations. Include the specific qualifications of each individual (resumes).

B. Equipment operability

(1) Identify and describe the integrated tests planned and required to confirm operability of equipment during initial operations. Include the purpose and a summary of the acceptance criteria of the tests.

(2) List management responsibilities for approval of test commencement and management observer oversight of test performance. Include management approval requirements for key events or progression to the next phase of testing.

(3) Provide a summary level schedule that clearly illustrates the systematic approach to full operations.

C. Procedure viability

(1) Identify and describe the mechanism for verification of the viability of procedures during actual performance, including requirements for management observer participation in the first time execution of procedures.

(2) Summarize the process for procedure changes as a result of identification of inadequacies in the field. Include any provisions for increased procedure revision support during periods of high levels of first time execution of procedures.

D. Operator Performance

(1) Identify and describe the mechanism for real time in-plant management observer evaluation of operator performance to verify the adequacy of operator training.

(2) Identify and describe the mechanism established for remediation of any identified weaknesses.

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APPENDIX 4

WRITING GUIDE

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OPERATIONAL READINESS REVIEW
WRITING GUIDE

Introduction

The process of determining the operational readiness of DOE facilities is complex, involving many technical and management issues at each specific facility or site. Operational Readiness Reviews (ORR) must be accomplished by experienced, dedicated people and conducted with sufficient rigor and discipline so Departmental leadership and independent oversight groups have confidence in the findings and recommendations.

ORRs should be assumed to be subject to public scrutiny. In addition, results from these reviews may form the basis for improvements at DOE facilities. For these reasons, it is essential that team members substantiate their observations in writing, factually, accurately, and in such a way as to make clear the details of observed strengths and weaknesses. Written reports from an ORR should be of the highest technical accuracy and quality.

This guide is intended to assist team members in documenting their activities and findings.

Criteria Review and Approach Documents (CRADs):

CRADs are the documents used in the implementation plan to establish the depth of the ORR and provide guidance to the ORR team members. As such, the quality of these documents will have a significant impact on the overall quality of the ORR. CRADs are the bases used to evaluate the core requirements of an ORR. The core requirements of an ORR include the 20 minimum core requirements of the DOE O 425.1B, as well as any additional core requirements specific to the particular ORR. Each core requirement is evaluated based on the criteria established. The criteria should be specific and as objective as possible, dependent on the given situation.

The development of the CRADs is the means through which the graded approach is applied to the scope of the ORR. Those areas significant to the startup or significant to the shutdown should be assessed to a greater depth than other areas. For example, if in a maintenance shutdown, a system was modified or a new system was added, the training, procedures, documentation, safety basis, etc., for that new system should be reviewed exhaustively. Another system in that same facility that did not undergo modification would receive a less comprehensive review. This review could be a sampling of the training and procedures associated with the system. For example, 20 % of the qualified operators of unmodified systems could be interviewed to assess level of knowledge, whereas the percentage could be higher for the modified or new system. In a shutdown that was caused by a OSR/TSR violation due to a personnel error, the training and qualification program for the facility should be assessed in detail while the implementation of the safety basis itself would need a less comprehensive assessment. For a new, high hazard facility, the depth of the review should be complete in all areas. For a restart of a low hazard facility, the review should be focused on the areas significant to the startup or shutdown with the remaining core areas addressed to a lesser extent, via a less extensive criteria. In general, the discussion in the plan-of-action will guide the consideration that results in the level of detail in any particular review area.

Each CRAD should begin with a core requirement or some portion of the core requirement. This will ensure that all core requirements are addressed by criteria regardless of the approach used in developing the criteria. The specific criteria, which address the core requirement or portion of a core requirement, should follow and should be related clearly to these requirements. Each criterion then, is a statement of the specific actions, or attributes, the inspector(s) use to make a judgement as to the readiness of the site, facility, or process to operate in this specific area. The next section of the CRAD is the Review

Approach. This section describes the documents to be reviewed, the personnel to be interviewed, and the shift evolutions, including tours and walkdowns, to be observed that will lead to the conclusion as to whether the criteria have been met. The final portion of the CRAD should include any references, e.g., DOE Orders, mandatory standards, or site specific requirements against which the preceding criteria are to be assessed. The alpha-numeric identification methodology chosen for the ORR implementation plan should represent a logical “work breakdown structure” chosen to describe the entire ORR effort so that all elements can be related back to the core requirements for safe operation of the facility.

Keep in mind that every ORR is different and hence the depth of the evaluation specified by the CRADs will be unique in every case. These following examples are by no means inclusive and serve to provide CRADs previously deemed appropriate in specific situations. In some cases, the criteria and specific review approaches are combined. In other examples, they have been separated. Either method is acceptable as long as an adequate, documented evaluation of the core requirement results.

Sample CRADS

EMERGENCY PREPAREDNESS (EP)

OBJECTIVE

EP.1 An emergency operations drill program, including program records, has been established and implemented. (**CORE REQUIREMENT 11**)

Criterion:

An effective emergency preparedness program has been established. Drills and exercises are conducted and an adequate response capability exists. (DOE O 151.1, S/RID FAs 04 and 05)

Approach:

Record Review: Verify that the XXX (name of site, facility, activity, or process) has been adequately incorporated into the K-Area operational and emergency drill program. Review the records that describe the recent emergency preparedness drills and review the results from each. Determine if the drill scenarios were adequate and if the necessary number of drills have been conducted to fully verify and test compliance with the approved safety bases of the facility. Determine if lessons learn from drills are factored into following drills and training.

Interviews: None

Shift Performance: Observe pre-drill briefings, conduct, and post-drill critiques of an Emergency Preparedness drill.

MANAGEMENT (MG)

OBJECTIVE

MG.1 A process has been established to identify, evaluate, and resolve deficiencies and recommendations made by oversight groups, official review teams, audit organizations, and the operating contractor. (**CORE REQUIREMENT 15**)

Criterion

A system for identifying, reviewing, cataloging, and resolving deficiencies and recommendations is adequately implemented. (5480.19, Ch. VI and VIII; 10 CFR 830.120, Conduct of Operations Matrix; DOE P 450.4; S/RID FA 02)

Approach

Record Review: Review the issue management tracking system, selecting representative issues and assessing the adequacy of XXX incorporation into the program. Assess the backlog and prioritization system to ensure appropriate emphasis on the XXX.

Interviews: Interview issue management personnel to establish their qualification and understanding of the program.

Shift Performance: Evaluate the Issue Management Programs' effectiveness in ensuring that corrective actions are being completed and tracked to closure through the system.

OBJECTIVE

MG.2 An adequate startup test program has been conducted which verifies the operability and integration of the XXX equipment. The plant is in a material condition to support the safe startup of program work. **(CORE REQUIREMENT 12)**

Criteria

The program is adequate and is on schedule per approved startup plans to support safe startup. (S/RID FAs 07, 08, and 10)

Approach

Record Review: Review documentation of test results and resolution of open items for at least three tests of safety systems or plant components. Verify the satisfactory integration of these new plant systems with the existing K-Area systems. Verify that maintenance records and requirements have been updated to reflect the new systems requirements.

Interviews/Shift Performance: Observe management review of the test plans and results for adherence to procedures and management of any resultant actions.

OPERATIONS (OP)

OBJECTIVE

OP.2 Personnel exhibit an awareness of ISMS expectations and through their actions, demonstrate a high priority commitment to comply with these requirements. A routine drill program, including program records, has been established and implemented. **(CORE REQUIREMENT 11 and 1)**

Criteria

Operations personnel, including operators, supervisors, and facility shift engineers understand the importance of procedural compliance and adhere to the principles of the Integrated Safety Management System (ISMS) Policy. (DOE P 450.4, 5480.19, Ch. I and XVI)

An effective routine operations drill program has been established. Drills and exercises are conducted and an adequate response capability is demonstrated. (S/RID FA 04)

Approach

Record Review: Review the training records that indicate that operations personnel have received instruction on safety and environmental protection requirements and their implementation, and the procedure compliance policy. Review the drill records that describe the routine drills that have been conducted and review the results from each. Determine if the drill scenarios were adequate and if the necessary number of drills have been conducted to fully test personnel, procedures and equipment in a broad range of facility operations.

Interviews: Interview operators and supervisors to assess their understanding of the safety envelope, and the implementation of the safety and environmental protection requirements in procedures and operator round sheets. Interview personnel responsible for the development and conduct of drills to evaluate their understanding and their ability to execute the drill program.

Shift Performance: Observe drills and evolutions to assess the understanding and significance operators and supervisors place on ensuring facility operations meet environmental protection requirements and are within the established safety envelope. Assess procedure compliance when conducting evolutions and responding to abnormal conditions.

Observe operational drills to verify they test operations personnel with realistic and challenging scenarios. Evaluate whether an adequate response capability exists.

RADIOLOGICAL PROTECTION (RP)

OBJECTIVE

RP.1 Radiological protection programs are established, sufficient numbers of qualified personnel are provided, and adequate facilities and equipment are available to ensure operational support services are adequate for safe operations. (**CORE REQUIREMENT 1)**

Criteria

The radiological protection organization is established and functioning to support the operations organization. Functions, assignments, responsibilities, and reporting relationships are clearly defined, understood, and effectively implemented. It is adequately staffed with qualified personnel. (10 CFR 835, Conduct of Operations Matrix, S/RID FA 11)

The radiological protection program meets or exceeds the requirements of 10 CFR 835. (10 CFR 835, S/RID FA 11)

Approach

Record Review: Review the documentation (e.g., administrative procedures, organizational charts, position descriptions, or internal memorandums) which establish the roles, responsibilities, interfaces, and staffing levels for the radiological protection support organization. Review the necessary records and program procedures to ensure that the radiological protection program includes the items identified above. Review records of radiation protection evaluations of off-normal occurrences with identified necessary corrective actions. Review implementation of rule 10 CFR 835, S/RID FA 11.

Interviews: Interview those radiation protection personnel who support operations to determine if they are familiar with their roles, responsibilities, and interfaces with the operations organization.

Shift Performance: While observing operations and maintenance evolutions and drill response, determine if the radiation protection personnel who support XXX operations are providing adequate support to the operations organization, and that they are giving adequate attention to health, safety and environmental protection issues.

SAFETY ENVELOPE VERIFICATION (SE)

OBJECTIVE

SE.1 Facility safety documentation is in place that describes the "safety envelope" of the facility. The safety documentation should characterize the hazards/risks associated with the facility and should identify mitigating measures (systems, procedures, administrative controls, etc.) that protect workers and the public from those hazards/risks. A system to maintain control over the design and modification of facilities and safety-related systems is established. (**CORE REQUIREMENT 7**)

Criterion

The safety documentation addresses appropriate hazards/risks associated with operations. Administrative controls are in place to ensure that repairs (or modifications) are adequately analyzed to identify and to ensure that design changes are documented and approved prior to implementation. (5480.23, para 8, Attachment 1, section 3 and 4, DOE-STD-1073-93, Ch.1.3, S/RID FAs 03 and 08)

Approach

Record Review: Review safety basis documentation to assess whether the safety basis adequately includes appropriate hazards/risks associated with XXX operations. Review recent design changes and modifications to the facility to ensure that they have been reflected in drawings and documents available to operators and maintenance personnel.

Interviews: Interview personnel associated with developing/processing facility modifications to determine if they understand configuration management requirements for the facility.

Shift Performance: Perform a facility walk down to determine that there are no uncontrolled modifications to safety systems. This walk down should evaluate the accuracy of drawings and other documentation for plant operation and maintenance. At least one recently completed modification should be observed and changes verified, including changes to operating procedures if applicable.

TRAINING (TR)

OBJECTIVE

TR.1 The training and qualification programs encompass the range of duties and activities required to be performed. (**CORE REQUIREMENT 3**)

Criteria

The tasks required for competent job performance are identified and documented through a systematic analysis of job requirements. The training program is based on the results of this analysis. Learning objectives are derived from the analysis. (5480.20A, Ch. 1, para 7, S/RID FA 04)

Requirements for continuing training have been adequately defined and programs have been developed. Continuing training includes conduct of realistic drills to maintain proficiency in responding to abnormal and accident situations, including those involving radiological hazards. (S/RID FA 04)

Training programs for operations and maintenance personnel include training on the requirements contained in the approved operating basis for the facility. (5480.20A, Ch. I, para 7, S/RID FA 04)

Training programs for operations and maintenance personnel emphasize the importance of compliance with procedures and safety requirements. (5480.20A, Ch. I, para 7, S/RID FA 04)

Training for technical staff personnel is based on an assessment of position duties and responsibilities. (5480.20A, Ch. 1, para 5, S/RID FA 04)

Approach

Record Review: Review operations and maintenance lesson plans for incorporation of safety requirements. Review the continuing training program plan to verify its adequacy to support safe operations.

Review the systematic analysis of job requirements conducted to provide reasonable assurance that all tasks that are essential to safe and efficient operation.

Ensure that subject matter experts, line management, and training staff developed and maintain a valid facility-specific task list as the basis for the training program. The facility-specific list of tasks selected for training is reviewed periodically and updated as necessary by changes in procedures, facility systems/equipment, job scope, and advances in technology. DOE and other appropriate training guidelines are used as a guide for selecting, sequencing, and verifying training program structure and content.

Verify that the current facility safety analysis report, operating procedures, technical and professional references, and facility/industry operating experience are used to identify facility specific training content and information for use in developing training materials.

Review the degree to which on-the-job training and hands-on evaluations for operations and maintenance personnel are used to reinforce classroom activities.

Review examinations (both written and oral) and performance evaluations to verify that they are based on learning objectives, are reviewed by Subject Matter Experts, are changed frequently enough to avoid compromise, and are formally controlled.

Interviews: Interview training personnel responsible for continuing training, and drill scenario development and implementation. Interview personnel responsible for establishing training needs for operations and maintenance personnel.

Shift Performance: Observe operator and maintenance personnel response to drills. Evaluate a continuing training classroom lecture or field training activity for technical and administrative adequacy.

OBJECTIVE

TR.2 Modifications to the facility have been reviewed for potential impacts on training and qualification. Procedures have been revised to reflect these modifications and training has been performed to these revised procedures. (**CORE REQUIREMENT 10**)

Criteria

Qualification programs are based on the latest modifications to the facility. (5480.20A, Ch. I, para 7. S/RID FA 04)

Training has been completed and documented for the latest revisions of procedures performed by operators, maintenance personnel, facility shift managers, facility shift engineers, and supervisors. (5480.20A, Ch. I, para 7, S/RID FA 04)

Approach

Record Review: Review the process used to evaluate changes to operations and maintenance personnel training needs. Review lessons plans, and supporting examinations. Determine if lesson plans accurately reflect recent facility and/or procedure changes.

Interviews: Interview training personnel to determine their involvement with facility and/or procedure changes affecting lesson plans.

Shift Performance: Observe operations and maintenance personnel in the performance of on-the-job training. Observe classroom training or a field training activity. During observation of operations involving procedures with revisions, verify proper conduct and understanding of the procedures by the operators.

CRAD REFERENCES

DOE-STD-1027-92	*Guidance on Preliminary Hazard Classification and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Safety Analysis Reports,* including Change Notice 1, September 1997
DOE-STD-1063-2000	*Facility Representative*
DOE-STD-1073-93	*Guide for Operational Configuration Management Program*
DOE O 151.1	*Comprehensive Emergency Management System*
DOE O 232.1	*Occurrence Reporting and Processing of Operations Information*
DOE O 420.1	*Facility Safety*
DOE O 425.1A	*Startup and Restart of Nuclear Facilities*
DOE O 430.1A	*Life Cycle Asset Management*
DOE O 440.1	*Worker Protection Management for DOE Federal and Contractor Employees*
DOE O 442.1	*Department of Energy Employee Concerns Program*
DOE Order 4330.4B	*Maintenance Management Program*
DOE Order 5480.19	*Conduct of Operations Requirements for DOE Facilities*
DOE Order 5480.20A	*Personnel Selection, Qualification, Training, Requirements for DOE Nuclear Facilities*
DOE Order 5480.21	*Unreviewed Safety Questions*
DOE Order 5480.22	*Technical Safety Requirements*
DOE Order 5480.23	*Nuclear Safety Analysis Reports*
10 CFR 830.120	*Final Rule, Quality Assurance*
10 CFR 835	*Final Rule, Radiological Controls*
DOE P 450.4	*Safety Management Policy*

TEAM MEMBER QUALIFICATIONS DOCUMENTATION

DOE O 425.1B specifies the areas of qualification which is required for each ORR Team member. The record of the ORR must include evidence of the qualification of each team member. In addition, the Team Leader is responsible for selection of the team based on the technical and assessment qualification of each prospective member. The specific requirements described in sections 5.1.5.1 and 5.4.2 include:

Technical knowledge of the area assigned to evaluate,
Knowledge of evaluation processes and methods,
Facility specific information, and
Independence.

The attached form has been developed both to assist the Team Leader in his selection process as well as to provide a consistent, consolidated record of the team qualifications for inclusion in the record of the ORR. While the use of the form is optional, the information which it requires must be available in the ORR record and must be persuasive that the individual team member is qualified to participate in the ORR in each of the four areas noted above.

The form is intended to be a summary of the relevant factors which qualify the individual to assess the core requirement(s) specified and not a complete resume of the individual team member. It is appropriate that the team members resume be attached. In addition, it is recommended that a required reading program be utilized to ensure team member familiarity with site and facility documentation such as specific procedures and documents which forms the facility safety basis. The completed required reading record sheets would be attached to provide the basis for the facility familiarization qualification requirement. In addition, specifics such as site visits, specialized, site specific training, and presentations would be recorded on the summary form.

DOE O 425.1B requires that each core requirements be assessed by a qualified team member. It is therefore necessary that the aggregate of the team member qualification summaries include each core requirement within the scope of the ORR described in the approved plan-of-action.

The entry for “basis for acceptable independence” is to include information which demonstrates that the chosen team member meets the criteria for independence specified in DOE O 425.1 and this standard. In essence, the requirement is that the individual not have been responsible for the work he is to review either as a worker or supervisor and that he not be responsible or in the direct line management for the facility.

TEAM MEMBER QUALIFICATION SUMMARY

Name:

Objectives Assigned:

Employer/Normal Work Assignment:

Summary of Technical Qualifications:

(Bullet format please, no narrative)

Summary of Assessment/ORR/Inspection Qualifications:

(Bullet format please, no narrative)

Basis for Acceptable Independence:

Summary of Facility Familiarization:

Required Reading	Date/Initials
SAR, XYZ Sections in Chap X	_____
DOE Plan of Action	_____
DOE Implementation Plan	_____
ORR Standard: Writer's Guide (Appendix 4)	_____
TSR's for XYZ Operations	_____
Training Study Guide for facility/activity	_____

Training

Familiarization briefing _____

Rad Worker I Training/Qualification _____

Facility/Activity Access Training _____

General Employee Training _____

Tour, XYZ Facility and Operating Areas _____

Qualified

Team Leader Signature: _____

ASSESSMENT FORM (FORM 1)

Form 1s are used to document the methods and actions taken by a team member in the criteria evaluation process. Each Form 1 covers a specific objective and lists the means the team member used to measure the site's performance relative to the objective provided in the Criteria and Review Approach Document (CRAD) or Criteria and Review Approach (CRA) lists[2]. The form should be complete enough to allow a reviewer of the form to follow the inspection logic and means utilized to verify the facility's performance with respect to the criteria and to thereby validate the ORR's completeness and adequacy. Ensure that the approach used is what the CRAD called for. If for some reason the approach used does not exactly match the approach described in the CRAD, the reason should be documented.

Functional Area:

Print the ORR functional area to which the CRAD has been assigned.

CRA Number/Title:

Specifically identify the CRAD or portion of the CRA that the Appraisal Form is to support. Provide the name and number of the CRA or portion of CRA.

Date:

Provide the date on which the form is generated. Change the date as updates or revisions to the form are generated.

Method of Appraisal:

Use this section to clearly describe the approach taken to review the criterion against the CRAD guidance. If for some reason the approach used does not exactly match the approach described in the CRAD, the reason should be documented here.

Note: CRA and CRAD are used interchangeably in this document and refer to the criteria document upon which the ORR is based.

Personnel Contacted/Positions:

The individuals contacted while reviewing the criterion should be listed by title.

Records and Other Documents Reviewed:

The documents should be listed in bullet format.

Evolutions/Operations Witnessed:

List evolutions/operations with location (e.g., building) in bullet form.

Spaces Visited:

Indicate the areas of the facility visited.

Discussion:

Provide a discussion of the performance against the criteria

Conclusion:

Provide a conclusion as to whether the criteria have been met, and if not met, reference applicable Form 2s. This section of the Form 1 will provide the basis for the ORR Report and conclusions as to readiness to startup. This section should be a stand alone statement that describes in detail whether or not the criterion was met and why. It is anticipated that the wording in this section can be transcribed directly into the report.

Inspected by:

The inspector who generates the form prints their name in order to identify the generator of the form.

Approved by:

The ORR Team Leader signs the form after all revisions/changes have been incorporated. This signature indicates that the form is in final form. The team member should also sign the form to indicate agreement with the content.

DEFICIENCY FORM (FORM 2)

The Form 2 is used to document the findings identified during the criteria evaluation process. A separate Form 2 should be generated for each finding related to a particular core requirement. For instance, in reviewing a CRA or portion of a CRAD, an inspector will generate a single Form 1 which describes the methods utilized in the investigation. If three distinct findings are discovered, the inspector would then generate three Form 2s to detail the deficiencies. A single Form 2 may be used to identify a generic problem for which a number of individual examples are listed. Clear communication is the objective and the specific number of Form 2s used to detail findings will necessarily be up to the discretion of the team member and Team Leader.

Proper completion of Form 2s takes a significant amount of time. During the ORR, time should be set aside daily to complete the discussion section of the Form 2s. Experience has shown that it is easier to produce a quality write-up the day of the inspection rather than trying to reconstruct events at a later date. There are daily meetings between the Group Leaders and Team Leader to discuss ORR progress and results. Team members should provide the Group Leader who attends that meeting with essentially complete, draft Form 2 write-ups from inspections conducted that day. This allows the Team Leader to present site management a daily briefing of emerging issues. Draft Form 2s will be left with the site daily in order facilitate the validation process. Findings should be documented (i.e., a Form 2 drafted) as soon as there is reasonable evidence to substantiate a finding. Avoid delaying the drafting of a Form 2 until there is overwhelming evidence as this may excessively delay the validation and correction processes. The following is some detailed guidance for writing Form 2s that are based on lessons learned from previous ORRs.

How well the ORR Final Report reflects actual readiness conditions at the facility, fundamentally depends upon the quality of the Form 2s completed by individual ORR team members.

Revisions to Form 2s should be a stand alone document and contain all the information from the original Form 2 that is still applicable.

Functional Area:

Print the ORR functional area to which the CRAD has been assigned.

CRA Number/Title:

Specifically identify the CRA or portion of the CRA that the Appraisal Form is to support. Provide the name and number of the CRA or portion of CRA.

Date:

Provide the date on which the form is generated. Change the date as updates or revisions to the form are generated.

ID #:

The Review Coordinator will issue a number that uniquely identifies the issue. This number is used to correlate the findings (Form 2) and disposition documents (Form 3). Once assigned this number should appear on all revisions and updates.

Requirement:

The applicable portion of the CRA should be quoted to clearly state the standard of performance utilized to generate the deficiency.

Reference(s):

All applicable references, e.g., DOE Orders, CFRs, etc., should be listed. The reference should be specific down to the section to allow for easy referral.

Issue:

Provide a brief description of the issue. This should in the nature of a title for the finding that can be used to identify the finding verbally, much as the ID # is used to identify the finding numerically. The appropriate block should be marked to indicate whether the issue is a finding (deficiency) or an observation (criteria is met; suggestion for improvement).

Discussion:

The key to preparing quality Form 2s is staying focused on the core requirement and criteria. Avoid speculation and stick to specifics when describing observed strengths and weaknesses. Sweeping

generalities based on a small sample should be avoided. However, drawing conclusions that assert programmatic deficiencies based upon multiple observed inadequacies or weaknesses are valid. Team members should avoid superlatives of the type: ". . . is the worst . . . or is the best. . . ." Again, the key is to stay focused on whether the core requirement is being met as measured by the criteria. Following are a few sample Form 2 Discussion sections demonstrating some desirable and some undesirable traits.

1. Review of Training and Qualification Issue; Required Reading Program

   (a) Desirable; specific, objective, measured traits...

   Implementation of the Required Reading Program was examined. Twenty-five items in the program were tracked to determine if the 16 qualified Stationary Operating Engineers (SOEs) have signed-off as having read the required documents. Over half the required reading checked was found deficient. That is, over half of the 400 (16 x 25) items checked were not documented as complete. In addition, some significant items from the required reading items were provided to ORR interviewers to sample SOE retention of the material covered in the readings. The retention of the key points in these required reading items was poor. Of eight SOEs interviewed on three items, over half produced unsatisfactory responses.

   (b) Not Desirable; extreme, speculative, too general, inappropriate...

   The Required Reading Program was examined. It was determined to be one of the worst programs this reviewer has encountered. Many of the operators had not done the reading and their attitude was unacceptable. Management said they had a procedure for the program, but I couldn't locate it. The ORR interviewers asked some of the SOEs about items in their required reading. Their responses were unsatisfactory. This area needs work.

2. Review of Operational Experience Review Program; Occurrence Reporting and Processing System (ORPS) Program

   (a) Desirable; specific, objective, descriptive...

   The Occurrence Reporting and Processing System was examined. Requirements from DOE Order 5000.3 are programmatically implemented at the XXXX facility by the contractor through XXXX 5000.3. The contractor's procedure is judged to be satisfactory in that it requires occurrence reports to be generated and reported to the Department as required by the DOE Order. All specifications in the DOE Order are adequately implemented by the contractor's procedure.

Some observations were noted. A significant one is that the threshold for an unusual occurrence regarding the release of "hazardous materials above limits. . ." is unclear. The descriptive guidance given in the contractor procedure is too general and leads to inconsistency and confusion. Seven managers of organizations within the facility that dealt with hazardous materials were interviewed regarding the threshold for reporting under this Order. All were interpreting the guidance differently and required different responses for similar occurrences involving hazardous material.

A sample of five occurrence reports revealed that all but one were on schedule regarding reporting to DOE Headquarters. Lessons learned training required in three of the five reports was complete. A spot check of operators during interviews (13 interviews) confirmed the effectiveness of the lessons learned training.

(b) Not Desirable; no specifics, personalized, irrelevant...

The contractor's ORPS Program was examined. It's one of the best I've seen - almost as good as XXX in XXXX. A sample of reports were looked at and found to be in excellent condition. Headquarters likes this program too and was very complimentary about it when I was up there last month.

3. Review of SAR/TSR implementation; maintenance of pressure differential in glove boxes for personnel protection.

(a) Desirable; objective, analytical, supported by background detail.

Chapter XXX of the SAR requires ". . . absolute pressure in a glovebox in operation with radioactive material in it shall be maintained below the pressure of the surrounding area such that any air flow shall be from the surrounding area into the glovebox. This is to prevent the escape of airborne or potentially airborne radionuclides from the glovebox to the surrounding area." This requirement has been implemented through Technical Safety Requirement (TSR) xxxx that requires a differential pressure (DP) of xx in. of water to be maintained between a glovebox and its surrounding area.

The gauges installed to monitor this DP are not calibrated on a regular basis and have not been calibrated since installation 5 years ago. These gauges are the principle means of surveillance to ensure that the TSR is complied with. The DP gauges are not considered

safety related equipment by the contractor and are, therefore, not part of the calibration program. The contractor's position is that the gauges are informational only and not "safety related equipment." The ORR team disagrees with this interpretation and asserts that the DP gauges are "safety related equipment" in that they provide the means to monitor a TSR and need to be reliable and, therefore, should be part of the M&TE Calibration Program.

(b) Undesirable; confusing, argumentative, lacking in detail and background, requirement not established...

The DP gauges installed on the glove boxes are out of calibration. I looked at 13 of them and all were out of calibration. The contractor maintains that they do not have to calibrate them per the SAR. We disagree.

Finding Designation:

This section defines whether the finding is a prestart or post-start finding. The ORR Team Leader in consultation with the Inspector and Senior Advisers, if applicable, will make this determination using the criteria specified in the ORR plan-of-action.

FINDING RESOLUTION FORM (FORM 3)

The Finding Resolution Form is used by site management to document the plans and actions taken to correct findings identified during the ORR and when completed would form the closure certificate described in section 5.7.3 of the ORR standard. A separate Form 3 should be generated for each finding related to a particular objective. For instance, if three findings are discovered while reviewing a CRA the inspector would then generate three Form 2s to detail the deficiencies thereby requiring three Form 3's to document the resolution of the findings.

Functional Area:

Print the ORR functional area to which the CRAD has been assigned.

CRA Number/Title:

Specifically identify the CRA or portion of the CRA that the Appraisal Form is to support. Provide the name and number of the CRA or portion of CRA.

ID #:

This number correlates the finding (Form 2) and resolution (Form 3) documents and should be the same number listed on the applicable Form 2.

Issue:

The finding issue statement from the corresponding Form 2 is placed here.

Finding Designation:

This section indicates whether the finding is a prestart or post-start finding.

Responsible Individual:

The individual that management has assigned to be responsible for correcting the finding is identified in this block. The name and phone number of the person should be provided.

Action Plan:

A description of the plan to resolve the finding, along with proposed dates of completion, is presented in this section. A compilation of these plans taken from all the Form 3s generated during the ORR would form the basis for the action plan that is submitted to the appointing authority for approval. Modifications to the action plan made by the appointing authority would need to be incorporated in the Form 3.

Resolution:

A description of the actual actions taken, the reasons for concluding that closure has been achieved and how referenced documents support closure, along with dates of completion, is provided. This becomes the formal documentation of the corrective measures used to resolve the finding.

Certified:

This block is used by management to certify that the actions specified in the action plan and detailed in the resolution block have been completed. The designated manager would sign this block when satisfied that all corrective action are completed.

Verified:

This signature block is used by the official designated by the appointing authority to verify management's successful fulfillment of the corrective actions.

ORR ASSESSMENT FORM 1

FUNCTIONAL AREA:	**OBJECTIVE , REV. 0 DATE:**	**CRITERIA MET**	
		YES	**NO**

OBJECTIVE: *as stated in the CRAD*

Criteria *as stated in the CRAD*

Approach *as stated in the CRAD*

Record Review*: as stated in the CRAD*

Interviews: *as stated in the CRAD*

Shift Performance*: as stated in the CRAD*

Records Reviewed:
C
C

Interviews Conducted:
C
C

Shift Performance Observed:
C
C

Discussion of Results:
Note: Discussion of results in three distinct sections related to Records, Interviews, and Shift Performance may not be the most efficient and clear manner to discuss the results of the review. In some cases, it may be preferable to discuss the overall results. In others, it may be preferable to discuss the results by individual criteria. The method chosen must ultimately end in clear communication of the results of the review. The team leadership must provide direction or guidance in this area.

Record Review: *Write the results of your review here.*

Interviews: *Write the results of your interviews here.*

Shift Performance: *Write the results of your observations of the shift here.*

Conclusion: The criteria for this objective have/have not been met. *You will make a statement on every Form 1 you write that the Criteria have (or have not) been met.*

Issue(s):

C
C

Inspector:_____	Team Leader: _____

ORR DEFICIENCY FORM

(FORM 2)

Functional Area:	CRA Number/Title:	Finding: Observ.:	Prestart: Post-start:	Issue No.: Date:

ISSUE: (The identified finding or observation) This section reads exactly (word for word) the issue documented on the Form 1. For every issue on a Form 1, you will write a Form 2.

REQUIREMENT: (Requirement statement from reference)

REFERENCE(S) (specific as possible, including section):

DISCUSSION:

Inspector: _____	Approved: _____ ORR Team Leader Date:

ORR FINDING RESOLUTION FORM

Functional Area:	CRA Number/Title:	ID #:
Issue: Finding Designation: Prestart Post-start		
Date Received: Responsible Individual: Phone #:		

Action Plan:

a. *Evaluation of root cause or systemic failure that results in the finding.*

b. *Specific corrective action, including completion dates and responsibilities.*

c. *Compensatory measures (post-start findings).*

d. *DOE approval (for DOE ORR only)*

Resolution:

Actual actions taken and justification for difference from approved action plan.

Corrective Action Completion

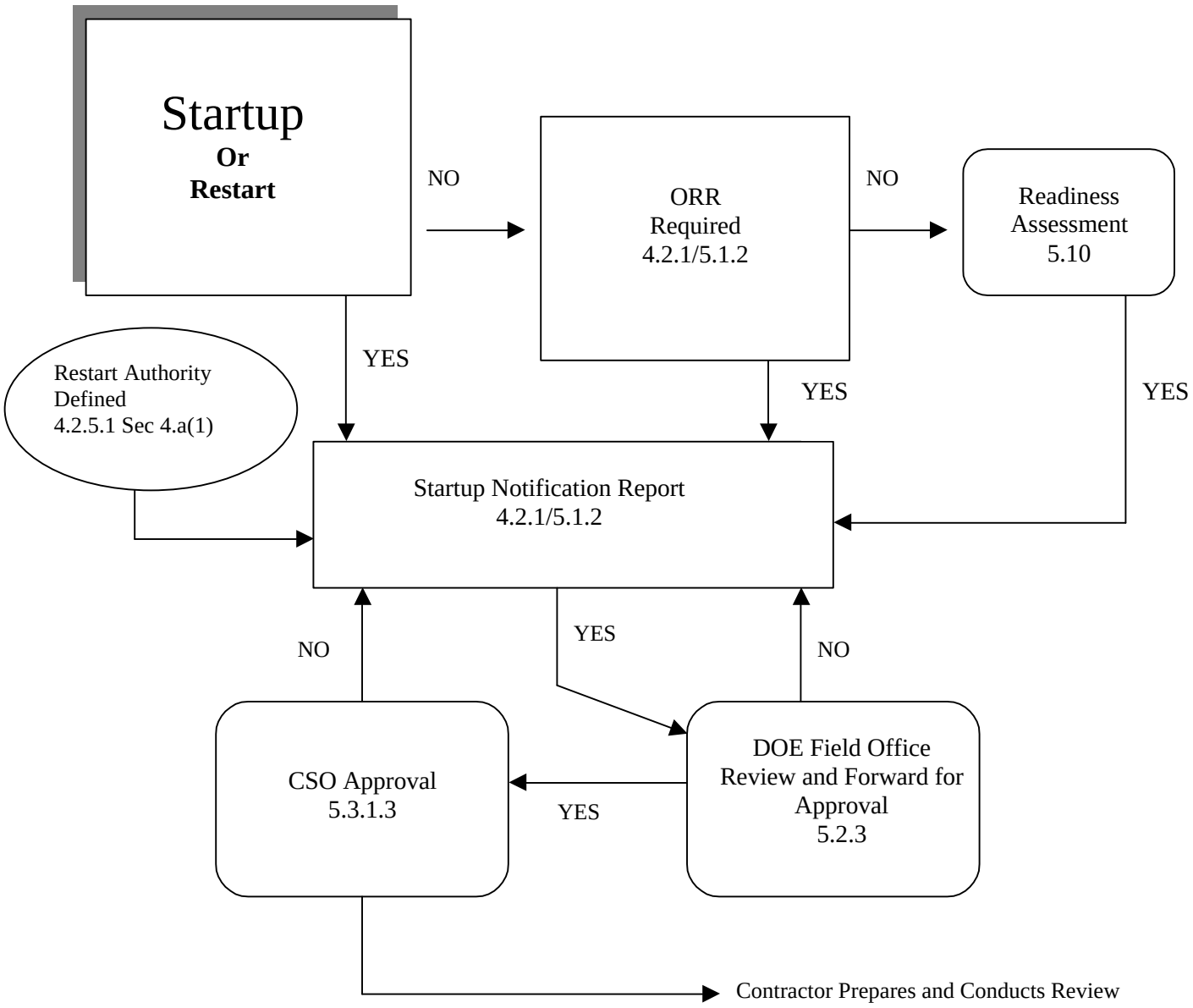
Certified By: _____ Date:
Verified By _____ (DOE ORR only): Date: DOE Designated evaluator

APPENDIX 5

START/RESTART PROCESS FLOW CHARTS

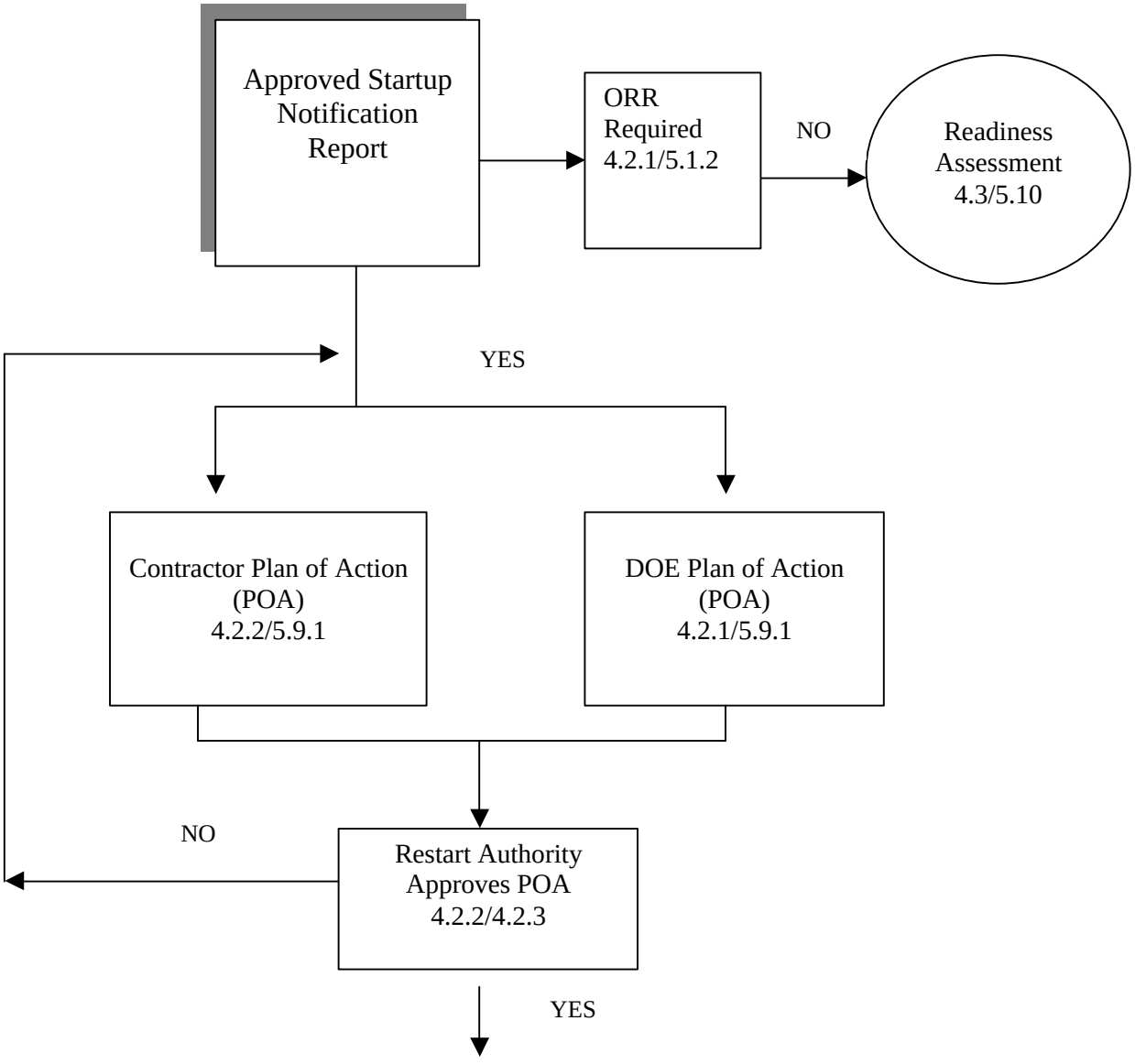
INTENTIONALLY BLANK

STARTUP OR RESTART PROCESS



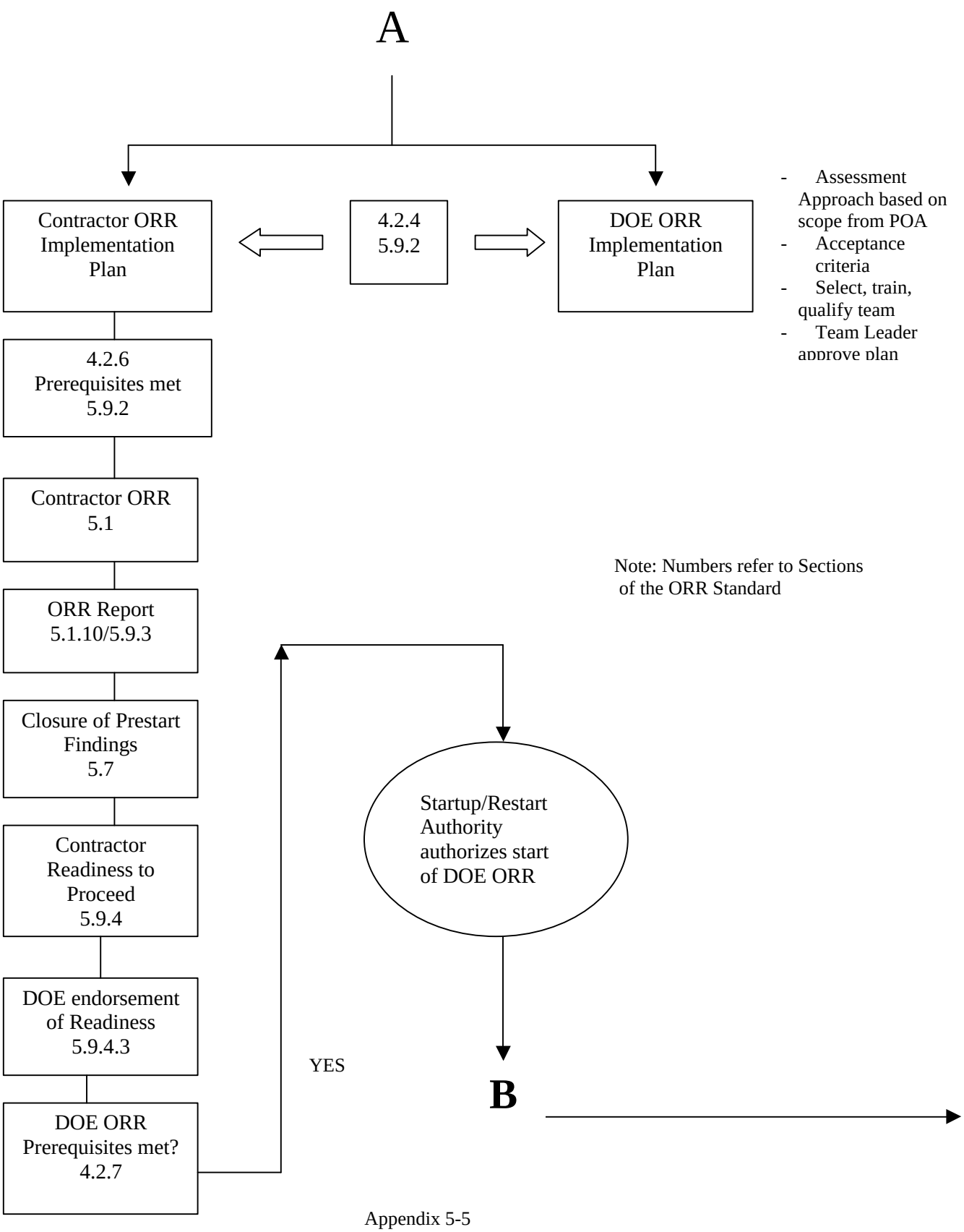
Note: Numbers refer to Sections in the ORR Standard

STARTUP OR RESTART PROCESS

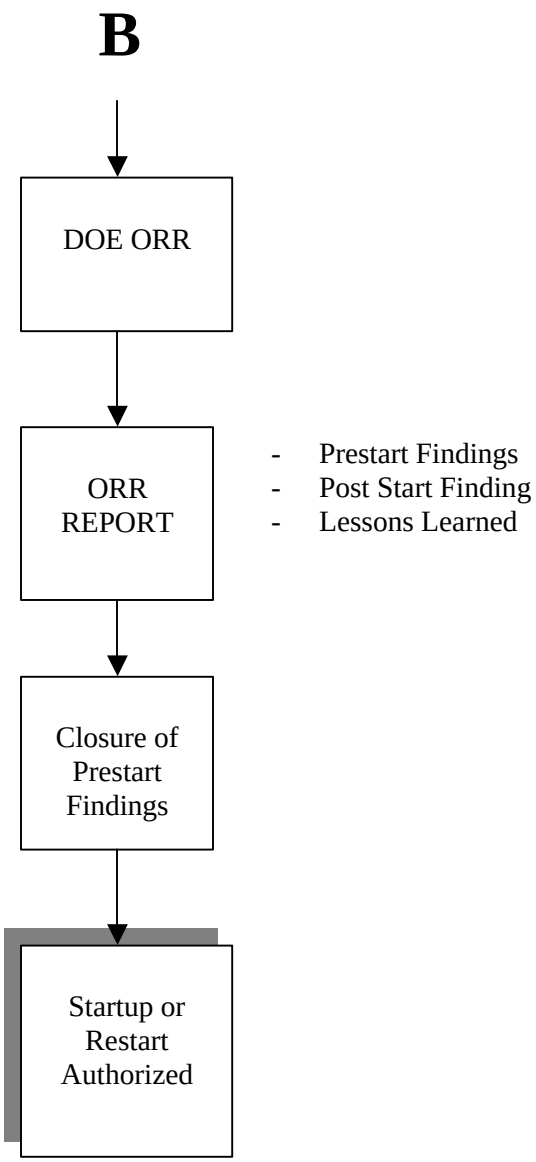


Note: Numbers refer to Sections in the ORR Standard

STARTUP AND RESTART PROCESS



STARTUP AND RESTART PROCESS



CONCLUDING MATERIAL

Review Activity:

DOE
DP
EH
EM
NE
NN
ER

Field Offices
AL
CH
ID
NV
OR
RL
SF
SR
Fernald

National Laboratories
BNL
LLNL
LANL
PNL
Sandia

Area Offices
Amarillo Area Office
Kirtland Area Office
Princeton Area Office
Rocky Flats Area Office

Preparing Activity:

DOE-DP-45

Project Number:

OPER-0003