



U.S. Department of Energy Office of Enforcement

Enforcement Process Overview

Preamble

As a result of the formation of the Office of Health, Safety and Security (HSS) in late 2006, the Office of Price-Anderson Enforcement expanded its duties and responsibilities to include the enforcement of 10 CFR Part 824, *Procedural Rules for the Assessment of Civil Penalties for Classified Information Security Violations*, and 10 CFR Part 851, *Worker Safety and Health Program*. Correspondingly, the Office was renamed the Office of Enforcement. The HSS Office of Enforcement is now an integral component of an organization that is responsible, in part, for the development and maintenance of safety and security regulations, the oversight of how effectively these regulations are implemented by the Department of Energy's contractor community, and the enforcement of these regulations whenever a significant noncompliance occurs.

The goal for publishing the *Enforcement Process Overview* was to integrate into a single, cohesive document the Office of Enforcement's internal procedures and enforcement guidance for nuclear safety, worker safety and health, and classified information security. One requirement of this effort was to employ a document format that was (1) relatively easy to maintain, update, and distribute, and (2) compatible with common methods for viewing information using the Internet, personal computers, and other information devices.

The HSS Office of Enforcement believes it has accomplished this with the development and issuance of this living document.

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Abbreviations and Acronyms

ALARA	As Low As Reasonably Achievable	OHA	Office of Hearing and Appeals
ANSI	American National Standards Institute	ORPS	Occurrence Reporting and Processing System
CAIRS	Computerized Accident Incident Reporting System	OSHA	Occupational Safety and Health Administration
CAP	Corrective Action Plan	OSR	Operational Safety Requirement
CFR	Code of Federal Regulations	PAAA	Price-Anderson Amendments Act
D-M-FA	Design-Manufacture-Final Assembly	PNOV	Preliminary Notice of Violation
DART	Days Away, Restricted, or Transferred	QA	Quality Assurance
DNFSB	Defense Nuclear Facilities Safety Board	QAP	Quality Assurance Program
DOE	Department of Energy	R&D	Research and Development
DOJ	Department of Justice	RAM	Radioactive Material
DOL	Department of Labor	RCA	Root Cause Analysis
DSA	Documented Safety Analysis	RP	Radiation Protection
EA	Enforcement Action	SSC	Structures, Systems, and Components
EFCOG	Energy Facility Contractors Group	SSIMS	Safeguards and Security Information Management System
EGS	Enforcement Guidance Supplement	TSR	Technical Safety Requirement
EOC	Extent of Condition	USQ	Unreviewed Safety Question
ES&H	Environment, Safety and Health		
FNOV	Final Notice of Violation		
IA	Independent Assessment		
INPO	Institute of Nuclear Power Operations		
ITAC	Incident Tracking and Analysis Capability		
M&IA	Management and Independent Assessments		
MA	Management Assessment		
MOU	Memorandum of Understanding		
NCR	Nonconformance Report		
NNSA	National Nuclear Security Administration		
NOV	Notice of Violation		
NRC	Nuclear Regulatory Commission		
NTS	Noncompliance Tracking System		
OGC	Office of General Counsel		

I. Purpose

The Office of Enforcement, within the Department of Energy's (DOE or Department) Office of Health, Safety and Security, is responsible for implementing the enforcement programs related to nuclear safety, worker safety and health, and the protection of classified information. This *Enforcement Process Overview* describes the processes used by the Office of Enforcement in implementing its regulatory obligations under:

- The *General Statement of Enforcement Policy* in 10 CFR Part 820, appendix A, as amended, for violations of nuclear safety requirements, and
- The *General Statement of Enforcement Policy* in 10 CFR Part 851, appendix B, for violations of worker safety and health requirements.
- The *Enforcement of Classified Information Security Requirements* in 10 CFR Part 824, for violations of classified information protection and control requirements.

The *Overview* supersedes the following previously-issued guidance by the Office of Enforcement. For reference, these are still available at www.hss.energy.gov/Enforce/, the Office of Enforcement web site:

DOE Enforcement Program Roles and Responsibilities Guidance Handbook (DOE-HDBK-1085-95)

Identifying, Reporting, and Tracking Nuclear Safety Noncompliances (Operational Procedure, June 1988)

Enforcement of DOE Nuclear Safety Requirements under Price-Anderson Amendments Act of 1988 (Operational Procedure,

June 1988)

Enforcement Guidance Supplements issued by the Enforcement Program since its inception.

The material in this *Overview* is structured to provide a common approach to both nuclear and worker safety enforcement where possible. Unless noted otherwise, this guidance applies to both areas. In some areas, guidance specific to nuclear or worker safety is provided and noted as such.

Exclusions

The Office of Enforcement has also been assigned the responsibility for implementing the enforcement process established by 10 CFR Part 824, *Procedural Rules for the Assessment of Civil Penalties for Classified Information Security Violations*. The implementation guide specifically addressing this enforcement process was issued in March 2006, updated in 2007 and is available at www.hss.energy.gov/Enforce/SecEnforce/824Implementation.pdf. Processes for implementing the Security Enforcement Program are included in this Enforcement Process Overview document.

Principles

To promote strong safety and security performance by contractors, the Office of Enforcement is authorized to exercise considerable discretion in applying the enforcement tools at its disposal and to apply mitigation when enforcement actions are taken to recognize positive performance by contractors. In brief, the DOE enforcement program is premised on "rewarding" contractors for early identification, reporting, and effective

correction of safety and security noncompliances.

The *Enforcement Process Overview* describes factors that the Office of Enforcement considers in judging positive steps taken by contractors, as well as the factors affecting the application of enforcement sanctions. If enforcement actions are considered necessary, they are applied in accordance with the provisions of the enforcement policies noted above. The overall goal of the Department's enforcement policies is to improve nuclear safety for our workers and the public, occupational safety and health for workers, and the protection of classified information at DOE facilities. This goal is the prime consideration in exercising enforcement discretion and in application of mitigation.

Additional Enforcement Guidance

From time to time, enforcement issues will arise that require the Office of Enforcement to clarify or supplement the guidance and procedures set forth in this *Overview*. Such clarifications or supplements will be issued as an update. Timely notification of such updates will generally be forwarded to DOE and contractor enforcement coordinators¹ at each site and be made available on the Office of Enforcement web site.

¹ Throughout this revision, the term “enforcement coordinator” replaces the previously-used term “PAAA coordinator.” This change has been made to reflect the expanded responsibilities (including worker safety and health and, potentially, information security) of DOE and contractor coordinators participating in the DOE Enforcement Program. This change in terminology is not at all intended to revise any coordinator’s current title or position description.

Background

The *Atomic Energy Act* provides indemnification² to DOE contractors who manage and operate nuclear facilities in the DOE complex. In 1988, the Price-Anderson Amendments Act (PAAA) was signed into law to continue this indemnification. The PAAA subjects DOE-indemnified contractors, subcontractors, and suppliers to potential civil penalties for violations of DOE rules, regulations, and compliance orders relating to nuclear safety requirements. As part of its agreement to continue the indemnification coverage, Congress mandated that DOE enforce nuclear safety requirements to minimize the risk to workers and the public. On August 17, 1993, DOE published its nuclear safety enforcement procedural rules and enforcement policy (10 CFR Part 820, appendix A, *General Statement of Enforcement Policy*), which was further amended on November 7, 1997, and March 22, 2000. The Office of Enforcement has the responsibility to carry out the statutory enforcement authority provided to DOE in the PAAA. The Office of Enforcement commenced enforcement of the nuclear safety rules in 1995.

The *Bob Stump National Defense Authorization Act for Fiscal Year 2003* extended current indemnification levels until December 31, 2004, and required DOE to promulgate final rules to enforce Occupational Safety and Health requirements. The *Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005* extended indemnification until December 2006. The *Energy Policy Act of 2005* extended indemnification of DOE contractors to December 2025, increased liability coverage to

² By indemnifying the contractor, the government acts as an insurer against any findings of liability arising from the nuclear activities of the contractor within the scope of its contract.

\$10 billion per incident, and repealed remission of civil penalties for nonprofit organizations upon the signing of a new contract.

On January 26, 2005, the Department published 10 CFR Part 824 to implement Section 234B of the *Atomic Energy Act*. Section 234B stipulates that a contractor or subcontractor to the DOE who violates any rule, regulation, or order relating to the safeguarding or security of Restricted Data, other classified information, or sensitive information shall be subject to a civil penalty. In publishing Part 824, DOE decided that civil penalties will be assessed only for violations of requirements for the protection of classified information (Restricted Data, Formerly Restricted Data, and National Security Information). This regulation applies to entities that have entered into contracts with DOE, rather than to individual employees of contractors and subcontractors. Contractors and their subcontractors will be held responsible for the acts of their employees who fail to observe classified information security requirements.

On February 9, 2006, DOE issued the *Worker Safety and Health Program* rule, 10 CFR Part 851, which includes in subpart E the enforcement process to be applied to worker safety violations, and, in appendix B, the enforcement policy for such violations. Part 851 went into effect on February 9, 2007, and as of May 25, 2007, no work may be performed at a covered workplace unless an approved worker safety and health program is in place.

II. Enforcement Philosophy

In brief, the purpose of DOE's enforcement program is to enhance and protect the radiological safety of the public, workers at DOE facilities, occupational safety and health for employees at DOE facilities, and the protection of classified information at DOE facilities through a process that encourages the effective understanding and proper implementation of safety and security requirements; critical self-assessment of activities; and the timely identification, open and prompt reporting, and prompt, aggressive correction of noncompliance conditions by DOE contractors. To paraphrase the enforcement philosophy stated in 10 CFR Part 820, appendix A (for nuclear safety), 10 CFR Part 824 (for classified information security), and in 10 CFR Part 851, appendix B (for worker safety):

The single most important goal of the DOE enforcement program is to encourage early identification and reporting of deficiencies and violations of DOE occupational safety and classified information security requirements by the DOE contractors themselves rather than by DOE, and the prompt correction of any deficiencies and violations so identified. DOE believes that the contractors are in the best position to identify and promptly correct noncompliances.

The DOE enforcement program is a civil enforcement process that focuses on the performance of contractor organizations as it relates to compliance with DOE classified information security and nuclear and worker safety rules. The Office of Enforcement does not issue enforcement actions against individual contractor employees. If the Office of Enforcement becomes aware of the possibility of criminal behavior through any of its activities, the

Office of Enforcement will refer the issue to the U.S. Department of Justice, as further described in chapter VIII.

The Office of Enforcement's approach is founded on several key elements:

- Emphasizing contractor implementation and assurance of compliance with classified information security and nuclear and worker safety rules
- Driving a continuous improvement focus, rather than acceptance of the status quo
- Promoting contractors' timely self-identification and correction of noncompliance conditions and underlying problems affecting compliance
- Exercising broad discretion when contractors exhibit the desired approach
- Taking selective enforcement action for significant security or safety events or significant precursor conditions, including continued repeat events, close calls, and generally adverse performance
- Periodically reviewing contractor screening and reporting processes, and selectively reviewing compliance issues by means of program reviews or focused inspections
- Stimulating contractors' transition from a reactive, event-driven approach to identifying and correcting deficiencies toward a proactive, assessment-driven approach
- Broadly sharing information on enforcement actions and

identified generic safety and security issues to serve as lessons learned to promote proactive improvement before an enforcement action is required

- Promoting the desired management and compliance assurance attributes so that contractors can achieve excellence in safety and security without the need for enforcement actions. Such attributes include assessment programs, safety and security cultures, and corrective action processes.

III. Roles and Responsibilities

DOE and contractor personnel are required to assure strong safety and security compliance and performance; an effective self-regulatory or compliance assurance process; proper identification, reporting, and resolution of noncompliances; and effective interface with the enforcement process.

The Office of Enforcement Director and staff are the principal individuals who set guidance and implementation practices for enforcement activities. To maintain effective interface with the Office of Enforcement, DOE Program and Field Element managers assign enforcement coordinators, who are also generally the principal interface with contractors on matters involving safety and security rules, noncompliances, and enforcement proceedings. Contractors also designate a single individual to be their enforcement coordinator, who serves as the principal interface with the corresponding DOE enforcement coordinator and the Office of Enforcement, as well as the principal lead in the contractor organization for rule implementation, noncompliances, and enforcement proceedings. Senior contractor management personnel are also key to ensuring effective compliance with safety and security requirements and excellent safety and security performance. While some organizations or positions may not function as described herein, the following provide the Office of Enforcement's perspective on the roles and responsibilities of key positions within and beyond the Office.

Director, Office of Enforcement

The Director is the principal officer for DOE enforcement

activities. The Director manages all DOE enforcement activities, directs the technical and legal reviews, supervises investigations, prepares enforcement actions, and is responsible for the administrative litigation of contested enforcement actions, issuance of consent orders, and appropriate referral of potential criminal actions to the Department of Justice and, in the case of waste, fraud, or abuse, to the Office of the Inspector General. The Director is authorized to issue enforcement correspondence and enforcement actions, except that enforcement actions involving National Nuclear Security Administration (NNSA) facilities require the signature of the NNSA Administrator, based upon the recommendation of the Director. If the Administrator disagrees with any aspect of a recommended enforcement action, and the disagreement cannot be resolved, the matter may be referred to the Deputy Secretary for resolution. The Director regularly communicates to senior DOE and contractor management the state of the enforcement program and observations on safety and security compliance issues identified in the enforcement program. The Director is also responsible for providing guidance and training for implementation of the Department's Enforcement Program.

Office of Enforcement

Office of Enforcement staff perform the following tasks, among other duties:

- Review and evaluate available information on noncompliances, including information reported to the Noncompliance Tracking System (NTS), the Incident Tracking

- and Analysis Capability (ITAC) system, and the Safeguards and Security Information Management System (SSIMS).
- Identify to the Director significant noncompliance conditions and recommend investigation, focused inspection, and/or enforcement action.
 - As needed, conduct investigations or focused inspections associated with potential violations of DOE safety and security requirements, and prepare summary reports and/or technical evaluations as required.
 - Participate in enforcement conferences, and may chair the enforcement conference in the absence of the Director.
 - Provide recommendations during post-conference, DOE-only discussions and deliberations. The final decision on enforcement action rests with the Director (or NNSA Administrator, for NNSA facilities).
 - Inform DOE personnel of their obligation to maintain confidentiality on the details of planned enforcement actions and communications until issuance of the action.
 - Prepare for the Director's signature (or NNSA Administrator for NNSA facilities) all recommended enforcement actions, including notices of violation (NOV) and appropriate transmittal letters to the contractor, as well as draft press releases.
 - Prepare for the Director's signature enforcement letters for precursor conditions that need attention, but for which an enforcement action is not being taken.
 - Conduct program reviews of contractor voluntary noncompliance screening and reporting processes as well as selective compliance issues, and prepare summary reports for the Director's signature.
- Maintain the NTS.
 - Maintain docket files for: enforcement actions; enforcement letters; exemptions to nuclear safety requirements issued pursuant to Part 820, subpart E; variances to worker safety requirements issued pursuant to Part 851, subpart D; and rule implementation program plans and updates. The docket files for security enforcement actions and enforcement letters will be maintained according to the Office of Enforcement protocols and requirements. Docketing functions are performed by the Office of Enforcement Docketing Clerk.
 - Conduct periodic training workshops, including introductory DOE enforcement program training for new DOE and contractor enforcement coordinators, and refresher training for DOE enforcement coordinators.
 - Share information and guidance on enforcement actions, lessons learned, compliance issues, and other program details through various mechanisms, including the Office of Enforcement web site, Enforcement Guidance Supplements (EGSs), coordinator conference calls, presentations at Energy Facility Contractor Group (EFCOG) sessions, and meetings with senior DOE and contractor managers.
 - Prepare an annual report summarizing enforcement program activities over the past year, and planned activities and initiatives for the coming year.

DOE and Contractor Senior Management

For effective coordination and to ensure DOE achieves a high level of safety and security performance, both senior DOE and contractor management must take on critical enabling roles, including:

- Ensuring that safety and security are the number one priorities, and are not trumped by strong contractual emphasis on program objectives and schedules.
- Regularly demonstrating emphasis on safety and security performance, compliance with safety and security requirements, positive safety and security cultures, and an ethic of continuous improvement, as well as facilitating the transition from being event-driven to being an assessment-driven organization.
- Demonstrating strong support for the noncompliance screening and reporting process, assessment programs, and the corrective action process, both within the Field Element and by their contractors.
- Considering the regulatory screening and reporting program an integral part of the safety and security management programs and not just “check the box” exercises.
- Ensuring that the individual selected for the DOE enforcement coordinator position has strong credibility within the organization and with senior management.
- Placing the enforcement coordinator at a senior reporting level, demonstrating management commitment to the program, and providing access to senior management when necessary.
- Being supportive of and relying on the views of the enforcement coordinator.
- Maintaining regular and open communication with the contractor, Program Office, and the Office of Enforcement on safety and security, noncompliance conditions, and noncompliance report resolution.

There are also critical enabling roles specific to each management group. For DOE Field Element senior management, it is important that staff be assigned to provide support to and, as needed, participate with the Office of Enforcement in investigations or reviews.

Accordingly, contractor senior management also has the following specific critical enabling roles:

- Delegating strong authority to safety and security managers and the enforcement coordinator, and ensuring that clear roles for and responsibilities of the coordinator are defined.
- Driving the organization to a centralized issues management system utilized as an action-forcing mechanism for lasting, effective corrective actions.
- Driving the organization to achieve a level of performance sufficient to ensure that few programmatic or significant safety and security problems are disclosed by events, i.e., most are prevented through effective contractor performance assessment activities.

DOE Enforcement Coordinator

A key step toward facilitating safety and security performance, enhancing compliance with safety and security requirements, and effectively interfacing with the Office of Enforcement is the designation of a point of contact from each DOE and contractor organization. Each organization with responsibility for management or oversight of activities that come under the DOE safety and security rules should identify an enforcement coordinator. Examples of desired enforcement coordinator roles

and responsibilities are:

- Being knowledgeable of security and nuclear and worker safety requirements and the enforcement process.
- Maintaining a broad understanding of the activities and operations undertaken by their contractor/organization.
- Acting as the focal point to promote effective communications within DOE and with the contractor on DOE regulatory compliance matters.
- Identifying and openly communicating security and safety concerns and adverse trends to senior DOE and contractor management.
- Ensuring that Federal managers are adequately trained in the elements of the DOE regulatory compliance program.
- Providing oversight of contractor identification, screening, trending, reporting, and correction of noncompliances.
- Being knowledgeable of NTS reporting thresholds and information security incident reporting requirements and having sensitivity for programmatic issues, negative trends, and repetitive issues.
- Collecting information or coordinating with appropriate personnel to provide information and collaborate with the Office of Enforcement in evaluating noncompliances reported into the NTS, ITAC and SSIMS.
- Coordinating the identification of DOE and contractor personnel for technical support when necessary to bring an issue to closure.
- Coordinating a periodic review of noncompliances tracked locally by the contractor.
- Conducting routine oversight of the contractor's program for identifying and screening deficiencies and reporting and closing noncompliances.
- Entering into the NTS noncompliance conditions that the DOE coordinator believes are above the NTS reporting threshold, but which the contractor has declined to enter into NTS.
- Entering into the ITAC information security incidents that the contractor has declined to enter.
- Verifying the proper and timely completion of corrective actions (with the assistance of Facility Representatives and subject matter experts) for NTS items and (with the assistance of designated security professionals) for ITAC and SSIMS items.
- Entering verification results into NTS, ITAC and SSIMS with clear recommendations for closure.
- Providing input, with their DOE management, to the enforcement process (e.g., for preliminary investigation strategy discussions, enforcement conferences, and post-conference deliberations) and framing any enforcement action.
- Actively participating in dialogues between DOE and the contractor in any investigation or compliance review to ensure the facts and technical issues surrounding the noncompliance are understood, and the impacts on safety and security are properly considered.

Contractor Enforcement Coordinator

The contractor enforcement coordinator position is pivotal in driving safety and security performance within the contractor

organization. As the primary interface with the Office of Enforcement, and with proper support from senior management, the coordinator can positively influence the organization's attention to and assurance of compliance with safety and security requirements and drive continuous improvement. To achieve these benefits, each contractor organization should formally designate a contractor enforcement coordinator. Examples of desired roles and responsibilities are:

- Being knowledgeable of the enforcement process and the requirements for information security and nuclear and occupational safety. In some organizations, it may be appropriate to designate information security, nuclear safety, and worker safety leads to support the overall enforcement coordinator.
- Maintaining a broad understanding of the activities and operations undertaken by their contractor/organization.
- Serving as the focal point in the contractor's organization for rule implementation and compliance, and championing excellence in the organization's compliance assurance and continuous improvement efforts.
- Through broad awareness of safety and information security issues and performance across the organization, identifying and reporting to management areas of weakness or systemic problems not otherwise recognized by the organization.
- Ensuring that contractor managers are adequately trained in the regulatory screening and reporting program.
- Monitoring contractor compliance assurance program effectiveness and progress in moving toward an assessment-driven, continuous improvement-focused organization.
- Managing or overseeing screening of problems, issues, findings, and conditions to identify noncompliances.
- Ensuring timely screening of a broad set of issues from a variety of sources, such as events, performance assessment reports, nonconformance reports, radiological assessment reports, ITAC reports, inspections, and audits, for potential regulatory noncompliance.
- Being knowledgeable of reporting requirements and thresholds and having sensitivity for programmatic issues, negative trends, and repetitive issues.
- Regularly performing, or ensuring regular performance of, assessments to evaluate implementation of the contractor's processes for screening and NTS, ITAC, SSIMS, and internal reporting.
- Ensuring proper and timely reporting of noncompliances into NTS, ITAC, and local tracking systems.
- Ensuring validation of NTS, ITAC and SSIMS corrective actions prior to closure; verifying that corrective actions address the causes, are comprehensive, and have been completed; and marking NTS, ITAC and SSIMS reports as "complete" only when all actions have been validated.
- Ensuring that comprehensive effectiveness reviews are conducted for NTS, ITAC and SSIMS issues when corrective actions have been completed.
- Within the contractor organization, facilitating coordination and scheduling of responses to Office of Enforcement requests for information, onsite investigations, enforcement conferences, focused inspections, and investigations.
- Actively participating in the dialogue between DOE and the contractor in any investigation, focused inspection, or

compliance review to ensure that the facts and technical issues surrounding the noncompliance are understood, and that the actual or potential adverse impact on safety and security is properly considered.

- Regularly informing senior management of compliance issues, safety and security performance issues, enforcement actions elsewhere in the DOE complex, and the status of the regulatory screening and reporting program.

IV. Compliance Assurance and Reporting

Contractor Compliance Assurance

DOE's rules for nuclear and worker safety and security are structured to place responsibility and compliance on DOE contractors. DOE's enforcement policies use the terminology of "compliance assurance" to refer collectively to the set of actions that a contractor should take to ensure that it operates DOE's facilities in a manner that complies with safety and security requirements.

When the Office of Enforcement reviews or investigates noncompliance conditions, the Office of Enforcement often notes breakdowns in the processes that the contractors use to ensure compliance. The Office of Enforcement typically notes these deficiencies in an NOV, enforcement action transmittal letter, enforcement letter, or program review report.

To aid in effectively implementing DOE's safety and security rules, the following are key attributes of top industry performers for assuring that their operations are safe and secure and in compliance with governing safety and security requirements:

- Designated key senior managers are responsible for major safety and security programs and have the authority to set institutional requirements and provide oversight of implementation. Such program areas under DOE's safety and security rules include quality assurance, radiological protection, worker safety, safety basis, and classified information protection and control and cyber security.
- A principal regulatory compliance officer serves as the institutional expert and interface on regulatory matters. For DOE safety and security rules, this is typically the enforcement coordinator.
- Comprehensive steps are taken to ensure that requirements are fully understood and effectively implemented down to the facility, process, and activity levels.
- Sound program plans and procedures set out the policy-level requirements for the program within the organization.
- There is a strong focus on continuous improvement, including benchmarking against other contractors and adopting best practices to improve safety and security compliance.
- Comprehensive management and independent assessments are effective in identifying deficiencies and broader problems in safety and security programs, as well as opportunities for continuous improvement within the organization.
- Critiques of performance and safety/security by outside parties and peers are actively solicited.
- Rigorous problem resolution processes are in place to manage issue prioritization, assign responsibility, evaluate and determine causes, identify adverse trends and dominant safety and security issues, determine extent of condition, develop corrective actions, track completion of corrective actions, and review the effectiveness of actions taken.
- Performance metrics and monitoring of ITAC trends are established to evaluate performance and compliance, and care is taken to assure that statistics are used appropriately

and that incident reporting is encouraged and incentivized.

Additional critical roles and responsibilities that are crucial to accomplishing compliance assurance and sound performance are summarized in chapter III.

Nuclear Safety and Security Excellence

The objective of DOE's safety regulations is to ensure the safety of the workforce at DOE facilities and the public in the communities that are adjacent to DOE sites. The objective of DOE's security requirements is to ensure classified information is appropriately protected. The regulations establish requirements for objectives and process controls that if performed well would result in excellence in performance. Minimum efforts to comply may keep performance generally acceptable in many instances, but may also result in a higher frequency of noncompliance conditions, occasional close-call safety events, incidents of poor security controls designed to protect classified information and potentially more serious events.

The Office of Enforcement would prefer contractors to achieve excellence in safety in such a way that enforcement actions are not required. To promote this concept, the Office of Enforcement has developed a Nuclear Safety Excellence model that captures the key attributes critical to achieving excellence in nuclear safety performance.

The Nuclear Safety Excellence model includes many of the key attributes listed above. In brief, the Nuclear Safety Excellence model calls for contractors to have no serious nuclear safety events, rare occurrences of other important safety events, a strong assessment-driven approach to identifying weaknesses

and problems, strong management processes for planning and conducting work and analyzing and correcting problems, and a high degree of compliance with quality assurance, radiological protection, and safety basis requirements.

The Office of Enforcement plans to expand the Nuclear Safety Excellence model to incorporate similar attributes for excellence in worker safety health and security.

Contractor Screening Processes

DOE's goal is that contractors implement safety and security requirements correctly, with no noncompliance conditions. However, it is also important to focus on identifying and correcting any noncompliances in order to ensure continuous improvement. As noted in chapter II, DOE's enforcement philosophy provides positive incentives for contractors to critically self-assess their activities and identify, report, and comprehensively correct noncompliance conditions in a timely manner.

DOE promotes a voluntary contractor process for screening problems and deficiencies to determine whether those issues represent noncompliance conditions and then reporting these conditions into the NTS, or ITAC. The positive incentives for such voluntary action are described in chapters I, II, and VII. Prompt contractor identification, reporting, and effective correction of safety and security noncompliances gives DOE a basis for exercising discretion in deciding whether to take enforcement action or mitigate civil penalties. The desired attributes of the contractor screening and reporting processes are described below, along with commonly observed weaknesses in these processes.

Noncompliance Identification

Rigorous assessment processes, effective trending and evaluation of historical data, worker and management attentiveness, and a questioning attitude are the preferred primary means of identifying safety, security and quality problems, some of which will represent noncompliance conditions. DOE intends that these issues should be discovered through such proactive means in a timely manner—that is, shortly after they occur. If safety or security issues are not found in a timely manner, the goal and expectation should be that a problem is found through an assessment activity or by worker attentiveness before it results in an adverse event. Obviously, the least desirable case is disclosure of a problem through an investigation, survey or evaluation following an adverse event. When safety or security events occur, the Office of Enforcement's expectation is that the contractor will undertake an investigation, causal analysis, extent of condition review, and aggressive corrective action in an expeditious manner to prevent recurrence of the event.

To meet these expectations, contractor efforts need to focus first on comprehensive implementation of requirements, effective assessment processes, and establishment of a safety and security culture in which individuals can raise questions and report potential problems to management without fear of harassment, intimidation, or retaliation.

Methods of identifying problems include, but are not limited to:

- Contractor assessments: Problems may be identified during contractor internal management or independent assessments.
- Internal review processes: These include receipt inspection, maintenance and surveillance activities, and vendor surveillances.
- Worker identification: In an organization that promotes compliance and safety-consciousness, when workers observe abnormal conditions or potential deficiencies, they report them through a defined process. Ultimately, these observations should be reported to management and entered into the appropriate problem resolution process.
- External assessments: Problems may also be identified during the course of external assessments, surveillances, inspections, and visits conducted by DOE Headquarters Oversight, Field, Site, or Operations Office personnel; Defense Nuclear Facility Safety Board (DNFSB) representatives; or employees of a state or the Federal government, such as the Environmental Protection Agency, Department of Transportation, Inspector General, General Accounting Office or Occupational Safety and Health Administration (OSHA). If the contractor has an effective internal assessment program, only a minimal number of problems should remain to be identified through this mechanism. The goal should be that outside organizations never reveal a significant safety or security issue that the contractor organization does not already know and is not already addressing.
- Data review: Trending and evaluation of operational data and issues management databases to identify adverse trends, dominant problem areas, and potential repetitive events or conditions.
- Employee concerns: An additional source for the identification of safety or security problems may be concerns

- reported into an established employee concerns program.
- Event-related: Problems may be identified during the evaluation of an undesirable event, such as Occurrence Reporting and Processing System (ORPS) or a Security Incident Notification Report (DOE Form 471.1). Of prime importance are the underlying problems that led or contributed to the incident. As noted, this is the least desirable method of identifying problems.

Safety, security and quality assurance problems found by way of the above processes should be subject to an appropriate problem resolution process that can be relied upon to correct effectively the identified problems.

Deficiency Screening for Noncompliance Identification

The processes noted above may identify problems ranging from serious events with corresponding underlying programmatic problems and noncompliances, to relatively minor issues that may need attention but do not represent noncompliances. To determine which are noncompliances and what reporting is appropriate, contractors need to have effective processes for screening the identified problems. Such screening processes should be under the purview of the contractor's enforcement coordinator, be governed by one or more formal procedures, and receive input from a broad range of noncompliance identification mechanisms. Sources of issues to be screened for nuclear and worker safety and security noncompliances typically include:

- Internal management and independent assessment findings.
- External assessment findings.
- Internal issues management or deficiency reporting system.

- Nonconformance reports.
- Radiological event or radiological deficiency reports.
- Injury reports.
- Security Incident Notification Reports.
- ITAC and SSIMS reports.
- Computerized Accident Incident Reporting System (CAIRS).
- OSHA 300 logs.
- ORPS reports.
- Operating logs (for issues involved in non-ORPS events).
- Protective Force Daily Event Logs
- Employee concerns.
- Subcontractor deficiency resolution processes analogous to those listed above.

Common Weaknesses in the Screening Process

In its first ten-plus years of nuclear safety enforcement, the Office of Enforcement has observed a number of common weaknesses or errors in processes for screening deficiencies for potential noncompliance conditions. Although contractors should structure their processes to meet *all* of the objectives and guidance in this chapter, the following common weaknesses or errors may be considered as lessons learned:

- Failure to consider all appropriate sources for screening, such as assessment reports, etc.
- Screening out issues because they were corrected promptly.

- Screening out issues that are noncompliant with rule requirements, but are judged to be of low safety significance.
- Establishing criteria that are not stipulated in the rules with the effect of limiting the applicability of the rule; for example, treating as noncompliances *only* matters covered specifically in the safety basis, or *only* violations of work controls in work involving direct handling of nuclear material, or *only* violations of procedures specifically listed in rule-required program plans.

Further examples are contained in the program review reports on the Office of Enforcement web site.

NTS and ITAC Reporting

The Office of Enforcement has some discretion in pursuing enforcement actions for many conditions that are contractor-identified, receive timely and effective corrective actions, and are properly reported to DOE. To implement that authority, the Office of Enforcement has established a process for reporting directly to DOE noncompliance conditions that are potentially more significant, and thus are judged to need closer monitoring by the Office of Enforcement and DOE and contractor coordinators. Such conditions include certain events listed in ORPS, Security Incident Notification Reports, as well as other management issues. NTS and ITAC are the mechanisms used for reporting directly to DOE. Matters that do not meet the NTS reporting thresholds (see appendices A and B) are to be reported into a contractor's internal issues tracking system and trended to identify potential recurring or programmatic issues, as described herein. All Security Incident Notification Reports relating to classified information will be reported into ITAC.

NTS and ITAC Background and Reporting Thresholds

The NTS centralized, web-based systems that allows contractors to promptly report any noncompliances that meet DOE's established reporting thresholds for safety. NTS also provides on-line "Help" to guide and train users in use of the system. The contractor's enforcement coordinator initially approves contractor employee access to the NTS. DOE provides formal authorization to access the NTS in accordance with information at the following web page: www.hss.energy.gov/Enforce/nts.html

The Office of Enforcement periodically takes steps to improve interfaces between the NTS and other DOE data reporting processes for sharing of common data, where possible. Changes or improvements in this area are addressed on the NTS web page and through the system's on-line "Help" functions. The NTS web page is located at: <https://nts.eh.doe.gov>

The Office of Enforcement encourages contractors to use the NTS and ITAC for the timely reporting of NTS/ITAC-reportable noncompliances, and to include concise and factual information. For nuclear and worker safety enforcement purposes, prompt reporting is generally considered to be within 20 calendar days after determining that a noncompliance exists. Some of the noncompliance conditions may be evident when an event occurs, and the NTS report should be filed in a timely manner for those noncompliances. For security enforcement purposes, reporting timeframes should be based on the security significance and adhere to Impact Measurement Index listed in DOE M 470.4-1, *Safeguards and Security Program Planning and Management*. Other noncompliances that led to the event may not be identified until a more comprehensive investigation or causal analysis is completed. When such other noncompliance conditions are

identified, the NTS report and ITAC should be appropriately updated.

To obtain consideration for nuclear and worker safety enforcement discretion as well as mitigation based on prompt reporting, the contractor should report noncompliances into the NTS in accordance with the reporting thresholds in appendices A (for nuclear safety noncompliances) and B (for worker safety and health noncompliances), and enter those that are below the NTS reporting thresholds into the contractor's internal tracking system. Guidance on the attributes of the contractor's internal tracking system is provided later in this chapter. For security enforcement consideration, the contractor should report noncompliances into ITAC in accordance with the Impact Measurement Index (IMI) listed in DOE M 470.4-1.

Although NTS reports are usually entered by contractor personnel, DOE enforcement coordinators may also submit an NTS report if the contractor declines to do so. However, the preferred approach is to first discuss the reportability of the matter with the contractor.

ORPS Occurrence Associated with a Noncompliance

A number of ORPS event categories that have potential significant safety implications, and the Office of Enforcement is interested in the reporting of identified nuclear or worker health and safety rule noncompliances that are associated with one of these potentially significant safety events—that is, the noncompliance(s) led to the ORPS-reportable event or condition, or the event or condition subsequently resulted in the noncompliance(s). A contractor is expected to report into NTS the noncompliances associated with an event or condition that

meets any of the ORPS criteria listed in appendix A, table A-1, or appendix B, table B-1, as further explained by the corresponding notes. Appendix A pertains to nuclear safety noncompliances, and appendix B to worker safety and health noncompliances.

It is emphasized that NTS reporting is in the contractor's best interest when a nuclear or worker health and safety rule noncompliance is identified in association with an ORPS reportable event in the specified categories. NTS reporting is not necessary if the event lacks an associated noncompliance.

Reporting a Programmatic or Repetitive Noncompliance

DOE also expects programmatic or repetitive noncompliances to be reported, as noted in appendix A, table A-1, and appendix B, table B-1. A programmatic problem is typically discovered through a review of multiple events or conditions with a common cause, but may also be found through causal analysis of a single event. A programmatic problem generally involves some weakness in administrative or management controls, or their implementation, to such a degree that a broader management or process control problem exists. When management determines that a problem or series of events or conditions dictate the need for broad corrective actions to improve management or process controls, management has concluded that the problem is programmatic.

Repetitive problems are generally two or more different events that involve substantially similar conditions, locations, equipment, or individuals. These tend to be narrower in scope than a programmatic problem, and it is reasonable to assume that they should have been prevented by a contractor's corrective actions for a previous noncompliance condition. They typically involve

similar circumstances or root causes, separated by a period of time that suggests the possibility of a common solution.

Programmatic or repetitive problems should not be considered only when NTS or ITAC reporting is required. DOE's expectations for safety and security management and quality improvement processes dictate that when a problem arises, consideration is given to the potential scope of the problem. Further, assessment and trending activities should be in place to identify potential programmatic and repetitive problems in a timely manner. Enforcement coordinators' database reviews may provide an additional avenue for identifying programmatic and repetitive noncompliance conditions. Programmatic or repetitive deficiencies identified through such processes are normally placed in a corrective action management process, and then go through the noncompliance screening process to identify any noncompliances. If the identified programmatic or repetitive deficiency involves a safety or security noncompliance, it should be reported into the NTS or ITAC. Such reporting does not necessarily indicate any conclusion regarding the significance of the particular noncompliance condition(s) on the part of the contractor making the report.

Reporting an Intentional Noncompliance or Misrepresentation

The Office of Enforcement also promoted NTS reporting of any intentional noncompliance with safety rules, as noted in appendix A, table A-2, and appendix B, table B-2. An intentional or willful noncompliance may involve records or inventory results that are falsified intentionally, such as indicating that work or inventory activities occurred in circumstances in which the worker knows that such an activity did not occur. In these cases,

noncompliance with Part 820.11, Part 824, Appendix A or DOE M 470.4-1 and 4-4 regarding accuracy of information may be involved, in addition to any other noncompliance issues. The determination that a record is false, based on additional evidence that the work did not occur, provides the basis for classifying the condition as an intentional/willful noncompliance or misrepresentation that should be reported into the NTS or ITAC. An NTS or ITAC report is warranted, irrespective of the significance of the activity involving a false record, because the act of falsifying the record and providing inaccurate information is serious, and thus warrants significant DOE and contractor management attention.

Alternatively, an intentional or willful noncompliance may involve a case in which a worker is warned by a co-worker that a certain contemplated action would violate requirements, and then proceeds to take the action anyway. The co-worker's reporting of the incident becomes the evidence that the noncompliance was intentional. Such individual instances of intentional or willful noncompliance should be reported into the NTS or ITAC. The Office of Enforcement must then determine whether the matter should result in an enforcement action.

The Office of Enforcement expects that whenever evidence is available to show that the noncompliance was intentional or willful, the matter should be treated as an intentional noncompliance and reported into the NTS or ITAC. On the other hand, the determination of intention requires some care. For example, if a worker was trained to do a certain action but then subsequently failed to do that action, there may simply have been a lapse in recalling the training or, possibly, inadequate training, rather than an intentional disregard of the safety or security requirements. Without further evidence, there is no basis for

reporting the noncompliance as intentional or willful.

NTS and ITAC Report Content and Closure

The initial description of a noncompliance may be limited. DOE does not require contractors to complete a full investigation and causal analysis before reporting a noncompliance or a security incident, nor does DOE normally pursue an enforcement action based solely on the initial description of a noncompliance or the initial Security Incident Notification Report. However, the Office of Enforcement expects the contractor to update the NTS/ITAC report as additional information becomes available.

In general, the NTS and ITAC reports should summarize the noncompliance, along with appropriate information so that DOE understands the circumstances of the noncompliance or the events that led to the incident. If there is a corresponding ORPS report, the NTS report may simply refer to the ORPS report sufficiently to allow NTS readers to locate further details of the event itself in ORPS. For noncompliances relating to classified information, a security incident report is completed if the facility has not implemented the ITAC reporting system. The contents of the security incident report will be transferred to an ITAC report format at a later date. The NTS or ITAC report may need to provide more information specifically related to the noncompliance(s) than is covered in the ORPS or security incident report. Additionally, the NTS and ITAC reports should state the principal corrective actions needed to address the noncompliance conditions; these may be a subset of those listed in the ORPS or ITAC reports. Examples of the level of detail that contractors provide for these reports can be viewed in the NTS and ITAC systems.

DOE expects NTS and ITAC reports to be submitted without contractors making a detailed evaluation of safety or security significance, or a prediction of whether the Office of Enforcement would pursue an investigation after receiving the report. Contractors should simply follow the reporting safety thresholds referenced in appendices A and B. For security incidents, accordance with the IMI requirements listed in DOE M 470.4-1. Contractors may include their preliminary assessment of a noncompliance's safety significance in the "Description of Noncompliance Condition" portion of an NTS report or in the narrative portion of the ITAC report for security incidents.

Contractors are expected to undertake as many corrective actions as needed to resolve a noncompliance and prevent it from recurring. The Office of Enforcement expects the corrective action section of an NTS or ITAC report to include the principal corrective actions related to the noncompliance. When the corrective actions have been completed and all completion dates entered into the NTS/ITAC systems, the contractor should mark the report "Completed." At this point, it is essential that the cognizant DOE Field Element conduct a verification. The Field Element enforcement coordinator subsequently indicates in the NTS or ITAC report either that the Field Element is satisfied that all corrective actions have been completed or that a discrepancy remains, and recommends further action to the Office of Enforcement. After the Field Element indicates that all corrective actions have been completed and appropriately verified, the Office of Enforcement staff reviews the NTS or ITAC report and makes a recommendation for closure to the appropriate Office Director. The NTS or ITAC report is officially closed after the Office Director concurs with the staff recommendation to do so, and the report's status is subsequently changed in the respective databases.

Contractor Tracking of Non-NTS Reportable Noncompliances

For enforcement purposes, reporting a noncompliance that is below an NTS reporting threshold into a contractor's tracking system also constitutes formal reporting to DOE. By policy, the Office of Enforcement may exercise discretion in pursuing enforcement action for such items. For example, actions might not be pursued if the item has low safety significance, or if the contractor is taking timely steps to correct the condition. The Office of Enforcement could later choose to take action on these issues if, for example, a program review shows that the contractor is not taking timely action to correct the issue.

The Office of Enforcement expects these noncompliances to be tracked and managed to resolution by the contractor's internal issues management or corrective action process. Contractors are expected to have such a process and procedures in place.

Contractors are also expected to use their internal tracking processes to capture, track, and trend worker and nuclear safety noncompliance conditions. An adequate noncompliance reporting process should, as a minimum:

- In some form, annotate those problems or issues that are noncompliances.
- Indicate how the problem was discovered.
- Reference the specific rule section violated.
- Ensure proper resolution (development and completion of corrective actions) of the noncompliance. Allow retrieval of the noncompliances for review and trending by the contractor and DOE.

- Be readily accessible by DOE Field and Program Office coordinators, as well as Office of Enforcement staff when on site.

As noted, contractor problem resolution processes should provide a means for trending and evaluating data to identify adverse trends, dominant problems, and potential repetitive problems. The Office of Enforcement has observed that the better screening and reporting processes include similar provisions for an additional level of trending and evaluation through review of internally tracked noncompliance conditions.

V. Office of Enforcement Reviews and Communications

Review of NTS and ITAC Reports

Office of Enforcement staff, in coordination with DOE enforcement coordinators, routinely review noncompliances reported into the NTS and ITAC. Submission of a noncompliance report does not mean that an enforcement action will be taken. Rather, the Office of Enforcement will review and evaluate all available information before making that determination.

When a noncompliance is reported into the NTS or ITAC, the report is assigned to an Office of Enforcement staff member for a review that encompasses:

- A review of the facts contained in the report and, possibly, other information to determine whether a DOE safety or information security requirement has been violated.
- An initial evaluation of the noncompliance's safety or security significance to determine whether a more comprehensive evaluation by the Office of Enforcement is warranted.

The Office of Enforcement staff review often involves communication with DOE Field Element staff and the contractor. If the information in the NTS or ITAC is not sufficient to evaluate the significance of the issues, the staff member obtains additional information, such as an event critique, a causal analysis, or the contractor's investigation, injury, or preliminary inquiry report.

After this review, the staff member makes a recommendation to the appropriate Office Director on whether to undertake further action. If no enforcement action is to be taken, the Office of

Enforcement simply tracks the noncompliance report to closure. If it is concluded that a more comprehensive review, focused inspection, or investigation is to be performed, the process will follow the guidance in chapter VI, *Investigation Process*.

From time to time, Office of Enforcement staff and the DOE enforcement coordinators may also evaluate contractors' non-NTS or non-ITAC reportable noncompliance issues documented in the internal reporting system. An evaluation may result from a program review but may also be initiated by an unexpected decline in NTS or ITAC reporting by a contractor or an apparent inconsistency between a contractor's ORPS, NTS and ITAC reports. The results of the evaluation are then fed into the decision process described above.

Review of Other Sources of Noncompliance Information

The Office of Enforcement regularly monitors sources of information other than the NTS and ITAC, including:

- Individual ORPS reports.
- Security Incidents that may obliquely indicate potential compromises or risks to classified information
- DOE Field Element or Headquarters inspections, surveys, or assessments.
- Security findings documented in the Safeguards and Security Information Management System (SSIMS)
- DNFSB reports.

- Areas of concern raised by senior DOE management.
- Information provided by the DOE Office of Hearings and Appeals, or the DOE Office of the Inspector General.
- Allegations communicated directly to the Office of Enforcement by a contractor or DOE worker.
- Media reports of events, accidents, or injuries.
- Congressional inquiries.
- Information from other agencies, including the Nuclear Regulatory Commission (NRC), Department of Labor, OSHA, or state and local officials.

DOE expects that initial notification of significant noncompliances, including security noncompliances, will come primarily from contractor and DOE enforcement coordinators, as part of the desired informal communications maintained with the Office of Enforcement. However, when material becomes available from these other sources, the Office of Enforcement will evaluate the conditions and request additional information from contractor and DOE coordinators as appropriate.

Program Review

The Office of Enforcement regularly conducts program reviews of contractor processes for the identification, screening, reporting, and correction of classified information security and nuclear and worker safety issues, as described in chapter IV. These program reviews also address contractors' assessment processes. The purpose of these reviews is to ensure that contractors apply a sound process to identify noncompliances, make proper decisions on reportability, and undertake timely steps to correct noncompliances. With regard to contractors' assessment

processes, the Office of Enforcement's review focuses on their effectiveness in identifying issues and on specific improvements in those processes. A program review may also evaluate selected contractor compliance issues in the areas of radiation protection, safety basis, quality assurance, worker safety, or classified information security.

Program reviews are typically planned and scheduled on a near-term, quarterly basis. Selected contractors are contacted prior to the review in conjunction with a document request. Programs are selected for review based on a number of factors, such as input from Field Element personnel, site NTS or ITAC reporting history, the Office of Enforcement's familiarity with the contractor's program, and contractor replacement. On occasion, the Office of Enforcement may conduct a program review in conjunction with a noncompliance investigation.

Typically, DOE and contractor enforcement coordinators are formally notified of planned program reviews approximately four weeks in advance of the review. The Office of Enforcement staff member leading the review contacts the DOE Field Element enforcement coordinator before issuing the program review notification; this coordinator then acts as the Office of Enforcement's liaison to the Field Element and contractor management and oversees arrangements in support of the program review. The notification contains details on participants, scheduling, agenda items, and other logistics. As part of the notification, the Office of Enforcement requests specific documentation from the contractor relating to the implementation of its program. Specifics regarding the document submittal will be included in the request; typically, the contractor is asked to provide documentation within ten working days. Appendix C includes the standard program review document request, which

may be tailored to the specifics of the review.

The program review is generally conducted by a number of Office of Enforcement representatives and typically lasts several days. Office of Enforcement staff routinely conduct formal entrance and exit meetings with DOE and the contractor as part of the review. Preliminary conclusions on the strengths and weaknesses of the contractor's program are discussed during the exit meeting.

The review criteria in appendix C are the Office of Enforcement's guidance for conducting the review. The scope of a particular review may be either broader or more limited than implied by the criteria, depending upon the specifics of the review.

The Office of Enforcement typically sends a draft report describing the scope and results of the review to the local DOE office for review within approximately 30-days after the onsite review. This draft is for DOE internal review only and is not shared with the contractor. The final report of the program review and accompanying transmittal letter are typically distributed within 30-days after receipt of DOE comments. Copies of the final report are mailed directly to the contractor and affiliated DOE offices, and all program review reports are posted on the Office of Enforcement web site.

The final program review report describes both program strengths and weaknesses in an effort to promote communication and lessons learned among the contractor community. The Office of Enforcement recognizes that some strengths may be program- or site-specific, so it is not intended that all contractor programs necessarily implement actions to address the program strengths described in each report.

On the other hand, the Office of Enforcement does intend that contractors correct the identified weaknesses, after appropriate consultation with and approval by local DOE. While such action and coordination are not typically mandatory, the contractor's failure to correct identified weaknesses in a regulatory screening and reporting program may limit its ability to successfully argue for mitigation of any later enforcement action.

In some cases, a program review may identify noncompliances that the contractor had not previously recognized or addressed (though this is not the focus or intent of such reviews). The contractor will be informed of any identified noncompliances as soon as possible, and the Office of Enforcement will subsequently consider whether to address such matters in an enforcement action or an enforcement letter.

The approach described above is used for contractor program reviews for major DOE sites. For contractor programs where the scope of DOE operations is relatively smaller, the Office of Enforcement conducts limited, or "desktop," reviews, using an abbreviated document request and without an onsite visit. A sample document request for a desktop review is provided in appendix C.

Enforcement Letter

If the Office of Enforcement identifies a matter of security or safety concern but decides not to pursue an enforcement action, the Office of Enforcement may issue an enforcement letter. An enforcement letter is not a formal enforcement action in that it imposes no requirements, enforcement citation, or civil penalty on the contractor. The enforcement letter usually identifies one or more conditions or situations (a) where performance may have

been less than desired but not of sufficient significance to warrant an enforcement action, and (b) where contractor attention is required to avoid a more serious condition that would result in an enforcement action. Thus, the enforcement letter can serve as a strong warning on matters that need attention. It may also highlight any contractor actions that were appropriate and contributed to the decision not to take enforcement action. The Office of Enforcement coordinates with the DOE enforcement coordinator and his or her management on the message and conclusions in the letter prior to its issuance.

Enforcement letters do not require a response to the Office of Enforcement. Instead, the Office of Enforcement relies on the normal interface between the contractor and local DOE Field Element for communications on follow-up and resolution of the matter.

Enforcement Program Information Sharing

The Office of Enforcement uses a variety of means to disseminate lessons learned and program changes related to noncompliances and DOE enforcement.

The major source of information shared by the Office of Enforcement is on its Internet web site, which provides information to the Federal and contractor communities and the general public. Relevant Federal regulations, standards, Office of General Counsel interpretations, enforcement actions, enforcement letters, press releases, enforcement guidance, program review letters, annual reports, and coordinator training workshop information are available there. The Office of Enforcement routinely updates its web site to support timely communication and to promote lessons learned across the

complex. The Office of Enforcement web site was accessed nearly 141,000 times in 2006, an indication that the site is a vital avenue of communications for the DOE enforcement program.

The Office of Enforcement also shares information about its expectations and processes through its annual training workshop for enforcement coordinators. The workshop typically includes a one-day introductory training session for new DOE and contractor coordinators, and a one- to two-day refresher and updating session for experienced enforcement coordinators. The training highlights noncompliance-related actions taken during the prior year, circumstances of the problems, and the bases for Office of Enforcement action, as well as the status of ongoing initiatives and changes in the enforcement program.

The Office of Enforcement also takes advantage of other avenues of communication, including regular participation in EFCOG senior management meetings and EFCOG PAAA Working Group sessions; periodic teleconferences with DOE enforcement coordinators; providing information on enforcement actions to the DOE Lessons Learned Program; periodic briefing of Safeguards and Security Directors; and frequent meetings with contractor and DOE senior managers.

VI. Investigation Process

Overview

The goal of the enforcement program is to encourage proactive behavior by DOE contractor organizations to improve safety and security performance so that enforcement actions are not required. The result of such proactive behavior is that contractors will find and address safety and security issues through performance assessments and other similar processes before they result in safety or security events³.

However, when circumstances do warrant the consideration of enforcement action, the Office of Enforcement uses the investigation process described in this chapter. Note that this process has substantial flexibility, so the actual steps taken may differ from case to case depending on the circumstances.

The following steps typically occur for a noncompliance that the Office of Enforcement decides to investigate:

- Determine whether a noncompliance requires an investigation, based on a significance evaluation or other contributing factors, and obtain the Director's concurrence to undertake an investigation.
- Initiate the investigation activities in a timely manner.
- Conduct an Office of Enforcement investigation strategy meeting.

³ For this purpose, the Office of Enforcement considers a "near miss" to be a safety event, because in such cases, safety breakdowns have already occurred and the absence of an injury is simply fortuitous in most cases.

- Inform Field Element and Program Office management.
- Provide a formal notification letter to the contractor informing them of the pending investigation, with an information request if such is needed.
- Conduct an onsite investigation, if needed.
- Prepare an investigation summary report.
- Decide whether to close the case with an enforcement letter or without any further action.
- If necessary, conduct an enforcement conference.
- Determine the severity level of the violations, the associated civil penalty or contract fee censure, and application of mitigation factors.

Any resulting enforcement action is processed using the guidance presented in chapter VII.

Enforcement Process Timelines

Decision to Investigate (45 calendar days):

- Identification of Issue
- Management Review/Approval
- Request for Documents
- Announcement Letter

Investigation (120 calendar days)

- Review of Documents
- On-site Interviews

- Investigation Summary Report

Enforcement Action (60 calendar days)

- Enforcement Conference
- Draft PNOV
- QRB/Technical Edits Reviews
- Review and Issuance

Request for Office of Enforcement Investigation

In some cases, an investigation may be initiated based on a request. 10 CFR Part 851.40(c) provides that a worker or his/her representative has the right to request the Director to initiate an investigation or inspection for worker safety issues. Similarly, Part 820.21 provides any person the opportunity to request an investigation or inspection for nuclear safety issues. A worker or worker representative may also submit an anonymous request for an inspection or investigation, or may request for confidentiality. When requesting confidentiality, the requester should be aware that although the Office of Enforcement will take every precaution to avoid disclosing the individual's identity, the nature of the issue itself may provide some indication of who the requester is. Furthermore, if the Office of Enforcement does initiate an investigation, maintaining the requester's confidentiality may limit the effectiveness of that investigation. These limitations will be fully discussed with the requester to ensure that they are understood. Regardless of whether a requester is anonymous, requests confidentiality, or allows his or her identity to be known, the Office of Enforcement will treat each request equally and seriously, and will work toward an appropriate conclusion.

Note that Part 851.20(a)(6) requires management to establish procedures for employees to report, without reprisal, job-related

fatalities, injuries, illnesses, incidents, and hazards and make recommendations about appropriate ways to control those hazards. In addition, sections 851.20(b)(7), 851.20(b)(8), and 851.20(b)(9) give workers the right, again without reprisal, to express concerns related to worker safety and health, to decline to perform an assigned task if the task poses an imminent risk of death or serious physical harm, and to stop work if they discover worker exposures to imminently dangerous conditions or other serious hazards.

The Office of Enforcement expects that before requesting an investigation, workers and their representatives will exhaust all contractor and local DOE mechanisms to express and resolve their concerns.

The Office of Enforcement is developing a web-based request form to facilitate requests for investigation, and will place it on the Office of Enforcement web site when developed. Until the web-based form is available, requests for investigation should be transmitted to the Office of Enforcement via U.S. mail at the following address:

HS-40/270 Corporate Square Building
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585-0270

The request for investigation should, to the extent possible, include the following information:

- Requestor's name, job title, and contact information (phone number, e-mail address, work address). If the request is made by a worker representative, it should also describe the

nature of the representation (e.g., union, elected representative, attorney) and the name of the worker or workers for whom the request is made.

- Request for confidentiality (if preferred).
- Date of request.
- The DOE site location.
- Employer's name.
- Specific work area where the alleged hazard or potential violation exists.
- Description of the alleged hazard or potential violation, including activities involved, number of workers potentially exposed and for what duration, any previous incidents (e.g., injuries, near misses) involving the hazard, and the requestor's role in the activity. Supporting documentation or information, such as internal inspection results, e-mails, written workplace procedures, etc., should also be included.
- Description and results of efforts to resolve the concern through existing contractor and local DOE mechanisms, including the formal employee concerns program. Include available documentation of such efforts, if any.
- Signature of the requestor (if submitted by mail).

On receiving such a request, the Office of Enforcement notifies the Program and Field Element enforcement coordinators of the receipt and nature of the request. If so requested, the Office of Enforcement will honor the requestor's desire for confidentiality. The Office of Enforcement then evaluates the request as described in this chapter to determine whether an investigation is warranted. If additional information is needed to make this determination, the Office of Enforcement coordinates with the

DOE enforcement coordinator and the requestor (where appropriate) to obtain the information needed to make the determination.

The judgment to pursue or not pursue such requests rests solely with the Office of Enforcement, and is based on all of the information and evidence available to the Office of Enforcement, including that obtained from DOE enforcement coordinators or other sources. If the Office of Enforcement decides to undertake such an investigation, it follows the investigation process described in this chapter.

The Office of Enforcement communicates to the requestor its decision and the basis of its determination on whether to investigate, and the results of any investigation are documented and processed as described in this chapter. At the end of the process, the requestor is notified of the results.

The Office of Enforcement processes anonymous requests for investigation in the same manner. However, as noted, the investigation may be hampered by not having access to the individual(s) with first-hand knowledge and information about the alleged noncompliance.

It should be noted that 10 CFR Part 824 does not provide for such requests. However, a worker or worker representative may submit an anonymous request (as describe above) to the Director for their consideration to pursue an investigation involving safeguarding classified information issues. If the worker request confidentiality, the Office of Enforcement will take every precaution to avoid disclosing the individual's identity, although, the nature of the issue itself may provide some indication of who the requester is.

Safety/Security Significance – Investigation Decision

The Office of Enforcement generally investigates only those noncompliances with greater safety or security significance than the general population of reported noncompliances. The judgment of significance considers both the actual safety or security significance and associated programmatic breakdowns, as well as any potential safety or security significance. The Office of Enforcement also considers safety or security significance when determining the sanctions to be imposed in an enforcement action.

For nuclear safety noncompliances, the determination of safety significance is based on the “defense-in-depth” approach to nuclear safety embodied in DOE’s nuclear safety regulations:

- The extent to which the safety barriers intended to prevent an abnormal or accident condition have been violated, defeated, or not properly established.
- The extent to which mitigating safety features intended to protect workers or the public in an abnormal or accident condition have been violated, defeated, or not properly established.
- The extent or severity, or both, of an actual adverse nuclear safety event or condition or the potential that it could occur.

For worker safety noncompliances, the determination of safety significance is based on established principles for identifying hazards and implementing interim protective measures and controls for those hazards, as embodied in DOE’s worker safety regulation:

- The extent or severity, or both, of an injury or illness that actually occurred or the potential that it could occur.
- The extent to which hazards were not adequately identified or evaluated.
- The extent to which interim protective measures or hazard controls were violated, defeated, or not properly established.

The breakdowns in levels of controls associated with an event or condition, along with the actual or potential consequences of the event or condition, establish the relative safety significance. However, various other factors important to both nuclear and worker safety are also considered in evaluating cases for investigation and determining the enforcement outcome:

- Management involvement in, awareness of, or contribution to a noncompliance.
- A repetitive or recurring noncompliance.
- Prior notice by DOE of the problem, and inadequate resolution by the contractor.
- Duration of the noncompliance.
- Multiple examples of a noncompliance as opposed to a single occurrence.
- Discovery of the noncompliance by DOE or other external organization.
- Willful noncompliance or falsification of information.
- Prior enforcement actions (related or not related).
- Lack of timely notification to DOE or reporting into the NTS.
- Slow contractor response to investigate or to take appropriate

corrective actions, or both.

- Poor safety performance history combined with prior enforcement actions.
- Violation of a compliance order.

The presence of one or more of these factors generally increases the safety significance and may be of sufficient concern to lead to an investigation, even when the basic safety significance alone would not necessarily dictate such an outcome. After considering these factors and the basic safety significance, the Office of Enforcement decides whether the matter warrants an investigation. Typically, the initial recommendation comes from Office of Enforcement staff, and the decision to investigate rests with the Director.

In determining the significance of a classified information security violation, the documented evaluation should consider the potential impact on national security. If the Program Secretarial Office completed a damage assessment, it is considered during the course of the enforcement process. Additionally, any managerial policies and practices that may represent contributing factors must be considered. Consideration should be given to the matter as a whole, in light of the circumstances surrounding the violation. There may be cases in which the impact is low, but the failures of management are significant. Therefore, the severity level may be based upon the management failure(s) and not simply the low impact on national security. The following are examples of some factors that should be considered:

- Did the violation actually or potentially have an impact on our national security? A violation that involves no actual risk but that could have had an impact on national security may be

very significant, depending upon the risk of the potential threat (i.e., its likelihood) and the possible consequences involved.

- What was the root cause of the violation? Was it caused by training deficiencies? Failure to follow procedures? Inadequate procedures? Failure to follow up properly on activities or commitments? These broader programmatic weaknesses may have more significance than the present violation.
- Is the violation an isolated incident or were there multiple examples of similar violations in the same time frame? Is it indicative of a management or programmatic breakdown? Management or programmatic breakdowns may be more severe than an isolated incident.
- Was management aware of or involved in the violation, and, if it was involved, at what level of management and to what extent? Violations in which management was directly involved may be more significant than those of which management was unaware. Violations involving upper-level management should be considered more significant than those involving first-line supervisors. Inattentiveness on the part of management should also be considered, i.e., should management have been aware of the violation?
- What was the duration of the violation? If the condition existed for an extended period without discovery and correction, the risk generally is proportional to the duration of the violation, and the severity level of the violation should be increased.

- Was DOE notified promptly and provided complete information by the contractor when a violation was found? Delay in providing a comprehensive report to DOE may indicate lack of contractor initiative to understand the significance of the violation at a facility. Furthermore, failure of a contractor to report a violation to DOE in accordance with established reporting requirements may be considered a violation itself, in addition to the violation that occurred.
- Was the violation inadvertent or did it involve willfulness, and, if it did, to what extent? (See Section 6.3 for guidance regarding willful violations.)
- Was the violation related to a condition in a Compliance Order? These violations may be more significant because contractors have had prior notice of the violation and have not taken appropriate actions to correct it after having been directed to do so by the Secretary.
- Did the actual or potential impact involve severe consequences to our national security or involve lesser, but still substantial consequences?

Noncompliance Investigation

Planning

The Office of Enforcement generally commences investigation activities as soon as staff schedules permit after receipt of an NTS or Security Incident/ITAC report or other information source that is judged to have elevated safety and security significance. However, if a Type A or Type B safety accident investigation is under way, the Office of Enforcement typically postpones its

investigation until after the accident investigation report has been issued, relying to the extent possible on facts gathered in the Type A or B investigation report. Similarly, if a criminal investigation is in process for incidents involving classified information, the Enforcement Office will coordinate with the law enforcement agency to determine when to initiate an enforcement investigative action.

An initial step in the investigation activity is to conduct a strategy meeting on the case with the Director, the lead Office of Enforcement staff member assigned to oversee NTS and Security Incident/ITAC reports from the respective contractor, and other Office of Enforcement personnel and technical advisors assigned to the case. The purpose of this session is to establish the approach the Office of Enforcement intends to follow in identifying potential violations, establishing relevant facts and circumstances, determining significance, and deciding the need for an onsite investigation. Results of the strategy meeting are typically discussed only with affected DOE offices.

Notification and Information Request

Following the investigation strategy meeting, the Office of Enforcement communicates with the appropriate DOE Field and Program Office management to notify them of the planned investigation. The Office of Enforcement then sends the contractor a formal notice letter from the Director informing it of the Office of Enforcement's plans to conduct an investigation and the areas to be addressed, and reminding the contractor of the cost segregation requirement⁴. The notification letter may also

⁴ Contractors are required to segregate costs in accordance with the provisions of Public Law 100-700, *Major Fraud Act of 1988*.

contain a request for information to support the investigation. In urgent situations, the Office of Enforcement may forgo the normal notification process and require immediate access to contractor facilities, under the authority of Part 851.40(a) for worker safety issues, Part 820.8(a) for nuclear safety issues and Part 824 for classified information security issues

If an onsite investigation is to be conducted, the Office of Enforcement formally notifies the contractor and associated enforcement coordinators by letter (usually in its initial correspondence) of the need for the investigation and its proposed date. Office of Enforcement staff subsequently coordinate with the contractor to establish an agenda and a list of individuals to be interviewed.

The Office of Enforcement's information request is aimed at obtaining documentation that aids in understanding the facts and circumstances of the noncompliance condition. Investigation activities include a comprehensive review of the material submitted by the contractor and usually an onsite investigation. (In some cases, the Office of Enforcement may determine that it can adequately conduct its investigation activities without a site visit.)

Obtaining information through informal, cooperative means is the most efficient process, both for the Office of Enforcement and the contractor. If a contractor is reluctant to provide any documentation—before, during, or after the investigation—the Office of Enforcement is empowered by Parts 820.8(a) , 851.40(k) and 824.10(d) to obtain it by more formal methods, including a subpoena, if necessary.

Onsite Investigation Initiation

An onsite investigation typically commences with a DOE-only meeting to discuss the Office of Enforcement team's concerns and the areas to be pursued, and to obtain DOE Field Element management's input on the matter. The Office of Enforcement usually follows that session with an opening conference that includes both DOE and contractor personnel to summarize the purpose of the visit, the issues under review, and the protocols for interactions, subsequent communications, and deliberations. For worker safety issues, the Office of Enforcement offers the contractor workers involved with the noncompliance(s) under investigation, or their representatives, the opportunity to attend the entrance conference.

During the investigation, the Office of Enforcement may interview workers and managers, inspect facilities and work areas, review records, and identify additional documentation required by the Office of Enforcement. Contractors are required to provide complete and accurate information to the Office of Enforcement in support of the investigation or other inquiries, as stated in Parts 820.11, 851.40(b). and 824.12(e).

Focused Inspection Activities

Parts 851.40 and 824.5 authorize the Director, and thus the Office of Enforcement, to conduct inspections to determine contractor compliance with worker safety and classified information security requirements. As noted, the Office of Enforcement expects that contractors will perform regular and effective assessments of their own compliance with worker safety and classified information security requirements and that the Office of Enforcement will not need to undertake extensive inspection efforts. Further, the Office of Enforcement intends to

use the results of Office of Independent Oversight inspections in lieu of conducting its own routine inspections.

However, management issues, serious injuries and accidents, actual and potential compromises of classified information or adverse performance trends may lead the Office of Enforcement to conduct *ad hoc*, or focused inspections on specific areas of concern. Focused inspections are normally limited in scope and duration and concentrate on specific areas of concern. The Office of Enforcement may choose to conduct focused inspections for any reason. For example:

- Observations made during the onsite portion of an investigation may indicate a potential compliance problem in a specific location or functional area (e.g., during a building walkthrough, the enforcement specialist notes numerous electrical safety hazards and determines that a focused inspection is needed to evaluate electrical safety issues in the building or facility or conditions observed where classified information is left unattended or without adequate protection and an inspection is needed to determine the prevalence of these conditions). Regardless of whether the Office of Enforcement observes other relevant conditions during its onsite investigation, a focused inspection may be conducted in conjunction with the onsite portion of an investigation in order to use resources wisely.
- A review of data may suggest a possible negative compliance trend in a specific type of operation, work activity, or functional area (e.g., a trend analysis of NTS, ITAC, SSIMS or ORPS data suggests an increase in fall-related injuries across the Department). The Office of Enforcement may then determine

that a series of focused inspections is warranted at selected sites to evaluate the trend and its compliance implications.

- Other indicators or events may suggest a need for increased focus or attention at a specific location or in a specific functional area.

If a focused inspection is to be conducted in conjunction with an investigation, the enforcement specialist notifies the contractor (as well as the DOE and contractor enforcement coordinators) as soon as practical that the scope of the investigation will expand, or has been expanded. This notification describes the general scope of the focused inspection. If additional subject matter expertise is needed for the focused inspection, the Office of Enforcement may schedule a follow-up visit to conduct the focused inspection.

It is the Office of Enforcement's intent that the preliminary results of a focused inspection be provided to the contractor at the exit briefing, which summarizes any noncompliance conditions noted by the team (including the focused inspection) so that the contractor can address them in a timely manner. If the findings of the focused inspection are generally complete, the Office of Enforcement may consider the exit briefing as an informal enforcement conference (see below) and will so notify the contractor. Following such onsite enforcement conferences, the Office of Enforcement permits the contractor up to two weeks to provide supplemental information to clarify the facts and circumstances or refute the preliminary conclusions presented at the conference. However, if the Office of Enforcement has notified the contractor prior to the site visit that an investigation is to be performed, the process of advance notification and conduct of an informal enforcement conference at the Office of

Enforcement's office will typically occur.

Investigation Report/Documentation

In most cases, when investigation activities are completed, the investigation team will document the results. In some cases, the available documentation may be sufficient to support proceeding directly to a Preliminary Notice of Violation (PNOV) without the Office of Enforcement developing an investigation summary report or other investigation documentation.

When documentation, such as an investigation summary report or focused inspection report, is the sole basis for the Office of Enforcement's conclusions on noncompliance(s), the documentation typically includes:

- A summary of the facts and circumstances of the noncompliance(s) and associated event(s).
- Specific noncompliance that occurred and the regulation (s) involved.
- Specific document references or other factual details related to the noncompliances.
- A discussion of safety or security significance.
- Facts that may be relevant to consideration of enforcement mitigation (and potential escalation, if applicable).

The investigation and documentation also addresses the following factors, if relevant to the noncompliance(s):

- Duration.
- Management involvement.

- Timeliness of reporting.
- Causal analysis.
- Extent of condition.
- Assessment deficiencies in failing to discover the problems.
- Recurring events or problems.
- Prior DOE notice.
- Immediate actions.
- Corrective action plans.
- Plans to conduct effectiveness reviews.

If an onsite informal enforcement conference is conducted, a conference summary is included as part of the enforcement action documentation.

The investigation documentation includes the Office of Enforcement's recommendation to the Director on any subsequent course of action, which could include proceeding to an enforcement conference, proceeding with enforcement action, or not pursuing an enforcement action. If the Office of Enforcement is proceeding directly to an enforcement action, that action is processed as discussed in chapter VII, and the investigation documentation report is included. The decision to take an enforcement action rests with the Director (or NNSA Administrator, for NNSA facilities). If the Director's decision is to conduct an enforcement conference, the contractor is notified by letter and the investigation summary report is enclosed. If the decision is to not proceed with an enforcement action, the case may be closed through the issuance of an enforcement letter (described in chapter V) or by notation in the associated NTS or ITAC report(s). In some cases, the Office of Enforcement may

issue the investigation summary report with the issuance of the PNOV—for example, when an enforcement conference is held at the conclusion of an onsite investigation.

Enforcement Conference

An informal enforcement conference may be called at any time at the discretion of the Director. (A contractor may request an enforcement conference, but the Director decides whether to conduct the conference.) The primary purpose of an informal enforcement conference is to provide an opportunity for the contractor to address the facts and noncompliances noted by the Office of Enforcement in its investigation documentation, and to explain the steps being taken to resolve the noncompliances and underlying causes. An enforcement conference is held for most enforcement action proceedings, although it is not mandatory; the Director may choose, in certain cases, not to hold a conference. For example, an enforcement conference is generally not held for a nuclear safety issue that is expected to result in a nuclear safety-related severity level III violation.

Scheduling and Notification

In general, if an enforcement conference is planned, it is held before an NOV is issued. To provide for timely processing of an enforcement proceeding, the contractor is typically informed of the intent to conduct a conference at least two weeks in advance.

The Office of Enforcement typically notifies the contractor by a letter signed by the Director of the enforcement conference date, time, and location. The notification letter generally includes or references documents covering the facts and circumstances of the noncompliance(s), typically in the form of an investigation

summary report or other investigation documentation, the Office of Enforcement's conclusions on the noncompliance(s), and any issues that the contractor should discuss.

In some cases, the Office of Enforcement may hold an enforcement conference on site at the end of a focused inspection or investigation, generally when the facts and circumstances are clear and no further review of information is needed to identify the noncompliance(s). In such a case, after the Director authorizes the conference and designates the Office of Enforcement staff member who will chair it, the Office of Enforcement team notifies the contractor during the inspection or investigation that an enforcement conference will be held at the completion of the onsite visit.

The Office of Enforcement may convene an enforcement conference even when the investigation summary report was previously issued along with the PNOV, or if the Office has otherwise proceeded directly to a PNOV without an investigation summary report or other investigation documentation.

Attendance

DOE personnel, as a minimum, should include the Director or the Office of Enforcement staff member who will chair the conference, the responsible Office of Enforcement staff and technical advisors involved in the case, Program Office and Field Element management representatives, and the enforcement coordinators from the Field or Program Office. To achieve the best prospect of influencing contractor performance improvement via the enforcement conference, it is also highly desirable that senior Field Element and Program Office management attend. These individuals are notified of the conference and, through

verbal or e-mail communications, strongly encouraged to attend. Other DOE personnel may attend at the request of, and as permitted by, the Director.

The attending DOE contractor personnel should, as a minimum, include senior contractor management (e.g., Laboratory Director, President), key management personnel involved in the event or conditions as well as the actions to correct the underlying problems, and the contractor enforcement coordinator. Participation by representatives from the Board of Directors and corporate management of the parent company or governing university is strongly encouraged.

As stated in DOE's enforcement policies⁵, enforcement conferences are pre-decisional actions intended to provide a forum for open and candid discussion regarding a potential enforcement issue. Therefore, they are normally closed meetings between DOE and the contractor, including, at times, the parent organization's management. The media and public do not attend.

Conduct of Enforcement Conference

In general, conferences are informal and no transcript is made, in order to encourage candor. The Director or Office of Enforcement staff designee chairs enforcement conferences. After preliminary opening comments by the Director and the introduction of attendees, the conference is turned over to the contractor to address key factors related to the case. During the

⁵ *General Statement of DOE Enforcement Policy*, 10 CFR Part 820, appendix A, as amended, for nuclear safety violations; *General Statement of Enforcement Policy*, 10 CFR Part 851, appendix B, for worker safety violations; and *General Statement of Enforcement Policy*, 10 CFR Part 824, appendix A, for classified information security violations.

conference, all DOE officials are encouraged to pose questions to seek clarification or to ensure that key points are addressed.

The contractor should identify any factual issues related to the Office of Enforcement's investigation or inspection report, or any document relied on by the Office of Enforcement in identifying noncompliances. Additionally, the contractor should address the causes of the noncompliances, its views of their significance, the corrective actions taken to correct the immediate problems and to prevent recurrence, and the application of mitigation and discretion factors.

The level of detail of the contractor's briefing should be related to the complexity and significance of the issues. In general, a summary of the noncompliances, how they were discovered, their causes, and related circumstances is helpful, but need not be detailed. However, a substantive, thorough discussion of the corrective actions and measures to ensure that the violations will not recur is critical. It is also beneficial to demonstrate that representatives from the Board of Directors and corporate management from the parent company or governing university are involved in the oversight of safety and classified information security performance and ensuring that the violations are corrected. An effective conference typically lasts about two to three hours, but contractors are permitted to take whatever time they need. Any material provided by the contractor at the enforcement conference is placed in the docket file for the case.

At the conclusion of the contractor's presentation and response to questions from DOE, the Office of Enforcement closes the conference and make clear that the final DOE decision on the matters will be made after the conference and will be provided to the contractor at a later date.

Post-Conference DOE-Only Meeting

Following the enforcement conference, and after all the contractor's personnel and representatives have departed, the Director or designee reconvenes the DOE participants for preliminary discussions. The intent is to arrive at a consensus on any facts presented by the contractor, whether an enforcement action should be taken, the violations that occurred, their significance and severity level, the application of civil penalties, treatment of mitigation factors, and messages that should be communicated in the transmittal letter for the enforcement action. These discussions represent the preliminary deliberations on any enforcement action.

Enforcement Conference Summary Report

After the post-conference DOE-only meeting, the Office of Enforcement prepares a brief report documenting the enforcement conference discussions. This summary report typically includes the contractor's position on the accuracy of facts in the Office of Enforcement investigation summary or other documents that are the basis for any potential violations, a brief description of significant additions or corrections to the factual information, a brief description of any significant additional information that affects the significance or mitigation factors, and a summary of the contractor's short-term and long-term corrective actions.

Before finalizing the conference summary report, the Office of Enforcement solicits comments and input from the DOE Program and Field Elements via the DOE enforcement coordinators. The conference summary report is typically attached to the enforcement action.

Confidentiality of Deliberations

After the enforcement conference and before issuance of the enforcement action, all discussions and deliberations within DOE about the case and possible action by DOE, including the post-conference DOE-only meeting discussions, are confidential. Because these discussions involve a pre-decisional matter by DOE, no information pertaining to that action is to be communicated to the contractor or members of the public.

VII. Enforcement Action

Possible enforcement actions include notices of violation and compliance orders. Once the circumstances surrounding a noncompliance and its safety or security significance are understood and any enforcement conference and preliminary deliberations are completed, it is the Office of Enforcement's responsibility to consider the appropriate enforcement action. This chapter describes the process of developing the enforcement action and the Office of Enforcement's considerations in that process.

Summary of Enforcement Action Process

The process below summarizes the most typical enforcement process and applies to classified information security, nuclear safety, and worker safety and health violations, except where noted.

- Office of Enforcement staff develops a proposed aggregation of violations, specific violations to be cited, appropriate severity levels, corresponding civil penalties, and draft communication to the contractor.
- Office of Enforcement solicits Field and Program Office comments on the proposed action and correspondence, and the Director's approval (or NNSA Administrator, for NNSA facilities).
- DOE issues the PNOV or other action.
- The contractor has 30 days to respond in writing and may contest the notice with substantive evidence not previously considered; contest the civil penalty; request additional

mitigation, if applicable; or accept the notice and waive the right to contest.

- If the PNOV is uncontested, it automatically becomes a final order.
- If the PNOV is contested, the Director (or NNSA Administrator for NNSA facilities) considers the arguments made and determines the final action. DOE's response to the contractor converts the PNOV to a Final Notice of Violation (FNOV).
- Once an FNOV is issued, 10 CFR Parts 820, 851 and 824 provide an opportunity for the contractor to appeal, if desired; this is described further in this chapter. If the contractor does not appeal, the FNOV becomes a final order.
- In general, all records and correspondence related to a pending enforcement action before the issuance of a final order are considered "pre-decisional" and thus are not subject to disclosure under the Freedom of Information Act.
- Records related to an enforcement action are placed in the Office of Enforcement docket file.

The Director is authorized to issue PNOVs, FNOVs, final orders, and consent orders for non-NNSA facilities, and the NNSA Administrator issues these documents for NNSA facilities based upon the recommendation of the Director. Compliance orders must be executed by the Secretary. Consent and compliance orders follow some of the elements of the above process; the unique aspects of these actions are addressed later in this chapter.

Preliminary and Final Notices of Violation

Preparation of Preliminary Notice of Violation

A PNOV is a finding by DOE that, based on the evidence developed in its investigation, a safety or security rule violation has occurred. The PNOV includes the following elements, as a minimum:

- A concise, clear statement of the requirement(s) that was violated (legal citation for the violation).
- A brief statement of the circumstances of the violation, including the date(s) of the violation and the facts to demonstrate that the requirement was not met (e.g., “contrary to” paragraph).
- The severity level proposed for the violation or problem area (if violations are classified in the aggregate—see below).
- The civil penalty proposed for each violation or group of violations, as applicable. For a Part 851 violation, a monetary penalty against a contract performance award is an option.

The “contrary to” paragraph should clearly demonstrate how the DOE requirement was not met. It should specifically refer to evidentiary material, such as the specific standard procedure or specification that proves the violation. The PNOV also informs the contractor of the required response to DOE.

A group of violations that are related to the same requirement or a single event may be evaluated in the aggregate. A group of aggregated violations is designated a violation at the appropriate severity level warranted by the facts and circumstances of the specific case. By addressing a group of violations that

individually may have minor safety or security significance, the PNOV can highlight the more significant condition or underlying programmatic problem. Thus, when aggregated in this manner, violations may have a higher severity level than the individual violations. In addition, the circumstances involving an event and a series of corresponding violations may not warrant citing each of the violations individually, so the violations may be aggregated to mitigate the associated civil penalties.

The Director and Office of Enforcement staff prepare the draft of the PNOV and conduct any other required internal discussions within DOE before arriving at a position on the required action. The draft PNOV, transmittal letter, and the conference summary are provided to Field and Program Office personnel via the DOE enforcement coordinators for review and comment. For NNSA facilities, the proposed action is forwarded with a transmittal memorandum summarizing the basis for the recommended action to the NNSA Administrator for signature.

PNOV Transmittal Letter

The cover letter transmitting the PNOV to the contractor includes sufficient factual information, described in “executive summary” format, to permit contractor management to understand DOE’s safety, security, and management concerns; how DOE determined the proposed sanctions; and where DOE concludes that the contractor should focus attention to improve performance. The letter is specific enough that the contractor can clearly understand how the DOE enforcement staff applied the enforcement policy, and it clearly identifies contractor actions that reflect good performance and areas that require additional attention. The letter includes the following elements, as appropriate:

- When and where the inspection, investigation, or assessment was conducted.
- Who identified the violation(s), i.e., the contractor, DOE, or other external source.
- Whether and how the violation was reported.
- When and where an enforcement conference was conducted, and reference to any conference report.
- A summary of the violations, severity level, and any other major attributes of the violations that are related to their safety and security significance.
- Any factors that affected the escalation or decrease of the action, such as repetitive nature of the event, extended duration of violations, management deficiencies, or willfulness.
- Discussion of application of mitigation factors.
- Identification of resulting proposed civil (or monetary) penalty.
- The necessary contractor response (see “Contractor Response to PNOV,” below).
- A statement that DOE will determine what, if any, further enforcement action is required after review of the contractor's response to the PNOV, proposed corrective action, and results of future assessments.

Contractor Response to PNOV

The contractor is required to respond to a PNOV either by accepting its conclusions or by presenting new, previously unconsidered evidence that could lead to a different outcome. The PNOV transmittal letter typically informs the contractor of

options to: 1) admit or deny the alleged violations, (2) identify any facts that are asserted to be incorrect, and (3) provide the reasons for the violations if admitted, or if denied, the basis for the denial. The contractor is also asked to delineate in the NTS or ITAC, with target and completion dates, the corrective actions that have been or will be taken to avoid further violations.

The contractor's response is due within 30 days of the PNOV's date of issuance. The Director, Office of Enforcement staff, and responsible Field and Program Office personnel carefully review the contractor's response. If additional information is provided, the Office of Enforcement will consider whether the action should be modified.

If the contractor admits that the violation(s) occurred as described in the PNOV and pays the civil penalty (in a case involving a civil penalty), the Office of Enforcement sends the contractor a letter that acknowledges receipt of the monetary penalty (for a case with a civil penalty) and deem the PNOV to be a final order. Acknowledgment letters are generally issued within 30 days after receipt of the contractor's response to the PNOV.

The contractor has the option to challenge DOE's facts, the determination of violations, DOE's conclusions on significance or severity level, application of mitigation factors, or other elements regarding the PNOV. Following a review, the Director may conclude that it is appropriate to move to an FNOV.

Final Notice of Violation

As noted above, if the contractor admits the violation(s) as presented in the PNOV and pays any associated civil penalty, the

PNOV automatically becomes a final order, thus eliminating the need for an FNOV.

If the contractor challenges any aspect of the PNOV, the challenge is carefully reviewed by the Office of Enforcement in conjunction with DOE Field and Program Office management. On evaluation of contractor responses and all other relevant evidence, the Director may take one of the following actions, as deemed appropriate:

- Rescind all, or part, of the proposed civil (or monetary) penalty.
- Rescind all, or part, of the PNOV.
- Issue the FNOV and impose a civil (or monetary) penalty, as authorized by law, in cases where the PNOV is not fully rescinded.

The FNOV generally follows the same format and content as the PNOV, but is updated based on any new information to reflect DOE's final conclusions on the matter. The Director is authorized to issue FNOVs for non-NNSA facilities, and the Administrator, NNSA, for NNSA facilities.

A nuclear safety or classified information security FNOV without a civil penalty becomes a final order 15 days after service, unless it is modified by an order from the Secretary of Energy. All worker safety FNOVs, nuclear safety, and classified information security FNOVs with a civil penalty, become final orders if the contractor does not contest the FNOV within 30 days, pays any civil penalty, and complies with the other requirements set forth in the FNOV.

Processes for appealing an FNOV are established in Part 820,

subpart B, for nuclear safety FNOVs with a civil penalty, Part 851.44 for worker safety FNOVs, and Part 824.8 for classified information security FNOVs. In brief:

- For nuclear safety FNOVs with a civil penalty, the contractor may request an on-the-record adjudication. Alternatively, an appeal action can be commenced in Federal District Court.
- For worker safety FNOVs, the contractor may appeal within 30 days to the DOE Office of Hearings and Appeals, following the process in 10 CFR Part 1003, subpart G.
- For classified information security FNOVs, the contractor may request hearing concerning the allegations contained in the notice within 30 days of receipt of the final notice of violation as described in 10 CFR Part 824.8(a) and 8(b)(1) and (2). Alternatively, an appeal action can be commenced in Federal District Court.

The appeal processes set forth in these regulations are not discussed further in this document. The Office of Enforcement's processes are designed to ensure the completeness of the information provided by the investigation team, the accuracy of documentation referenced, and the correctness of the violations cited. Contractors have substantial opportunity to provide input during the process and feedback on factual accuracy. Accordingly, the need for a contractor appeal is rare.

Severity Level

The Office of Enforcement reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level best suited to the significance of the particular violation. In some cases, special

circumstances may warrant an adjustment to the severity level categorization.

Chapter VI provides guidance on determining safety and security significance, including other factors that affect significance. Guidance on the classification of safety and security violations is provided in DOE's enforcement policies as follows:

- For nuclear safety violations, section VI of the *General Statement of Enforcement Policy*, appendix A to Part 820. Violations are categorized as severity level I, II, or III.
- For worker safety violations, section VI of the *General Statement of Enforcement Policy*, appendix B to Part 851. Violations are categorized as severity level I or II.
- For classified information security violations, section V of the *General Statement of Enforcement Policy*, appendix A to Part 824. Violations are categorized as severity level I, II, or III.

DOE reviewers use these definitions as a starting point for determining a recommended severity level. In considering the severity level, reviewers consider both the actual and potential consequence (safety or security significance) of the violations, and the severity level may be adjusted up or down by DOE, based on the circumstances of the particular violation. The following sections summarize the Office of Enforcement's general approach to some common factors that affect adjustment of severity level.

Aggregation of Violations

When several violations are evaluated in the aggregate,

indicating a broader underlying problem, the underlying problem is generally assigned a higher severity level than that which the individual examples may have deserved. The resulting categorization may be referred to as a "Severity Level (specify problem)" rather than a "Severity Level (specify violation."

Severity Level Escalation

DOE's enforcement policy establishes specific considerations that may raise the severity level of a violation even in the absence of a significant radiological or national security risk. These include:

- The position, training, and level of the individual involved in the violation. Management involvement is generally dealt with more severely by DOE, particularly if senior management is involved.
- Prior notice of the problem. If such notice was clearly given—whether internal, such as an internal assessment, or external, such as by DOE—failure to adequately correct the problem results in a more significant action.
- Duration of a violation. If the matter existed for some time and was clearly identifiable through assessment activities, tests, inspections, or direct observation by workers or management in the course of conducting work activities or facility surveys, the Office of Enforcement generally classifies the condition at a higher level.
- Past performance of the DOE contractor in the particular activity area involved.
- Multiple or recurrent examples of a violation.

The Office of Enforcement considers these aspects of each case and addresses them appropriately in its investigation report. Additionally, these areas of concern are emphasized in the enforcement action transmittal letter.

For worker safety violations, these factors are not used to determine severity level. However, they may be considered as adjustments to the base civil (or monetary) penalty.

Civil Penalty Factors not Affecting Severity Level

DOE's enforcement policies establish various factors to be considered that may affect mitigation or escalation of the civil penalty. These factors are not generally considered in determining the severity level (to avoid a "double hit" for those factors). Such factors include adequacy of identification of the violation, reporting, causal analysis, and corrective actions. See the "Adjustment of Base Civil Penalty" section, below, for additional information.

Low Significance Violations

DOE's enforcement policies provide that NOV's need not be issued for noncompliance items that represent minor variances from safety or classified information security requirements. Part 851, appendix B, section VI, refers to such conditions as "de minimis violations." Part 824 discusses that a NOV may not be required if the matter does not appear to be of a recurring nature, pose an extreme impact on national security, or have a potential to lead to a more serious national security impact. This discretion is intended to allow DOE to focus its enforcement activities on matters that have greater actual or potential significant impact on worker and nuclear safety and the security of classified

information. However, noncompliances that do not result in an NOV should still receive appropriate contractor attention to ensure that they are adequately corrected, and they should be properly tracked and evaluated to identify repetitive conditions or to assess generic or facility-specific problems.

For nuclear safety and classified information security noncompliances, severity level III violations should be reserved for cases where calling attention to less-significant conditions can be expected to stimulate the contractor to address those conditions before they result in a more significant condition. The Office of Enforcement may also use an enforcement letter to direct contractor attention to resolving such precursor conditions in both worker and nuclear safety and classified information security.

DOE may refrain from issuing a PNOV for severity level III violations if (A) the contractor identifies and reports a noncompliance condition in a timely manner, (B) DOE is satisfied with the causal analysis and corrective actions, and (C) the matter does not appear to be of a recurring nature.

Base Civil Penalty

The worker safety (Part 851, appendix B), nuclear safety (Part 820, appendix A), and classified information security (Part 824, appendix A) enforcement policies state that civil penalties are designed to emphasize the importance of compliance and to deter future violations, as well as to encourage early identification and reporting of violations, and their prompt correction. Furthermore, the overall outcome of the enforcement action developed by the Office of Enforcement, including the magnitude of the civil penalty, generally takes into account the

gravity, circumstances, and extent of the conditions surrounding the violation. As a result, the Office of Enforcement may either group related violations, or cite them separately, so that the resulting enforcement outcome is commensurate with the significance of the case.

Civil penalties are not typically proposed for nuclear safety or security severity level III violations, as described in the previous section. However, a civil penalty may be appropriate in some circumstances in order to emphasize the importance of adherence to DOE's nuclear safety and classified information security requirements, or when the violation(s) are similar to previous violations for which the contractor had not taken effective corrective action.

Once the Office of Enforcement has established the specific violation(s) that are to be cited (including any grouped violations) and their applicable severity level(s), the base civil penalty is established for each, using the tables in the DOE enforcement policies provided in Parts 820, 824, and 851.

Adjustment of Base Civil Penalty

After the appropriate base civil penalty is determined for a case, the civil penalty adjustment factors outlined in the enforcement policies are used to determine the civil monetary penalty that is to be assessed.

DOE provides substantial incentive for early self-identification and reporting of violations (up to 50 percent mitigation of the base civil monetary penalty). Substantial mitigation (up to an additional 50 percent mitigation) is also possible if corrective action is prompt and aggressive. Accordingly, DOE applies a number of factors in assessing each potential enforcement situation. In

determining whether an enforcement action will be mitigated, DOE considers, among other factors, the opportunity available to discover the violation, the ease of discovery, the promptness and completeness of the notification report to DOE, and the scope and promptness of the corrective actions.

Mitigation for Identification and Reporting

The base civil penalty may be reduced by up to 50 percent if the DOE contractor identified the violation and promptly reported the violation to DOE. In weighing this factor, consideration will be given to, among other things, whether the problem was disclosed through an event; whether prior opportunities existed to discover the violation, and if so, the age and number of such opportunities; prior knowledge of the violation; the extent to which proper contractor controls should have identified the violation; whether the violation was discovered through a contractor assessment activity or by an external body, such as DOE; and the promptness and completeness of any noncompliance report.

Timely self-identification means identifying a nuclear safety or a classified information security problem before it leads to an incident with undesirable consequences. The contractor's focus should be on performance assessment or other means and processes to identify such problems, rather than being forced to react to an event. Hence, if identification of a noncompliance is the result of contractor initiative or through a contractor's efforts to understand the broader implications of a particular noncompliance condition or incident, DOE would generally grant mitigation for self-identification, assuming that proper reporting occurred. However, where an event discloses the existence of a problem, and the underlying noncompliances are identified only as a consequence of routine review of the incident; DOE would

likely not consider mitigation for self-identification, even if eventually reported by the contractor. The enforcement policies refer to this situation as a “self-disclosing” event. DOE’s desire is for contractors’ initiative to identify such problems before they lead to events with actual or potential safety or security consequences, primarily through excellence in performance assessment programs.

Mitigation for Corrective Actions

DOE aims for prompt, comprehensive, and effective corrective actions for safety and classified information security violations. As noted, up to 50 percent of the base civil penalty may be mitigated if these factors are present. In applying this factor, the Office of Enforcement considers (depending on the circumstances) the timeliness of the actions, the contractor's initiative to take action, the rigor with which the contractor identifies the underlying cause(s), the adequacy of extent-of-condition reviews, whether this is a repetitive problem or occurrence for which prior corrective actions were ineffective, and the comprehensiveness of the corrective actions.

The Office of Enforcement considers the following circumstances or factors in applying its authority to provide mitigation and to provide positive incentives for desired contractor actions:

- The Office of Enforcement does not normally give credit for a contractor’s corrective actions if DOE intervention was needed to broaden the scope or increase the extent of the corrective action.
- Mitigation is also not appropriate merely because immediate remedial actions are taken to correct a condition; broader corrective actions to prevent recurrence must be evident.
- The corrective action effort must include adequate and timely causal determination, extent-of-condition review, and corrective action development. The Office of Enforcement’s guideline for judging timeliness in this area is that most investigations, causal analyses, and development of corrective actions should typically be completed within 45 days of identifying the noncompliance. (The Office of Enforcement also recognizes that some significant events with broad deficiencies may need longer than the recommended 45 days.) Contractor failures associated with timely and adequate analysis and corrective action development could lead to full or partial reduction in the allowed mitigation.
- The judgment on adequacy of corrective actions is based on whether the actions appear sufficiently comprehensive to correct the noncompliance and prevent recurrence. The Office of Enforcement solicits DOE Field and Program Office input on this judgment.
- Due to the time required to form a basis for a judgment on effectiveness and the need for a timely enforcement action, the Office of Enforcement may not have complete data on the effectiveness of corrective actions when making this judgment. However, if data is available, it will be factored into the judgment on corrective action mitigation.
- If the violation or event is found to have followed a precursor event that should have led to earlier recognition, or if there is a recurring problem, the Office of Enforcement does not normally provide full mitigation for corrective actions. These conditions indicate that prior corrective actions were not effective and were not timely. However, comprehensive action once the problem is finally recognized could be considered in partial mitigation, judging by the egregiousness

of the failure to previously correct the problem, its duration, the seriousness of the subsequent event, and the degree of DOE involvement in effecting the proper attention.

- Both DOE's worker safety, nuclear safety and classified information security enforcement policies permit an increase of the base civil penalty if corrective actions are substantially inappropriate. For example, if DOE must expend substantial effort to convince the contractor to take corrective action, or if the contractor's corrective action is considered untimely and inadequate due to the contractor's failure to fully recognize or understand the extent of the problem, the Office of Enforcement may consider escalating the civil penalty above the base amount.

Appendix F provides information on common breakdowns and weaknesses in the contractor investigation, causal analysis, and corrective action processes that the Office of Enforcement has observed. These should serve as lessons learned for contractors to consider as they assess and strive to improve their own processes.

Application of "Per-Day" Provisions

The PAAA and the 2003 Defense Authorization Act each authorize a statutory maximum civil penalty (\$110,000 for nuclear safety, \$70,000 for worker safety and \$100,000 for classified information security) per violation) per day. Thus, a noncompliance condition that exists for several days could result in an enforcement action with a base civil penalty substantially above the base per-day amount. The Office of Enforcement's policy is to generally use the base single-day amount as the starting point for most violations, and to consider multiples of that value by applying the per-day provisions only for the most

significant longstanding or recurring problems. Contractors have been on notice for some time that recurring violations will be dealt with severely in the enforcement process.

A per-day calculation of a civil penalty will normally be considered when the violation is significant enough that the single-day base civil penalty would not convey the seriousness of the violation or circumstances leading to the violations, particularly if the violations existed for more than a single day and there were substantial opportunities to identify them. Examples of substantial opportunity to identify the violation include the following: (A) management was aware of the violation and chose not to take appropriate action to remedy the problem, or (B) the violation existed for an extended period and the problem would have been identified through proper assessment or evaluation activities.

The Office of Enforcement determines the number of days appropriate for citation in such cases such that the resulting action is consistent with the seriousness of the violations and their resulting actual or potential consequence.

Multiple Separate Violations

The above section on "Severity Level" noted that the Office of Enforcement could aggregate individual violations into a single "problem" and cite that problem at a higher severity level. Additionally, the Office of Enforcement can separately cite multiple violations and impose civil penalties for each of the multiple violations in a citation. Each violation is subject to the statutory per-day limit. This means, for example, that a single event involving violations of worker safety, radiological protection, classified information security, and quality assurance

requirements could result in a PNOV individually citing these violations and imposing a civil penalty for each.

The significance of a particular occurrence and the circumstances of the violations may dictate that DOE identify the multiple violations involved and impose civil penalties for each to emphasize appropriately the significance of the violations and the attention that is required by the contractor to correct the conditions that led to the violations.

Exercise of Discretion

Because DOE wants to encourage and support contractors' initiative in prompt self-identification, reporting, and correction of problems, DOE's enforcement policies grant the Office of Enforcement broad discretionary authority to recognize positive steps by contractors. That discretionary authority can include electing not to pursue enforcement action, grouping violations to reduce the magnitude of the enforcement action, or mitigating a civil penalty. However, as discussed previously, enforcement discretion can also be used to escalate the magnitude of an enforcement action in appropriate circumstances

A decision to not pursue an enforcement action is generally based on meeting all of the following criteria:

- The contractor identifies the noncompliance prior to some self-disclosing event and promptly reports it into NTS, ITAC or the contractor's self-tracking system, consistent with reporting thresholds.
- The violation is not willful.
- It is not a repetitive violation that could reasonably be

expected to have been prevented by appropriate corrective actions for a previous violation.

- Upon discovery of the noncompliance, the contractor promptly takes, or begins to take, action to correct the condition.
- The contractor takes, or agrees to take, comprehensive corrective actions.
- The event is not a serious or potentially serious event.

When an enforcement action will be taken, the decision to aggregate violations in order to reduce the potential magnitude of the enforcement action generally results from (A) unusually positive actions by the contractor in identifying and correcting the violations, or (B) ongoing improvements that the contractor had already started but were not yet fully effective at the time the violations occurred.

Also, discretion may be applied for latent conditions or legacy issues discovered by a contractor and likely due to the actions or inaction of a prior contractor. Whether to apply discretion will depend on several factors, including: whether the current contractor should have identified the problem earlier through routine activities, such as surveillance, survey, or assessment activities; whether the current contractor should have identified the problem through a required inspection or baseline review; whether the current contractor should have identified the problem in its due-diligence reviews; or whether the current contractor was notified of the existing problem by DOE or the prior contractor. In any such cases, the current contractor must have taken prompt and appropriate action upon identification and properly reported the noncompliance condition to receive consideration for this application of discretion.

Ability of Contractor to Pay Civil Penalty

DOE's enforcement policies grant DOE discretion in adjusting civil penalties based on judgment of the contractor's ability to pay. Although the policies generally regard the safety and security significance of a violation as a primary consideration in assessing a civil penalty, the contractor's (including subcontractor's) ability to pay may be a secondary consideration. DOE enforcement actions are not intended to be so severe as to put the contractor into bankruptcy; contract termination, rather than civil penalties, is used to terminate contractor activities for DOE. However, the burden of proving inability to pay is on the contractor and must be conclusively demonstrated by a present financial condition—not a future condition. If it appears that the economic impact of a civil penalty might put a contractor into bankruptcy, or interfere with a contractor's ability to safely or securely conduct activities or correct the violation to bring its program into full regulatory compliance, or both, it could be appropriate to decrease the base civil penalty.

This discretion is expected to be used only rarely, and only when the contractor can clearly demonstrate economic hardship. The Director may also request assistance from other DOE offices to substantiate a mitigating financial condition.

Consent Order

Contractors are provided opportunities to seek settlement with DOE through a consent order for a matter involving safety noncompliances that could have proceeded to an investigation and possible enforcement actions for both nuclear and worker safety and health matters (reference Part 820.23 and Part 851.41, respectively). A consent order is a document,

signed by both the Director and a contractor, containing stipulations or conclusions of fact or law, and a remedy acceptable to both DOE and the contractor. Normally, there is no press release for a consent order.

Consistent with DOE policy that encourages settlement of enforcement proceedings at any time, the Director and the contractor can meet at any stage of the process and reach a settlement in the form of a consent order. The consent order identifies the facts related to specific safety requirements and the remedy that is agreed. It need not include a finding that a violation has in fact occurred, and the contractor is not necessarily required to admit that any such violation occurred.

When submitting a request to the Office of Enforcement for consideration of a consent order, the contractor must demonstrate a history of strong, proactive performance, coupled with an aggressive investigation of the subject issues and comprehensive corrective actions. The Office of Enforcement recognizes that a contractor with a positive safety record may have an occasional event or other noncompliance issue that would justify consideration of potential enforcement action; in evaluating a request for a consent order, the Office of Enforcement therefore considers the contractor's performance history over an extended period, about two years in most cases. The Office of Enforcement expects the contractor to demonstrate a consistent, proactive approach to the anticipation, comprehensive investigation, and resolution of nuclear safety, and worker safety and health issues, or to have a performance history that reflects a consistently improving trend in performance.

A contractor organization that cannot demonstrate consistent, proactive behavior should not expect favorable action on a request for a consent order, even if there has been recent aggressive action to deal with nuclear safety issues, or worker safety and health issues. Recent proactive behavior may justify discretion or mitigation consideration in a possible enforcement action but would not justify the use of a consent order, and contractors should be aware of this distinction. Part 820, appendix A, section IX and Part 851, appendix B, section IX describe how the Office of Enforcement may apply enforcement discretion or mitigation or both to recognize contractors' initiative in promptly identifying, reporting, and correcting nuclear safety and worker safety and health-related problems, including investigation efforts, cause analysis, and corrective action development and implementation.

It is in the contractor's best interest to submit its request for a consent order as early as possible, and not delay it until after the Office of Enforcement has notified the contractor via correspondence of its intention to launch a formal investigation. Consent order requests must be accompanied by supporting documentation (if not provided previously to the Office of Enforcement through informal means), including, but not limited to:

- Factual description of the event.
- The contractor's investigation and assessment of specific root causes.
- A summary of the contractor's enforcement history during the 24 months preceding the event.
- Evaluation of the contractor's NTS reporting activity for the preceding 24 months, if available (level of reporting, extent to

which issues are proactively identified through assessment rather than being disclosed through response to events, rigor of actions taken, results of effectiveness reviews).

- A listing of comprehensive corrective actions developed and implemented as a result of the findings set forth in the contractor's investigation, with objective evidence of completion.
- Performance indicator information used to monitor the effectiveness of nuclear and worker implementation.

In making the final determination, the Office of Enforcement reviews the scope, thoroughness, and quality of the contractor's investigation. The contractor must demonstrate that corrective actions are timely and appropriate in scope and content and, when fully implemented, will resolve nuclear safety or worker safety and health problems.

The Office of Enforcement also consults with and takes into account the views and recommendations of DOE and NNSA Headquarters line management personnel, as well as Field Element personnel who have responsibility for safe operation of the various facilities in question. The Office of Enforcement may also solicit input from colleagues elsewhere in DOE who have conducted oversight reviews at the sites and facilities of interest. Finally, the Office of Enforcement reviews other sources of information on contractor safety performance, which may include:

- Results of contractor program reviews.
- Consistency in NTS reporting.
- Relevant assessments performed by DOE Field Element or Headquarters organizations.

- ORPS reports.
- Nuclear safety and worker safety and health program indicators.

In choosing to issue a consent order, the Office of Enforcement exercises its enforcement discretion based upon the contractor's aggressive response to the event and its judgment that the contractor has generally demonstrated positive performance. After issuance, the Office of Enforcement continues to coordinate with the Field Element to monitor progress on the implementation of corrective actions, as appropriate, and the overall effectiveness of applied controls.

The use of a settlement agreement in the form of a consent order is often beneficial to both DOE and the contractor: it avoids a potential investigation by DOE and possible enforcement proceedings, including the potential issuance of an NOV with the imposition of a civil penalty, and the agreed monetary settlement normally assures that DOE will not pursue an enforcement action or civil penalty for any potential violations pertaining to the event. However, DOE may subsequently consider enforcement action if it later becomes known that any of the facts or information provided were false or inaccurate, or if commitments to take corrective actions are not met.

The Office of Enforcement encourages the application of this approach whenever appropriate. However, it is incumbent upon the Office of Enforcement to apply this tool in a consistent manner and to assure that, when it is applied, it is in the best interest of DOE to do so.

Compliance Order

The Secretary's authority to issue a compliance order is established for worker safety and for nuclear safety violations (Part 851.4 and Part 820, subpart C), and for classified information security violations (Part 824.4(b)). A compliance order is generally considered in circumstances where an immediate and serious safety or security problem exists, repeated efforts by DOE to assure completion of appropriate corrective actions by the contractor to resolve safety and security problems have failed, and a significant safety or security deficiency persists. In such a case, the Office of Enforcement, in consultation with Field and Program Office management, begins to prepare a compliance order, including briefing material for the Secretary. A compliance order may be signed only by the Secretary.

The compliance order generally identifies violations of nuclear safety regulations, worker safety and health regulations, or classified information security regulations, and describes the conditions or underlying problems that have not been adequately corrected, specific contractor actions that must be completed, the basis for the actions, and required dates for completion of those actions. Requirements in the compliance order are effective immediately, unless a different effective date is specified in the order. For worker safety violations, the contractor is required to post the compliance order in a prominent location at or near where the violation(s) occurred and the order must remain posted until the violation(s) is or are corrected.

Within 15 calendar days of the issuance of a compliance order, the recipient of the order may request the Secretary to rescind or modify it. A request does not stay the effectiveness of a

compliance order unless the Secretary issues an order to that effect.

Failure to comply with a compliance order could subject the recipient to further enforcement action, including applicable civil penalties.

In addition to the compliance order, DOE may also issue an enforcement action with corresponding citations for the violations that have occurred and impose appropriate civil penalties.

Administrative Matters

Docket File

Part 820.10 specifies the establishment of Office of the Docketing Clerk for nuclear safety matters, with responsibilities for maintaining docket files for each enforcement case, exemption decisions, and interpretations, as well as maintaining files of approved nuclear safety program plans. The Docketing Clerk is also assigned responsibilities for notification and filings associated with any adjudication proceeding. To implement these requirements and responsibilities, the Office of the Docketing Clerk has been established in the Office of Enforcement.

Part 851 (worker safety) or Part 824 (classified information security) does not establish any similar formal requirements for the Docketing Clerk. However, as a matter of practice, the Docketing Clerk performs similar functions for these matters. For each enforcement case involving worker safety and classified information security violations, the Docketing Clerk maintains a docket file. The Docket Clerk also maintains copies of approved

Safety and Health Plans and approved variances to Part 851 that are provided to the Office of Enforcement.

Assignment of Enforcement Action Number

The Office of the Docketing Clerk assigns an enforcement action (EA) number to each proposed enforcement action after the decision is made to issue a PNOV, as a way to administratively docket and track cases. EA numbers are assigned sequentially according to the year of issuance (e.g., EA 07-01, EA 07-02, etc.). Once an EA number has been assigned to an enforcement matter, all subsequent filings, memoranda, and correspondence for that case should include the case name and its complete EA number. Enforcement action numbers are also assigned for NOVs and compliance order cases.

Target Enforcement Process Schedule

The Office of Enforcement attempts to move as expeditiously as possible in each enforcement case, within the limits of staff availability and existing caseload. The following are guidelines that the Office of Enforcement will attempt to follow, recognizing that prior workload or the circumstances of a particular case may dictate changes from these targets. The Director has the discretion to decide case priority and the schedule to be followed for each case.

To allow for expeditious completion of an enforcement proceeding, the enforcement conference is usually scheduled within four weeks after completion and issuance of the Office of Enforcement investigation summary report. As a minimum, the Office of Enforcement gives the contractor at least two weeks' notice of the intent to conduct a conference.

Following an enforcement conference, the Office of Enforcement generally issues its decision, typically a PNOV, within four weeks. If issued, the FNOV is generally released within four weeks after receipt of a substantive response from the contractor, either denying the violation or seeking further mitigation of the severity level or civil penalty.

Press Release

Press releases are generally issued for PNOVs and are discretionary for other enforcement actions. After the enforcement action has been signed, the Director forwards the package to the contractor by e-mail to provide immediate notice of the action, and sends the official copy via certified mail. The Office of Enforcement generally prepares the draft press release and assists the DOE Office of Public Affairs in completing it. The contractor organization is normally given notice about two hours before a press release is issued and the enforcement action posted on the Office of Enforcement's web site.

Release of Pre-decisional Enforcement Information to the Contractor and the Public

Investigation-related information is confidential and considered pre-decisional. For example, during the investigation phase of a case, discussions within DOE on planned areas or issues to investigate, lines of inquiry, preliminary conclusions on potential violations, and preliminary conclusions on mitigation factors are confidential to the investigation team and are not released to the public or the contractor.

Additionally, following the enforcement conference, information

pertaining to any pending enforcement action is pre-decisional, and should be treated carefully. In consultation with appropriate DOE officials, the Director is responsible for all decisions regarding the release of pre-decisional information to contractors and to the public. Such information may include the potential violations to be cited, the potential severity level of the alleged violations, civil penalty amounts, and the nature or context of a PNOV.

The criteria listed below are followed by the Office of Enforcement and should similarly be followed by other DOE personnel who have access to enforcement-related information for input, validation, or action:

- No information is released to the contractor or the public on the findings or conclusions of an investigation immediately after the investigation.
- The investigation summary report documenting the findings and conclusions of the investigation is released to the contractor only after the Director's approval. The contractor is provided this report to ensure the accuracy of facts and the contractor's understanding of alleged violations and preparation for any subsequent enforcement conference. Because the investigation summary report is part of the ongoing investigation, it is considered pre-decisional and is not released to the public.
- No information on a pending enforcement action is released to the public or the contractor between the enforcement conference and the issuance of a PNOV, unless so authorized by the Director.
- Pre-decisional enforcement information is released to the contractor only when necessary to ensure that prompt

corrective actions are taken to address a safety or security matter that is not already being addressed.

- Upon issuance of a PNOV, the DOE transmittal letter and PNOV are placed in the Office of Enforcement docket file and on the Office of Enforcement web site. Only then is this information available to the general public.
- For nuclear safety matters, between the issuance of a PNOV and the issuance of a final order, all meetings or conferences between DOE and the contractor pertaining to the enforcement action are transcribed as required by Part 820.10(c).
- The enforcement case is not closed until all corrective actions have been completed. After that time, records pertaining to the final decision may be made available to the public.

Closing a Case

The Office of Enforcement does not close the enforcement case at the time when the contractor concedes the violation and pays any civil penalty. DOE keep the enforcement case open until it has confirmed through the NTS or ITAC/SSIMS that appropriate corrective actions have been completed. If corrective actions are not completed in a timely manner or if DOE Field Element personnel find that the corrective actions were not properly completed, the Office of Enforcement could decide to take further enforcement action, such as issuance of a subsequent PNOV.

VIII. Application of Enforcement to Special Conditions

General Enforcement Approach

Recurring/Repetitive Problems

Chapter IV noted that recurring or repetitive problems should lead to an NTS or ITAC report and that this condition factors into the Office of Enforcement's consideration of safety and security significance when reviewing NTS or ITAC reports or other initial identification of noncompliance conditions, and making decisions on cases to investigate. Chapter VII also identifies this condition as one that impacts the enforcement action outcome, usually causing the Office of Enforcement to apply less mitigation in the corrective action area, as well as often leading to a Quality Improvement citation for a nuclear safety violation.

A large percentage of the cases that the Office of Enforcement investigates involve recurring issues—i.e., problems identical or similar to those that led to a serious previous event or condition within the same organization, facility, or site. Recurring problems indicate that the organization's corrective action management processes are flawed, in that either the prior corrective actions were not effective in preventing recurrence, or the corrective actions were not maintained. In turn, this means that the causal analysis may be deficient, trending processes may not be sufficiently developed, extent-of-condition reviews may not be performed or effective, or performance assessment processes do not discover issues before they result in significant safety or security events. In general, senior management attention often focuses on safety or security only after a very serious event or an enforcement action. In the Institute of Nuclear Power Operations'

terms (one of that organization's eight principles that form the basis for an excellent safety culture), leaders have not sufficiently demonstrated (as opposed to talked about) a commitment to safety.

Insufficient management commitment to safety and security is unacceptable at this stage of maturity of the DOE complex, in that it demonstrates too little attention to finding and fixing precursor issues and appropriately responding to safety and security events. As a result, the Office of Enforcement has put the contractor community on notice that enforcement actions involving recurring issues will generally result in a significantly greater civil penalty than would otherwise have been the case—for example, greater use of DOE's "per day" authority, separate citation of violations rather than aggregation, escalation of the severity level of the violations, or a combination of these remedies depending upon the circumstances.

To illustrate the underlying problem area(s) that can contribute to a recurrence of problems, lessons-learned information is provided in two appendices to this *Overview*. The information in appendix F addresses contractor investigation, causal analysis, and corrective action deficiencies that have been observed by the Office of Enforcement. Appendix G addresses contractor assessment program deficiencies observed by the Office of Enforcement.

Contractor Transition

From time to time, DOE sites and facilities transfer management and operation responsibility to a different contractor, and appropriate planning and transition for compliance with DOE security and safety requirements is required. The process of

transition normally includes a period of review and due diligence on the part of the incoming contractor. DOE's expectation is that the outgoing contractor retains responsibility for compliance with DOE security and safety requirements during the period of its contract, up to and including the date of turnover to the incoming contractor. However, even after turnover, DOE could pursue an enforcement action against the outgoing contractor for any case of noncompliance that occurred during the contract period.

The incoming contractor organization is expected to assume full responsibility for safe and secure operation and compliance with DOE security and safety requirements on the date it assumes contract responsibility for the site or facility. During its due-diligence review, the incoming contractor normally identifies any significant individual or programmatic issues of noncompliance with DOE requirements; these are then addressed with the appropriate DOE Field and Program Office managements before transfer of responsibility for the site or facility. Additionally, after assuming responsibility, the incoming contractor should (A) report any noncompliance conditions identified during the due-diligence period that meet NTS reporting thresholds and ITAC reporting criteria, and (B) assume, from the outgoing contractor, responsibility for completing or assuring completion of corrective actions and problem resolution that were ongoing at the time of turnover.

The Office of Enforcement may exercise reasonable discretion in considering a noncompliance issue that surfaces soon after the incoming contractor assumes responsibility and that could not have reasonably been identified during the due-diligence period. The Office of Enforcement generally does not pursue enforcement action during this early, near-term period if the contractor, upon identifying the condition, reports the

noncompliance to the NTS, ITAC or its internal tracking system (as appropriate) and responds with timely and effective corrective actions. However, for serious events or accidents, such as serious worker injury, compromise/potential compromise of classified information having a significant impact on national security or substantial actual or potential radiological uptake or exposure, the Office of Enforcement does not normally refrain from action, regardless of timing.

Accuracy of Information/Willful Violation

DOE relies on the accuracy and completeness of information provided by its contractors. Part 820.11, *Information Requirements*, requires that any information pertaining to a nuclear activity, provided to or maintained for DOE by a contractor, shall be complete and accurate in all material respects. Similarly, Part 824, Appendix A (Paragraph V.f.) and Part 851.40(b) requires contractors to provide complete and accurate records and documentation to the Office of Enforcement in support of investigation activities. Failure to comply with these requirements could involve either intentional or unintentional conditions. Unintentional errors in safety or security documents and records are undesirable; they should be considered noncompliances with the above referenced regulations and should be reviewed for possible reporting into the NTS or ITAC. Intentional errors, such as falsification, destruction, or concealment of records or information, should be treated as a willful violation and addressed as discussed below.

Willful noncompliance with a nuclear or worker safety or classified information security requirements receives close attention by the Office of Enforcement. As noted in chapter IV, such a noncompliance should be reported into NTS or ITAC. Chapter IV

also describes certain attributes that the Office of Enforcement looks for in considering whether a condition is a willful noncompliance and notes that the Office of Enforcement may consider such a condition to be more significant than the significance of the corresponding noncompliance itself. A willful violation is considered significant *per se*, regardless of the issue to which it pertains.

Department of Justice Referral

Parts 820 and Department security policies state DOE may refer a nuclear safety matter or a security event to Department of Justice (DOJ) if DOE believes a criminal action has occurred. Although not specified in Part 851 for worker safety issues, the Office of Enforcement, as a matter of practice, follows the Part 820 approach for worker safety matters that are believed to involve a potential criminal action. As a general policy, if a matter has been referred to DOJ, any DOE enforcement action would be held in abeyance, unless immediate action is needed for health, safety or national security reasons. The purpose of postponing DOE action is to avoid potential compromise of or conflict with the DOJ case, pending DOJ's concurrence that the enforcement action will not affect any potential prosecution. The Director is responsible for coordinating enforcement matters with DOJ.

If DOJ determines that a referred case lacks prosecutorial merit, it notifies DOE by a letter of declination. On receiving this letter, the Director determines whether to initiate an enforcement action, which would then follow the same process described in this document.

Executive Order 12958 and the Atomic Energy Act establish government policy for the protection of classified information.

Both documents require adherence to Federal laws applicable to the protection of this information. In section 4.2(f) of Executive Order 12958, each Federal agency is required to establish controls ensuring the adequate protection and prevention of unauthorized access to classified information. In section 5.7, the Executive Order states that each officer and employee of the U.S. Government, including contractors, shall be subject to sanctions in accordance with applicable laws for violation of the provisions of this Order. In the Atomic Energy Act, alleged or suspected criminal violations of the Act require an investigation by the Federal Bureau of Investigation (FBI).

Executive Order 12333, section 1-7(a), requires senior officials of the Intelligence Community to: "Report to the Attorney General possible violations of federal criminal laws by employees and of specified federal criminal laws by any other person as provided in procedures agreed upon by the Attorney General and the head of the department or agency concerned, in a manner consistent with the protection of intelligence sources and methods, as specified in those procedures."⁶

The National Industrial Security Program⁷ mandates the establishment of procedures to ensure that cleared employees are aware of their responsibilities for reporting pertinent information to appropriate authorities, including, but not limited to the "Federal Bureau of Investigation or other Federal authorities as required by the NISP Operating Manual, the terms of a classified contract, and U.S. law."

⁶ Memorandum, Johnson/IG-1, DP-1, and IA-1, dated April 29, 1982, subject: "Procedures for Reporting and Use of Information Concerning Federal Crimes."

⁷ Chapter I, Section 3, Reporting Requirements.

The Department has developed policy necessary to ensure the timely and accurate referral of information pertaining to the actual or suspected compromise of classified information to the appropriate agencies. This policy is designed to ensure the Department's compliance with these national directives and is contained in DOE Manual 470.4-4, *Information Security*.

Suppliers and Subcontractors

An NOV may be issued to a subcontractor or supplier who fails to comply with DOE safety or security requirements. For nuclear safety issues, enforcement regarding any subcontractor or supplier to a Price-Anderson indemnified DOE contractor is addressed in the enforcement policy, appendix A of Part 820. Nuclear safety rules Parts 820, 830, 835, and 708 apply directly to these indemnified subcontractors and suppliers. Noncompliances with such requirements are subject to the same enforcement process described in this chapter as well as chapter VII.

In the worker safety and classified information security areas, Parts 851 and 824 applies directly to DOE contractors as well as to their subcontractors that have responsibilities for performing work at a DOE site in furtherance of a DOE mission, subject to certain exclusions. DOE may issue an enforcement action to a contractor or subcontractor for violation of a Part 851 or Part 824 requirement. Part 851 permits the imposition of a civil or monetary penalty for an indemnified contractor, including any associated subcontractor, with certain limitations as specified in the rule. However, Part 824 permits imposition of both civil and monetary penalty.

In general, DOE holds its prime contractors primarily responsible

for safety and security at their respective sites of employment and may issue an NOV to the prime contractor for any violation by its subcontractor when an enforcement action is determined appropriate. However, depending upon the circumstances, an enforcement action may also be taken against the subcontractor, either alone or in addition to that taken against the prime.

Management and Independent Assessment Programs

Over the past few years, the Office of Enforcement has stressed the importance of contractor assessment programs as an effective tool in proactively identifying conditions adverse to quality before those deficiencies manifest themselves in significant safety and security events.

The Director has emphasized the importance of shifting from an event-driven to an assessment-driven culture and, accordingly, has established a goal of having the great majority of all NTS and ITAC reports being identified through contractor internal assessment activities by 2008. The term "assessment" is not meant to imply only those activities associated with formal management and independent assessments. Rather, the term is meant to include other self-identifying activities, such as audits, engineering reviews, surveillances, trend analyses, and even problems/event precursors that are identified by workers and supervisors during routine performance of their activities.

Distinguishing between "event-driven" and "assessment-driven" NTS and ITAC reports may involve some level of subjectivity, and many issues in contractors' internal tracking systems are uncovered by assessment activities. The mere fact that a self-disclosing event not explicitly meeting NTS or ITAC reporting thresholds or criteria is reported, due to a management concern,

does not imply self-identification through assessment. The important objective is to reduce the number of events and significant near misses by improving performance assessment processes.

The Office of Enforcement generally pursues investigation and enforcement action for events that disclose underlying safety, classified information security and management issues. These are almost always issues that could have been identified through an effective assessment process. However, many contractor assessment processes are known to have been deficient because they failed to find problems before disclosure by an adverse event. Appendix G describes some of the common assessment program deficiencies noted by the Office of Enforcement and summarizes the Office's approach to reviewing assessment programs. The Office of Enforcement's enforcement actions regularly cite assessment program deficiencies that contributed to the event under investigation. For this reason, the Office of Enforcement encourages the DOE community to review and use the performance assessment guide prepared by the EFCOG PAAA Working Group as a starting point in improving their assessment processes. The guide is available on the EFCOG web site.

DOE Contractor Employee Protection Program

The DOE Contractor Employee Protection Program, established in Part 708, applies to complaints of reprisals or retaliation against DOE contractor employees for certain conditions (protected activities), including employee disclosures, participations, or refusals related to various matters involving nuclear safety and/or worker safety, health issues. Specifically, Part 708 provides employees with a process to file a complaint

concerning retaliation and to obtain restitution from the contractor in the event of a finding of reprisal under the rule.

In the Federal Register notice adopting Part 708, Part 708 was designated a nuclear safety rule enforceable under the PAAA. Additionally, Part 708 states that insofar as an act of retaliation by a DOE contractor results from an employee's involvement in matters of nuclear safety in connection with a DOE nuclear activity, the retaliation could constitute a violation of a DOE nuclear safety requirement and could warrant relief to the employee under Part 708 and the imposition of civil penalties on the DOE contractor under Part 820.

The *Worker Safety and Health Program* final rule, Part 851, contains, in section 851.20, specific worker safety and health rights that parallel the employee-protected activities of Part 708. Acts of retaliation involving worker safety issues could warrant relief to the employee similar to that described above for Part 708, as well as the imposition of civil or contract penalties on the DOE contractor under Part 851.

Based on these rules, the Office of Enforcement has the authority to issue civil penalties against the company responsible for retaliation associated with protected activities involving either nuclear or worker safety and health matters. The Office of Enforcement conducts these activities for the purpose of issuing NOVs and civil penalties to DOE contractor entities in an effort to prevent acts of retaliation and to address violations of DOE nuclear and worker safety rules as discussed above.

It is important to note that the process for reviewing complaints and authorizing remedies to the individual complainant does not reside with the Office of Enforcement, as discussed in more detail

below. Employees subjected to and seeking appropriate resolution of a potential act of retaliation need to follow the process described in Part 708. No activities conducted by the Office of Enforcement can be viewed as a substitute for following Part 708 procedures.

The procedures for implementing Part 708 provide an individual with multiple options for pursuing a remedy for retaliation. Generally, such matters can be heard either by the DOE's Office of Hearings and Appeals (OHA) or by the U.S. Department of Labor (DOL). There are procedural and other reasons for selecting an appropriate forum for the matter, and that choice will not in any way affect the manner in which the Office of Enforcement addresses the issue. In general, and in an effort to conserve limited governmental resources, the Office of Enforcement's practice is to delay acting on a retaliation matter against a DOE contractor until OHA or DOL has completed its process, i.e., investigation, hearing, initial decision, and final agency decision. Although the Office of Enforcement has deferred a matter in one case (Safety and Ecology Corporation enforcement action, June 2005) until after it was dismissed on appeal by a U.S. District Court, that deferral has been judged too lengthy and generally not appropriate. Deferrals are to be used to avoid duplication of government investigation and adjudicatory efforts in pursuit of an appropriate remedy. It is clear that, barring unforeseen circumstances, the record is generally complete when an agency issues a final order. Therefore, even if the matter will be appealed, the Office of Enforcement intends to commence its enforcement activities at that point.

It is also important to note that although the Office of Enforcement defers that start of enforcement activities as they relate to an act of retaliation (as described in the preceding

paragraph), the Office of Enforcement does not defer actions to address any associated substantive nuclear or worker safety issue that represents a noncompliance, consistent with normal Office of Enforcement processes as described in this document. Such a noncompliance could lead to an Office of Enforcement investigation and an enforcement action solely intended to address the nuclear or worker safety rule violation well before the Office issues an action related to the act of retaliation. The Office of Enforcement considers many factors associated with retaliation cases when exercising enforcement discretion. These factors include the magnitude of the retaliation, the management level associated with the retaliation, the DOE contractor's response after the retaliation with respect to its work force, and the overall record of the contractor with respect to nuclear safety. The contractor's positive performance would probably not lead the Office to take no action on the retaliation, but could impact whether and how mitigation would be considered. Similarly, negative performance on the part of the contractor could be a factor in considering enforcement escalation. Another consideration is whether the retaliation resulted from the employee reporting his/her concerns to DOE or to another government agency. The ultimate decision whether to take enforcement action on a claim of retaliation does not in any way depend on whether the underlying nuclear or worker safety concern proves to be valid. In other words, the act of retaliation is itself a safety concern, because of the chilling effect it has on employees' willingness to speak up about safety issues.

Two cases of record involving such potential retaliation are posted on the Office of Enforcement web site. As described in an enforcement letter of April 19, 2005, an employee at the Savannah River Site was dismissed and maintained that retaliation was a factor in the decision. After an analysis and

report by a contractor team, the employee was rehired and provided with an equivalent position. An enforcement letter was issued to express DOE's concern regarding this matter.

In EA 2005-03, dated June 14, 2005, Safety and Ecology Corporation (SEC) was issued an NOV for retaliating against an employee by terminating employment. Although the former employee prevailed on the facts before both a hearing examiner and the head of OHA, the company took the matter to U.S. District Court, where a Motion for Summary Judgment filed by the government was granted. In addition to the reinstatement, back pay, and SEC's attorneys' fees, SEC was issued a civil penalty as a result of the Office of Enforcement's enforcement proceeding. SEC incurred further expenses in the matter, because under the Major Fraud Act, it was responsible for segregating non-compensable costs associated with all proceedings.

Nuclear Safety and Worker Safety and Health Noncompliances

Over the past several years, the Office of Enforcement has noted a number of cases that involved both nuclear safety and worker safety issues. Such cases include, for example, a fire or explosion that affected or may have affected radiological materials and worker safety, violation of lock-out/tag-out requirements affecting nuclear safety systems and the potential for an electrical shock, or a series of both nuclear and worker safety events that demonstrated a programmatic problem in work planning or execution. Since the worker safety and health rule had not yet been issued at the time, the enforcement actions focused on and cited only the related nuclear safety violations.

Cases with implications in both nuclear and worker safety areas will continue to surface. With the issuance of Part 851 in February 2006, if such a case occurs, the Office of Enforcement will generally conduct an integrated investigation that reviews the facts, circumstances, and noncompliances both areas.

Additionally, if the Office of Enforcement pursues enforcement action for noncompliances in both areas, it would generally be a combined action that cites both nuclear and worker safety violations. Such actions will be coordinated so that the same violation, as well as any associated civil penalty, is not cited twice in both the worker safety and nuclear safety areas. On the other hand, a single event or occurrence might have certain noncompliances in the worker safety area and certain other noncompliances in the nuclear safety area. Coordinating reviews and enforcement proceedings for both areas ensures proper consideration of the diverse noncompliances that may have occurred.

Enforcement Approach for Selected Worker Safety Issues

Pending Part 851 Variance Requests

The Office of Enforcement anticipates that certain contractors may not have pending variances approved by the required Part 851 compliance date of May 25, 2007, due to limited DOE resources and time available for variance review and approval. The Office of Enforcement may apply enforcement discretion when a violation involves a regulatory provision of 10 CFR Part 851 for which the contractor has a pending variance request. This process is similar to the Office of Enforcement's approach to the backlog of pending contractor exemptions during the early stages of 10 CFR 835 implementation.

As noted earlier in this document, the intent of the enforcement process is to promote and protect the safety and health of workers at DOE facilities. The Office of Enforcement has substantial authority to exercise discretion in applying enforcement mechanisms.

DOE acknowledges that some contractors have submitted requests for variances accordance with the requirements of Part 851, subpart D, and are awaiting final action from the Department. These contractors may therefore find themselves in a condition of noncompliance on the required compliance date of May 25, 2007. If the identified contractors have taken action in good faith and have implemented any necessary interim protective measures or compensatory actions to provide for adequate worker protection, using the Department's enforcement authority in such cases would not advance the Department's goals as stated in appendix B of Part 851. In these narrow cases, the Office of Enforcement does not intend to take enforcement action.

This policy does not apply to variance requests submitted after May 25, 2007. The Office of Enforcement's exercise of such discretion depends upon a good faith, timely submission by the contractor that completely addresses the requirements of Part 851.

Multiple Employer Worksite

Many DOE sites have multiple contractors and subcontractors performing work at the same workplace, which can make managing worker safety and health more challenging. Subparts B and C of Part 851 contain comprehensive requirements that each contractor must follow to protect its

employees. However, given the complexity of working with other contractors and subcontractors on site, coordination of work planning and execution to ensure worker safety and health must be given special consideration.

When investigating a matter involving risk to workers from multiple contractors, the Office of Enforcement determines the full extent of responsibility among those contractors for exposing employees to hazards. In such cases, the Office of Enforcement's investigation will focus on determining which contractor(s): A) created the hazard; B) had responsibility for correcting and controlling the hazard; and C) exposed the employees to the hazard.

To establish the extent of contractor responsibility, the Office of Enforcement reviews available records and procedures that describe roles and responsibilities, determines whether responsible employees have received appropriate training, and ascertains the actual practices and conditions in the workplace. The Office of Enforcement may cite any contractor found responsible, whether or not the contractor's own employees were exposed to the hazard in question.

If an enforcement action is taken, the Office of Enforcement also considers both mitigating and aggravating circumstances for each contractor involved, in accordance with the enforcement process described in this document. At a minimum, DOE would expect a contractor whose workers are exposed to a hazard to promptly correct the hazard (if it has the authority to do so) or to remove its workers from the exposure in a timely manner, adequately protect its employees, and promptly notify the responsible contractor to correct the hazard.

General Duty Clause

DOE will take enforcement action against a contractor who fails to provide a place of employment that is free from recognized hazards that are causing, or have the potential to cause, death or serious physical harm to workers, in accordance with Part 851.10(a). The intent of Part 851.10(a) is to parallel the requirements set forth in OSHA's general duty clause, section 5(a)(1) of the Williams-Steiger Occupational Safety and Health Act of 1970 (29 USC 654).

DOE contractors have a clear obligation to protect workers from death and serious physical harm resulting from recognized workplace hazards, even where:

- There is no existing standard that covers the hazard.
- There is doubt whether a particular standard applies to the hazard.
- A particular safety and health standard is inadequate to protect the contractor's workers against the specific hazard that the standard addresses, and the contractor is aware of the inadequacy.

In such situations, contractors must take whatever abatement actions are feasible to eliminate such hazards. If all four of the following questions can be answered in the affirmative, a contractor will be considered to be in noncompliance with Part 851.10(a) and may be subject to appropriate enforcement action and penalties:

1. *Are workers being exposed to a hazard?* This means that the hazard exists, workers are exposed to the hazard, and the

contractor has failed to remove the hazard. A hazard is defined as a "danger which threatens physical harm to employees." The contractor is not expected to follow any pre-defined abatement method, step, or precaution but to use any and all feasible means to protect employees from the hazard.

It is also important to attempt to identify, as early as possible, any general workplace hazards that could lead to a condition that creates another hazard or may result in an event. An undetected hazard may become apparent after the occurrence of an event, especially if it results in an injury or fatality. Contractors must be constantly vigilant to detect and correct any existing hazard, as well as any new hazard—for example, those that may result from a change in a process or work practice, or from the use of new or additional equipment.

2. *Is the hazard a recognized hazard?* This means that the contractor knew or should have known about the hazard in the situation, the hazard is obvious, or the hazard is recognized within the contractor's industry (i.e., it is identified and addressed in a recognized industry consensus standard, or other credible industry guidance or documentation). Using a work practice that is contrary to an accepted industry practice or standard, or contrary to a supplier's standard for use, or that safety experts in the industry acknowledge creates a particular hazard, indicates that the employer should have known about the hazard.

A contractor's recognition of a hazard is also evidenced by the contractor documenting or reporting any injury related to the hazard, as well as by workers calling the contractor's attention to the hazard. Any written or oral statements made by the contractor or a supervisor that relates to the hazard also establishes knowledge of the hazard.

If the hazard is unrecognized within the industry, DOE would still hold a contractor responsible for recognizing and correcting the hazard if DOE concludes that the hazard should have been recognized by a reasonable person.

3. *Is the hazard causing, or does it have the potential to cause, death or serious physical harm?* The hazard must be classified as Severity Level I or “serious,” meaning that there is a potential for serious injury, illness, or death if the hazard is not eliminated or controlled. This can include any potential acute or chronic impairment of the body that affects life functioning on or off the job (usually requiring treatment by a medical doctor), whether temporary or permanent. Alternatively, it could be an illness that significantly reduces physical or mental efficiency, e.g., occupational asthma.
4. *Do feasible and useful methods exist to correct the hazard?* The hazard must be correctable, i.e., there is a feasible and known way for the employer to correct, eliminate, or at least significantly reduce the hazard, either by applying an appropriate control or having workers use adequate personal protective equipment.

Employee Misconduct

Employee misconduct is a condition where the contractor was not aware of the problem or the underlying behavior, the contractor can demonstrate that other similar problems or behavior had not occurred, and the misconduct was a direct violation of an adequate work control that had been effectively implemented and was otherwise uniformly met.

Such a condition, if established by the contractor, would excuse the contractor from citation for a violation of a worker safety and

health requirement. This approach parallels a similar defense identified by OSHA. Other factors may also provide a basis for the Office of Enforcement to exercise discretion in not pursuing an enforcement action, not pursuing issuance of a civil penalty, or applying mitigation in an enforcement action. These other factors are addressed elsewhere in this document.

Coordinating Application of Civil Penalty and Contract Fee Reduction

10 CFR Part 851.5 states that contractors indemnified under the Atomic Energy Act (AEA) are subject to either civil or contract penalties, but not both. In addition, Part 851.1 states that only contract penalties can be levied against non-indemnified contractors since they are not subject to civil penalties. Most of DOE’s contractors are indemnified under section 170d of the Atomic Energy Act. Those that are not indemnified under section 170d are handled under the contract remedy provisions of the Rule. The preamble to Part 851 (see pages 6871 and 6876 of the *Federal Register*, vol. 71, no. 27, February 9, 2006) also states that for a worker safety violation, the Director will coordinate with the appropriate DOE Program Office and Field Element contract representatives on the type of monetary penalty (either contract or civil) and the amount to be assessed.

The current enforcement process includes a determination by the Director of the Office of Enforcement, in consultation with the appropriate Program Office and Field Element, that an enforcement action will be taken against a contractor and that a monetary penalty will be assessed. To ensure adequate consultation, the Office of Enforcement has built certain coordination steps into its enforcement process (see chapter VI, *Investigation Process*) to ensure that both DOE Program and

Field Element representatives' perspectives and views are considered throughout the entire enforcement process. The Office of Enforcement is actively working with DOE Program and Field Element representatives on revising its enforcement process to further address the added level of coordination needed to ensure effective implementation of both civil and contract penalties. Once completed, the updated process will be described in a revision to this program plan.

Applicability of Part 851 and “Work for Others”

Part 851 states that it applies to the conduct of contractor activities at DOE sites where a contractor is an entity under contract to DOE “that has responsibilities for performing work at a DOE site in furtherance of a DOE mission.” Often, DOE facilities, particularly in the science arena, are made available to representatives of various institutions, companies, and foreign organizations to conduct research studies and activities. Questions have been raised as to whether enforcement would apply to worker safety issues that involve such workers performing research for others using DOE facilities. DOE’s Office of General Counsel has developed guidance on application of Part 851 to work for others, as well as general guidance on the issues of who is a DOE contractor and what work is in furtherance of the DOE mission. That guidance is contained in a position paper on the following web site. This guidance may be revised from time to time.

www.hss.energy.gov/healthsafety/WSHP/rule851/851final.html

The Part 851 enforcement process that is outlined in this *Overview* applies to those contractors and that work where the Office of the General Counsel has determined that Part 851 is

applicable, as detailed in the above position paper.

Legacy Worker Safety Issues

It is expected that some pre-existing conditions at various DOE facilities may not be in compliance with Part 851 requirements, and the facility changes that would be needed to come into compliance may be impractical and expensive. Anticipated issues involve existing code of record that predates and differs from Part 851 requirements, previously granted equivalencies to Part 851 referenced standards, application of consensus standards, and other similar issues.

DOE’s Office of General Counsel has developed guidance on application of Part 851 to legacy issues such as code of record and reference standards. That guidance is contained in a position paper on the following website. This guidance may be revised from time to time.

www.hss.energy.gov/healthsafety/WSHP/rule851/851final.html

The Part 851 enforcement process that is outlined in this document applies to those contractors and that work where OGC has determined that Part 851 is applicable, as detailed in the above position paper.

Offsite Support for Emergencies

Part 851 applies to services provided under contract to DOE on a DOE site. In some cases, the Office of Enforcement may determine that it may apply to emergency response support. In any evaluation for potential enforcement, the following points will be of primary consideration:

- Whether the agreement for services is a contractual relationship and consequently falls within the scope of the rule.
- Where the activities took place. (Enforcement focus is limited to site activities only.)

Contractors are expected to conduct appropriate baseline needs assessments to ensure that 10 CFR 851 program requirements are addressed. Except for unusual or egregious deficiencies, the Office of Enforcement generally exercises discretion in evaluating noncompliances occurring during an emergency or event response involving offsite municipal fire-fighting or emergency response agencies, even when contractual relationships bring them under the scope of Part 851. Enforcement focus is normally directed toward the operating or management/integrating contractor in evaluating how well the program requirements are met. As in any potential enforcement situation, the Office of Enforcement will evaluate the situation based on its own specific merits.

Enforcement Approach for Selected Nuclear Safety Issues

Violation of Quality Assurance (QA) Requirements

As part of routine investigations and enforcement activities, the Office of Enforcement encounters situations in which DOE and

contractor organizations have incorrectly exempted activities from compliance with the QA requirements of 10 CFR Part 830, subpart A—for example, inappropriately limiting the application of subpart A to only one or more of the following:

- A limited set of facilities (hazard category 3 and above), or a limited set of equipment or operations as defined in or described within safety basis documents, or both.
- Work involving only a physical activity or the direct handling of radiological material, or both.
- Only when nuclear or radiological material is present in a facility.

In some cases, such issues have led to events and enforcement actions in which a key contributing cause was a failure to apply either adequate work control processes or QA controls consistent with the contractor's QA program and rule requirements. Appendix H provides guidance on the relevant subpart A requirements and the DOE General Counsel 95-1 interpretation as they relate to these applicability issues. Also provided is additional discussion of the three potential problem areas noted above, along with the Office of Enforcement's general enforcement approach.

Internal Dosimetry Program Issues

During the early implementation of Part 835, confusion regarding the internal dosimetry monitoring threshold contained in Part 835.402 (radiological workers "likely to receive" 100 millirem) led to questions related to enforcing this threshold, and the potential liabilities associated with implementing a discretionary monitoring program. Subsequently, in 1999, the Office of Enforcement issued guidance clarifying its approach to reviewing

such discretionary monitoring programs, the crediting of respiratory protection devices in estimated internal doses, and the relationship of monitoring thresholds to As Low As Reasonably Achievable (ALARA) programs and enforcement threshold values. Updated guidance on these issues is included in appendix E.

Discovery and Control of Legacy Contamination

Legacy radioactive contamination has been generally defined as radioactive contamination resulting from a historical operation that was unrelated to current activities. During the Office of Enforcement's early experience with legacy contamination issues, several contractors advanced the view that since the contamination was "legacy" and occurred during a previous contractor's activities, the discovery fell outside the scope of Part 835 and therefore did not represent a noncompliance. There was also a mistaken perception within the contractor community that as long as legacy contamination remained undiscovered, it could not be subject to an enforcement action. This latter perception was of particular concern to the Office of Enforcement, since it acted as a disincentive to implementing a proactive and effective survey program. Thus, the Office of Enforcement decided that enforcement discretion would be applied to a legacy contamination situation only if an effective survey program was already in place. See appendix J for further details.

Nuclear Weapons Program

The Office of Enforcement occasionally receives questions or concerns regarding the enforcement of Part 830, subpart A, associated with nuclear weapon programs. Additional enforcement guidance for this issue is provided in appendix I.

Appendix A - Reporting Nuclear Safety Noncompliances¹ into NTS (see chapter IV for use of these thresholds)

Table A-1 - Noncompliances Associated With Occurrences (DOE Manual 231.1-2)

Use the specific criteria in the DOE Manual for the reporting thresholds

Reporting Criteria Group	Subgroup	Occurrence Category and Summary Description ²
1. Operational Emergencies ³	N/A	(1) Operational Emergency (2) Alert (3) Site Area Emergency (4) General Emergency
2. Personnel Safety and Health	B. Fires/Explosions	(1) Unplanned fire/explosion
3. Nuclear Safety Basis	A. TSR Violations	(1) Violation of TSR/OSR Safety Limit (2) Violation of other TSR/OSR requirement (3) Violation of DSA hazard control
	B. DSA Inadequacies	(1) Positive USQ
	C. Nuclear Criticality Safety	(1) Loss of all valid criticality controls
4. Facility Status	A. Safety Structure/System/Component (SSC) Degradation	(1) SSC performance degradation ⁴
	B. Operations	(2) Actuation of Safety Class SSC (4) Facility Evacuation
5. Environmental	A. Releases	(1) Radionuclide release
6. Contamination/Radiation Control	A. Loss of Control of Radioactive Materials (RAM)	(1) Offsite RAM exceeding DOE limits (2) Loss of RAM (>100X 835 App. E)
	B. Spread of Radioactive Contamination	(1) Offsite radioactive contamination ⁵
	C. Radiation Exposure	(1) Exceedance of DOE dose limits (2) Unmonitored exposure (3) Single exposure > thresholds
	D. Personnel Contamination	(1) Offsite medical assistance (2) Offsite personnel/clothing contamination (3) Onsite personnel/clothing contamination ⁶
7. Nuclear Explosive Safety	N/A	(1) Damaged nuclear explosive (2) Introduction of electrical energy (3) Safety feature compromise

		(4) Inadvertent substitution (5) Violation of a safety rule (6) Damage to a training unit
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Table A-2

Management Issues Noncompliances⁷
Repetitive Noncompliances
Programmatic Issue
Intentional Violation or Misrepresentation

Notes to Tables

1. Reporting noncompliances with any of the nuclear safety rules or other nuclear safety requirements.
2. These summary descriptions are a brief characterization of the related criteria. Use the full statement of the criteria contained in Manual 231.1-2 to establish NTS reportability of event-related nuclear safety noncompliances.
3. Report nuclear safety noncompliances associated with any of the DOE Manual 231.1-2 Operational Emergency categories (Operational Emergency, Alert, Site Area Emergency, General Emergency).
4. Report noncompliances associated with a degradation of Safety Class Structure, System, or Component preventing satisfactory performance of its design function when required to be operable or in operation.
5. Report noncompliances associated with an offsite spread of contamination event where a contamination level exceeds 100 times the applicable value identified in 10 CFR Part 835, appendix D.
6. Report noncompliances associated with a personnel/personal clothing contamination where a contamination level exceeds 100 times the applicable total contamination value identified in 10 CFR Part 835, appendix D.
7. Refer to chapter IV, pages 17 and 18, for a description of these types of noncompliances.

Appendix B - Reporting Worker Safety and Health Noncompliances¹ into NTS (see chapter IV for use of these thresholds)

Table B-1 - Noncompliances Associated With Occurrences (DOE Manual 231.1-2)

Use the specific criteria in the DOE Manual for the reporting thresholds

Reporting Criteria Group	Subgroup	Occurrence Category and Summary Description ²
2. Personnel Safety and Health	A. Occupational Illnesses/Injuries	(1) Fatality/terminal illness (2) Inpatient hospitalization of ≥ 3 personnel (3) > 3 personnel having DART cases (4) Personnel exposure > limits requiring medical treatment (5) Personnel exposure > limits (6) Serious occupational injury
	B. Fires/Explosions	(1) Unplanned fire/explosion within primary confinement/containment (2) Unplanned fire/explosion in a nuclear facility that activates a fire suppression system (3) Unplanned fire/explosion in a non-nuclear facility
	C. Hazardous Energy Control	(1) Process failure resulting in burn, shock (2) Process failure/discovery of uncontrolled energy source
10. Management Concerns/Issues	N/A	(3) Near miss (Significance Categories 1 through 3)

The simple occurrence of an event in any of the listed categories is not enough to warrant NTS reporting. Reportable noncompliances require the identification of a 10 CFR Part 851 noncompliance (e.g., 29 CFR Parts 1910 and 1926) in conjunction with the event. The Office of Enforcement is interested only in those portions of the criteria with direct worker safety and health implications. Contractors identifying a significant worker safety and health noncompliance in association with an event type or category not listed on the table should evaluate the event for NTS reportability.

Table B-2 - Other NTS Reportable Conditions

Management Issues Noncompliances³
Repetitive Noncompliances
Programmatic Issue
Intentional Violation or Misrepresentation
Other Significant Conditions
Conditions meeting the criteria of Severity Level I (serious) violations and high relative risk ⁴

Notes to Tables

- 1 Noncompliances with 10 CFR Part 851.
- 2 These summary descriptions are a brief characterization of the related criteria. Use the full statement of the criteria contained in DOE Manual 231.1-2 to establish NTS reportability of event-related occupational safety and health noncompliances.
- 3 Refer to chapter IV, pages 17 and 18, for a description of these types of noncompliances.
- 4 Conditions of noncompliance identified by any method or means (e.g., contractor assessments, internal review processes, external assessments, employee concerns, event evaluation) that would not otherwise be reported into NTS as either a Management Issue or Occurrence, but that represent a condition of high relative risk. Conditions with an associated low or medium relative risk should not be reported. Guidance on risk assessment criteria can be found at www.hss.energy.gov/healthsafety/WSHP/rule851/851final.html, clicking on the Implementation Guide link.

Appendix C - Program Review

C.1 Typical Agenda

Day 1

- Initial informal meeting with local DOE to provide overview of review and discuss contractor performance (1 hour).
- Entrance meeting with contractor, DOE (1/2 hour).
- Overview presentation by contractor on program implementation (1-2 hours).
- Review of selected noncompliance screening determinations for rule applicability (i.e., noncompliance determination) (1-2 hours).
- Review of selected NTS and ITAC reportability determinations (1-2 hours).

Day 2

- Personnel interviews/document review (typically half day).
- DOE only pre-exit meeting (1/2 hour).
- Contractor and DOE exit meeting (1/2 hour).

Interviewees

Contractor interviewees may include the enforcement coordinator; QA manager; radiological control manager; environment, safety, and health (ES&H) manager; safeguards and security director, lessons learned program manager; senior management personnel performing noncompliance screens;

individuals responsible for tracking corrective actions; personnel performing QA, radiological control, or worker safety assessments; security inquiry officials, members of regulatory compliance, safety, or oversight committees; and individuals with knowledge of specific events resulting in NTS or ITAC reports.

C.2 Standard Document Request

The following documentation is typically requested in advance of a program review. This standard list may be modified based on specifics of the review or the site.

- Contractor organization chart that shows the reporting position of the enforcement coordinator, the radiological control manager, the QA manager, and the Security Manager. Sections of site procedures identifying roles and responsibilities of these positions should be included.
- Site implementing policy and procedures addressing the following topics: noncompliance identification, screening, cause determination, NTS and internal reporting, ITAC and Security Incident Notification Reports, corrective action tracking, corrective action closeout and validation, and training.
- Site procedures related to quality improvement and the corrective action process, deficiency reporting, nonconformance/quality problem resolution, and injury reports.
- Summary listing (including title and status) of all the site's internally tracked noncompliances or security deficiencies

over the past 24 months, sorted by year if possible.

- Copies of logs/spreadsheets used in the initial screening of potential noncompliance issues or security discrepancies for the 12-month period prior to request. Documentation should list title of the issue, screening outcome, and status of corrective actions, if possible.
- Summary listing (including title and status) of all site radiological deficiency/awareness reports for the 12-month period prior to request.
- OSHA 300 log of reportable injuries and illnesses for the prior 12 months, and the most recent OSHA 300 summary report.
- Summary listing (including title and status) of all site ITAC reports involving the protection of classified information for the 12-month period prior to request.
- Copies of any external assessments of the QA, radiation protection (RP), and worker safety programs conducted for the 12-month period prior to request.
- Copies of any recent contractor assessments of implementation of the program.

In addition to the above, the contractor is encouraged to provide any additional information that would provide a perspective on the implementation of the regulatory compliance (i.e., annual regulatory compliance performance report or annual security survey report). If the information requested above is not maintained or sorted by the contractor, it should not be specifically created for this review. The contractor should instead supply the closest equivalent document.

C.3 Review Criteria

The following criteria have been developed by Office of Enforcement staff as a guide for performing program reviews. The criteria may be used (wholly or in part) during the conduct of the review. Office of Enforcement staff may evaluate additional areas as appropriate. Many of the following criteria may be evaluated before the onsite visit by reviewing documentation obtained independently or through the document request.

C.3-I. General

- A. Verify through discussion and document review that formally approved policy/procedures are in place to describe the program. Procedures should describe key program elements (roles and responsibilities, training, screening/reporting, trend evaluation, cause determination, tracking and completion of corrective actions, closure validation) in sufficient detail to provide for effective implementation.
- B. Verify through discussion and review of organizational charts that a contractor enforcement coordinator has been formally designated and has adequate authority and independence to make decisions without undue pressure from the line organization. Determine whether adequate numbers of qualified support/matrix staff are available to meet program responsibilities.
- C. Verify through discussion and document review that formal training has been established and is implemented on site (may be category/target specific - general training for managers, specialized training on forms/procedures for screeners, etc.).
- D. Verify through discussion that the scope of the regulatory

screening and reporting program applies to activities performed by subcontractors and suppliers, as well as principal site contractors. Ensure through review that policies and procedures reflect this scope.

- E. Determine through discussion whether the enforcement coordinator routinely discusses noncompliance trends with senior management. Verify that the enforcement coordinator has direct and frequent access to the site senior manager.
- F. Determine whether the enforcement coordinator is acting in an expanded coordinator role as proposed by the Office of Enforcement. Specifically, does the coordinator act as the champion for continuous improvement of nuclear safety, worker safety and security performance at the site? Does the enforcement coordinator act as a resource to provide senior management the “big picture” vision of safety and security performance and inform them of perceived vulnerabilities?
- G. Determine if the contractor enforcement program has been effectively integrated to include nuclear safety, worker safety, and classified information security.

C.3-II. Identification and Screening of Noncompliances

- A. Verify through review that noncompliance identification/screening procedures or ITAC reporting criteria to ensure that a diverse set of source documents is forwarded for screening. These may include assessments, nonconformance reports (NCRs), ORPS, employee concerns, external assessments, deficiency reports, safety reports, injury reports, ITAC.SSIMS reports, Security Incident Notification Reports, and security survey reports.
- B. Verify through review that procedures ensure that all

applicable noncompliances are captured; noncompliances should not be screened out on the basis of inappropriate criteria. *(Note: Examples of inappropriate criteria noted to date have included ruling out noncompliances on the basis of prompt corrective action, judgment of low significance by evaluator, or judgment that the noncompliance did not directly involve the handling of nuclear material or the compromise of classified information.)*

- C. Verify through interviews that personnel who perform initial screens of source documents are qualified (typically subject matter experts in the areas of QA, radiological controls, safety basis, worker safety, classified matter protection or control, cyber security, and the security incident program.) and have received training on the screening process.
- D. Review screening documentation for the past year to verify that a broad spectrum of source documents is represented. Determine whether input from secondary sources (i.e., subcontractor/supplier-related information) is being included.
- E. Before the site visit, independently review recent site operating experience via review of ORPS, DNFSB trip reports, inspection reports, ITAC reports, etc. Evaluate for potential trends, programmatic issues, etc. Determine through onsite review whether these deficiencies were appropriately dispositioned.
- F. Independently select several contractor source documents (e.g., assessment reports, deficiency reports, security survey reports) identifying deficiencies that represent potential noncompliances. Determine through review of screening documentation whether these source documents were formally screened and appropriately dispositioned.
- G. Verify that items identified as regulatory noncompliances are

forwarded for review of NTS reportability (see next section).

- H. Verify that items identified as noncompliances are entered into a formal problem resolution and tracking system to correct the noncompliance, and are identified as regulatory noncompliances on that system.
- I. Review the status list of non-reportable noncompliances identified by the contractor over the past year for the following attributes:
- A “reasonable” number of noncompliances were identified, based on volume of activities and number of source documents screened.
 - The noncompliances reflect a mix of 10 CFR Parts 830, 835, 851, and 824 items and were identified through the assessment program as well as through events.
 - Corrective actions are completed on schedule, with appropriate follow-up if not completed.
- J. Review selected ORPS, ITAC reports, and deficiency report items that were judged not to be noncompliances to evaluate the contractor’s judgment process.

C.3-III. Evaluation for Reportability

- A. Verify through review that procedures used to describe/control the process of evaluating identified noncompliances for NTS reportability and ITAC reporting criteria include the following:
- Identification/designation of individuals with responsibilities for evaluation for reportability, approval, and NTS or ITAC report generation.
 - Formal process to be used for reportability determination, with documentation of results. Specific evaluation

criteria/thresholds should be included in the procedure.

- Methodology for evaluating potential repetitive or programmatic noncompliances.
- B. Verify through interview that individuals who make the final determination on NTS reportability or ITAC reporting criteria are qualified and have received appropriate training.
- C. Verify that incidents of security concern are being appropriately categorized (IMI-1,-2, -3, or -4) and reported within the requisite timeframe.
- D. Verify that reportability threshold criteria and reporting timeframes contained in procedure(s) are consistent with Office of Enforcement guidance and that procedures do not allow screening-out of reportable noncompliances through use of inappropriate criteria (see C.3-II.B above). D.
Review the status list of NTS non-reportable noncompliances identified by the contractor over the past year for the following attributes:
- Observable trends and/or potential programmatic noncompliances are appropriately recognized and reported by the contractor.
 - For selected noncompliances of apparent significance, the contractor used an appropriate judgment process to determine NTS non-reportability.
 - The ratio of total number of NTS non-reportable/reportable noncompliances is appropriate. *(Note: Although ratios will vary, one would expect the number of NTS non-reportables to be greater than reportables, particularly at sites with a well-functioning assessment program.)*
 - Adequate documentation exists for several recent instances in which noncompliances were evaluated as

requiring NTS reportability to show that the decision process was performed in accordance with procedure, the conclusion was appropriate, and NTS reporting was timely (generally within 20 calendar days after determining a noncompliance condition exists).

- The contractor's process for evaluating regulatory noncompliances for repetitiveness ensures an appropriate judgment within a reasonable timeframe. *(Note: At one reviewed site, contractor procedures required an annual review for trending/repetitiveness. This timeframe did not provide for effective and timely identification of recurring deficiencies. More commonly, sites review individual noncompliances as they occur – a "rolling window.")*
- E. Determine whether program performance indicator data (number of NTS reportable noncompliances, total number of noncompliances, etc.) is maintained and routinely reported to senior management.
- F. Review recent NTS reports or ITAC/SSIMS reports to determine the ratio of contractor self-identified to non-self-identified noncompliances. For this purpose, "self-identified" includes assessment-based and rollup issues; "non-self-identified" includes event-disclosed and external assessment issues. Determine whether the contractor enforcement coordinator tracks this ratio as a performance metric and trends this metric as well. *(Note: As site assessment processes mature, it is expected that the percentage of self-identified noncompliances will increase.)*

C.3-IV. Cause Determination/Corrective Action Closure

A. Verify through review that contractor procedures include or

require the following elements relative to corrective action development, tracking, and closure:

- Identified noncompliances and associated corrective actions are formally tracked.
 - Significant noncompliances are evaluated by formal causal analysis. Corrective actions are developed and implemented in a timely manner.
 - Validation/verification of completion of corrective actions takes place for significant noncompliances prior to closure.
 - Effectiveness reviews of corrective actions are conducted for significant noncompliances.
- B. Review documentation for selected NTS or ITAC reportable noncompliances to ensure that:
- A formal investigation/causal analysis is performed in a timely manner (generally within 45 days of determining that a safety noncompliance exists and generally 60-days after determining an incident of security concern occurred.).
 - Developed corrective actions correlate to causes identified through analysis.
 - For repetitive noncompliances, the causal analysis for the more recent noncompliance takes into account earlier noncompliances, corrective actions, and their efficacy.
 - The NTS or the ITAC report and corrective actions are provided as input into the site lessons-learned process, as appropriate.
 - Actions actually taken to close a corrective action are the same as those committed to in the original action.

- The verification process for corrective actions is effectively implemented in accordance with procedures.
- C. Review the summary of corrective action closure status for identified noncompliances and any related databases (deficiency reports, ES&H assessments, ITAC, SSIMS, etc.) to determine whether the contractor is completing actions within committed milestone dates.
- D. Determine through discussion and a review of relevant procedures whether the contractor's processes for investigation/causal analysis include the following attributes (*for reference, see appendix F*):
- Extent-of-condition reviews.
 - Precursor/historical reviews.
 - Evaluation of assessment performance.
 - Effectiveness reviews of corrective actions.
- E. Verify, through a review of completed investigations/causal analyses for one or two recent significant events or other deficiencies, whether (*for reference, see appendix F*):
- The analysis reflects an appropriate depth and breadth.
 - The elements discussed in appendix F (e.g., extent of condition, precursor review, assessment performance, effectiveness review) are reflected in either the investigation or the corrective action plan, or both.
- C.3-V. Assessments/Quality Improvement**
- A. Review the requested assessments for overall adequacy, clarity of findings, etc.
- B. Verify that identified assessment findings are reviewed for applicability and NTS reportability/ITAC reporting criteria. Independently select several significant assessment findings and cross-check them against screening/evaluation documentation to verify that they were appropriately reviewed.
- C. Compare preliminary Office of Enforcement program review findings with the results of contractor assessments of this area. Discuss differences with appropriate staff (enforcement coordinator, lead auditor, etc.).
- D. Review any actions taken by the contractor to improve its assessment processes in the past two years.
- E. Verify, through a review of completed assessment documentation and thorough discussion, that a process is in place to regularly monitor the performance of the site program. The process should include assessments (management or independent), use of metrics, and daily review and oversight by the enforcement coordinator of the performance of the site program activities. Discuss with coordinators the use of results of program reviews performed at other sites to either evaluate or benchmark their performance, or both.
- F. Verify, through a review of documentation and discussion, that the contractor's management and independent assessment processes are adequately described in approved procedures and instructions. Determine whether the procedures adequately address:
- Organizational responsibilities.
 - Assessment prioritization, planning, and methodology.
 - Training and qualification requirements.
 - Reporting and records.

- G. Select and review the assessment schedule and completion status for the contractor's independent assessment group and at least two management assessment units. Verify that procedural expectations for scope and scheduling are met and that a reasonable scope of activities is being assessed in a timely fashion. For assessments that were not completed, evaluate the reasons or factors for not completing them.
- H. Select examples of completed management and independent assessments for review of overall adequacy and consistency with procedural requirements. Verify that quality problems identified during the assessments were evaluated and that significant problems were entered into a formal corrective action system consistent with site procedures.
- I. Review other sources of performance information in conjunction with the program review, such as radiological deficiency reports, NCRs, noncompliance screens, ORPS reports, ITAC/SSIMS reports, inspection reports, and external assessments. Based on that review, determine whether if reviewed management and independent assessment results are generally consistent with other indicators. If inconsistencies exist, determine whether they are known by assessment management and the rationale for such inconsistencies.

C.3-VI. Other Evaluations

- A. The Office of Enforcement may obtain information related to selected occurrences to understand their significance and compliance issues associated with for those events.
- B. The Office of Enforcement may also conduct a limited records review of worker safety issues or incidents of security concern.

- C. The Office of Enforcement may also conduct limited worker safety workplace walk-throughs as part of the program review.
- D. The Office of Enforcement may also chose to evaluate other information related to compliance for selected topical areas within Parts 824, 830, 835, and 851.

C.4 Desktop Review of Smaller Contractors

C.4-I. Typical Information Request

- A. Provide a listing of your facilities and activities that are subject to the requirements of (1) Part 835, (2) Part 830 (subpart A), (3) Part 830 (subpart B), and (4) Part 824. A brief characterization of the activities conducted at each would be helpful. (For any that are defense-related, do not include classified or sensitive information.)
- B. Identify your coordinator for noncompliance matters, and provide a contact phone number and email address.
- C. Provide your policies and procedures that implement your processes for noncompliance identification, screening, NTS and internal reporting, ITAC reporting and corrective action resolution processes. Alternatively, provide a description of the portions of these processes that are not controlled by a formal procedure.
- D. Provide your policies and procedures that implement management and independent assessment programs required by 10 CFR Part 830, or provide a description of those processes.
- E. Provide copies of logs/spreadsheets used in the screening of safety and security deficiencies (including title/subject) over the past 12 months that determined whether these were (1)

noncompliances, (2) reportable into NTS or (3) ITAC report developed.

- F. Provide a copy of your OSHA log of injuries and illnesses over the past 12 months, and your most recent OSHA 300 summary report.
- G. Provide a summary listing (including title/subject and status of resolution) of all the site's internally-tracked safety and security noncompliances over the past 12 months that were determined to be below the NTS reporting threshold or not meeting the ITAC reporting criteria.

C.4-II. Review Criteria/Plan

- A. Verify (ensure) that the contractor has designated an enforcement coordinator. (Add this to the list of coordinators, if not already shown.)
- B. Regulatory Screening/Reporting Procedure:
 - Verify that the contractor has a procedure to ensure consistent screening of potential noncompliances.
 - Verify that typical quality problem sources are screened (RP deficiencies, quality deficiencies, and assessment findings if different from other sources).
 - Verify that the procedure does not introduce inappropriate criteria that result in excluding issues from applicability or NTS reportability.
 - Verify that the procedure calls for non-NTS noncompliance issues to be tracked internally, identified as such, and managed to closure.
 - Verify that the timeline requirements in the procedure are consistent with Office of Enforcement guidance for timely

decisions.

C. Logs of issues screened for noncompliance applicability:

- Verify that the set of issues represent substantive problems and include matters from assessments, programmatic problems, and worker/supervisor/manager observations in addition to matters from events.
- Briefly review a few of these screens to ensure that inappropriate criteria are not generally used to screen out matters from regulatory applicability.
- Check ORPS for an example or two of matters that should have been screened, and confirm that they were screened.
- Identify matters that may have been screened inappropriately.

D. Logs of noncompliance issues screened out from NTS reportability:

- Check a few of these screens to make sure that inappropriate criteria are not generally used to screen out matters from NTS reportability.
- Identify matters or incidents that may have been screened or categorized incorrectly.
- Check the contractor's set of NTS or ITAC reports over the past year (if any) to confirm that proper decisions were made on reportability, issues were comprehensively investigated and evaluated (root cause analysis, etc.), and appropriate and timely actions were taken.

E. Internally tracked noncompliance issues:

- Determine whether the set of such issues is a reasonably

size, given the type of operations conducted, and whether the set includes a reasonable mix of QA, RP, and safety basis issues.

- Confirm that these issues are identified as nonreportable noncompliances and tracked to closure.
- Confirm, for several examples, that closure appears to be timely.

Appendix D - Enforcement of Internal Dosimetry

This appendix clarifies the Office of Enforcement's position on 10 CFR Part 835 requirements related to monitoring for internal exposure. Specific areas addressed include:

- Prospective determination of employees who are "likely to receive" 100 millirem or greater per Part 835.402, *Individual Monitoring*.
- Application of enforcement policy in taking credit for respiratory protection in prospective determinations.
- Use of the contractor's policies regarding personnel internal exposure to radioactive material.
- As Low As is Reasonably Achievable (ALARA) programs.
- Clarification of enforcement with regard to internal dosimetry programs.

Prospective Determination of Employees "Likely to Receive" 100 mrem or More

It is important that contractors perform a prospective determination to identify radiological workers who are required to be monitored by Part 835.402(c), i.e., those workers likely to receive 100 mrem or more from all occupational radionuclide intakes in a year. Contractors should establish and document a clear basis for the prospective determination as part of the contractor's existing internal dosimetry program and/or technical basis documents. Such documents should include the contractor's technical rationale for including or excluding populations of radiological workers from monitoring for internal deposition of radioactive materials. Contractors should maintain

these documents as part of the contractor's record system. However, if the contractor does not adequately document the basis for identifying the radiological worker population for the required internal dosimetry program, then (for compliance purposes) all workers participating in the internal dosimetry program will be considered likely to receive 100 mrem or more in a year and it will be assumed that they are being monitored in accordance with Part 835.402.

Facility operations or operational status can and do change, particularly in decommissioning and decontamination activities in which workers open and access previously-contained radioactive materials systems. Such changes require reconsideration of the working conditions and modifications in the determination of the "likely" exposed population of radiological workers when performing a prospective determination of employees likely to receive 100 mrem or more in a year. Contractors should also continually reassess the determination when initiating operations that are infrequently performed.

As with all safety programs implemented by the DOE contractor community, the technical bases, decisions, and implementation of the safety programs at various sites will continue to be subject to DOE review and evaluation. A contractor's determination that a population of workers does not require monitoring under Part 835.402 does not automatically result in the monitoring (or lack of monitoring) of those individuals being outside DOE's purview. As a result of DOE's review, differences in professional opinion may arise or new factors and considerations may result in the need to reassess prior conclusions. As always, DOE will work to resolve any differences. However, no programs, decisions, or bases supporting the determination of the population of workers required to be monitored under

Part 835.402 will be considered outside DOE's continued purview.

Application of Enforcement Policy in Taking Credit for Respiratory Protection in Prospective Determinations

In work situations in which a contractor is considering the use of respiratory protection in performing prospective exposure estimates to identify those individuals who require internal exposure monitoring per Part 835.402, credit for respiratory protection may be allowable in certain circumstances. For enforcement purposes, credit for respiratory protection may be considered provided that the contractor has well planned and controlled work activities, timely and accurate monitoring of work areas, a demonstrable history of implementing effective work controls, and a respiratory protection program that meets the applicable Part 851 requirements (specifically 29 CFR Part 1910.134(c) and ANSI Z88.2 (1969)). Credit for respiratory protection should not be taken, however, for situations in which potential airborne radiological releases are not highly predictable or controllable. Examples of such situations include facilities with multiple release points, unidentified or chronic releases, or instances of airborne release not closely associated with planned work activities. The contractor's analysis of the effectiveness of the site's respiratory protection program and documented position in taking credit for respiratory protection is just one aspect of the overall prospective determination and is, therefore, subject to Office of Enforcement review.

Use of Contractor Policies Regarding Personnel Exposure to Radioactive Material

Some contractors may voluntarily establish policies that do not

permit any intakes of radioactive material or that limit intakes of radioactive material to less than 100 mrem from all occupational intakes in one year. Such a policy by itself, however, is not sufficient to conclude that a routine bioassay program at such facilities would not be required. Policy implementation through detailed work control and internal dosimetry documents that ensure compliance with Part 835.402 would be required.

Additionally, the contractor at a site should have a documented technical basis that identifies known working conditions in the various facilities and a history of low internal exposures for the site's radiological workers. As discussed above, changes in a facility's operations or operational status can and do occur, particularly in decommissioning and decontamination activities where workers open and access previously "sealed or contained" systems. These operational changes would then require reconsideration of the working conditions and the potentially radiologically exposed working population.

ALARA Programs

ALARA is not a numerical value or dose level, but rather a process that has the goal of maintaining doses at a level that is as low as reasonably achievable. Consequently, the monitoring level of 100 mrem established by Part 835.402(c)(1) does not define a threshold value for ALARA or for enforcement considerations.

Clarification of Enforcement with Regard to Internal Dosimetry Programs

Some contractors have chosen, at their discretion, to extend bioassay monitoring programs to include individuals who do not

meet the “likely” criteria contained in Part 835.402(c)(1). Contractors may perform such discretionary monitoring for a variety of reasons, such as meeting union commitments or as a program quality control measure.

The Office of Enforcement views the following specific elements of a discretionary monitoring program as falling within 10 CFR 835 requirements and thus subject to review and potential enforcement:

- The contractor’s prospective analysis, determination, and supporting rationale for identifying the worker population that is not “likely to receive” 100 mrem.
- The contractor’s mechanisms for timely, continuing analysis and feedback from the results of the discretionary bioassay program. Positive bioassay results or trends may indicate that individuals within the “discretionary” population require re-evaluation and actually fall under the monitoring requirements of Part 835.402, in that these individuals may be likely to receive 100 mrem in one year.
- The contractor’s mechanism for recording the dose results from discretionary monitoring in accordance with Part 835.702.

Additionally, a failure of the discretionary monitoring program may indicate a similar failure of the mandatory program. Moreover, if a contractor operates its discretionary and mandatory bioassay programs together as a unified program, a failure of the discretionary program may correlate to a systemic failure in the entire program and would require evaluation by the Office of Enforcement. Therefore, a failure in the discretionary program may demonstrate a pattern of noncompliance in the mandatory

bioassay program required by Part 835.402(c).

In general, instances of procedural noncompliance related directly to the discretionary monitoring aspects of the bioassay program fall outside the constraints of Part 835.402 and are not subject to DOE enforcement, unless there is a significant breakdown that could affect compliance with the general requirements of Part 835.401. However, the contractor is cautioned not to reduce overall emphasis on bioassay procedure compliance. Attempting to implement a graded procedural compliance based on perceived regulatory significance may serve confuse and send an inappropriate message to the workforce. The Office of Enforcement will determine whether regulatory violations occurred with respect to the discretionary bioassay program on a case by case basis, taking into account the commitments established in the Radiation Protection Program for Part 835 and in the Quality Assurance Program for Part 830.121.

Appendix E - 10 CFR Part 851 References to Forthcoming Guidance and *Enforcement Process Overview* Cross-Reference

10 CFR 851 Section	Topic	<i>Enforcement Process Overview</i> Guidance
Preamble at Page 6866	Multiple employer worksites – Prime’s liability for violations by another DOE-contractor	Chapter VIII, p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6866	Voluntary Reporting Thresholds	Chapter IV, p. 14, <i>NTS Reporting</i> , and appendix B
Preamble at Page 6874	NTS Reporting Thresholds	Chapter IV, p. 14, <i>NTS Reporting</i> , and appendix B
Preamble at Page 6874	Affirmative Defenses	Chapter VII, p. 56, Affirmative Defenses
Preamble at Page 6874	Possible citation of Prime for subcontractor violation	Chapter VIII, p.50, <i>Suppliers and Subcontractors</i> , and p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6875	Enforcement policy for subcontractor violations	Chapter VIII, p.50, <i>Suppliers and Subcontractors</i> , and p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6877	Enforcement actions involving both nuclear and worker safety, and limits on combined penalties	Chapter VIII, p. 53, <i>Nuclear Safety and Worker Safety and Health Noncompliances</i>
Preamble at Page 6878	General Duty Clause	Chapter VIII, p. 55, <i>General Duty Clause</i>
Preamble at Page 6879	Terminology “free from hazards” in General Duty Clause	Chapter VIII, p. 55, <i>General Duty Clause</i>
Preamble at Page 6882	Multi-employer worksites – Prime liability for violations by another DOE-contractor	Chapter VIII, p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6883	Multi-employer worksites – Prime’s liability for subcontractor violations	Chapter VIII, p.50, <i>Suppliers and Subcontractors</i> , and p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6896	Use of National Consensus Standards	Need for any enforcement guidance is to be determined after HS-40 prepares guidance on open issues in this area.
Preamble at Page 6904	Guidance on screening of violations, enforcement process, and appeals process	<i>Overview</i> document in general, and chapters V, VI, and VII in particular.
Preamble at Page 6904	NTS Reporting Thresholds	Chapter IV, p. 14, <i>NTS Reporting</i> , and appendix B
Preamble at Page 6904	Affirmative defenses for enforcement proceedings.	Guidance is addressed in this document on attributes that are considered and credited in investigation activities, applying enforcement discretion, structuring enforcement actions, and mitigation considerations.

Preamble at Page 6905	Inspection protocols	Refer to chapters I – VII of this document for guidance on the enforcement process, and chapter VI in particular on investigation and focused inspection activities.
Preamble at Page 6905	NTS reporting thresholds	Chapter IV, p. 14, <i>NTS Reporting</i> , and appendix B
Preamble at Page 6910	Unpreventable employee misconduct	Chapter VIII, p. 56, <i>Employee Misconduct</i>
Preamble at Page 6924	Enforcement against Subcontractors and Suppliers	Chapter VIII, p.50, <i>Suppliers and Subcontractors</i> , and p. 54, <i>Multiple Employer Worksite</i>
Preamble at Page 6927	Unpreventable employee misconduct	Chapter VIII, p. 56, <i>Employee Misconduct</i>
Preamble at Page 6928	Enforcement philosophy on contractor self-reporting, NTS reporting process, thresholds	Chapters II, III, IV, and appendix B
Preamble at Page 6928	Coordination of DOE reporting processes	Chapter IV, p. 11, <i>Contractor Screening Processes</i>

Appendix F - Contractor Investigation, Causal Analysis, and Corrective Action

As part of the investigation of potential nuclear safety or classified information security noncompliances, the Office of Enforcement routinely reviews contractors' investigations of noncompliances, preliminary inquiry reports, the associated causal analyses, and the corrective actions developed to resolve the noncompliance and prevent recurrence. During those reviews, the Office of Enforcement has noted several common deficiencies.

Additionally, many of the Office's enforcement actions involve recurrent events or deficiencies, indicating weaknesses in contractor processes for developing and implementing effective corrective actions. The Office of Enforcement provides this information as potential lessons-learned for the DOE contractor community.

The Office of Enforcement believes that the following lessons-learned information is also applicable to worker safety and security, even though the observations to date result from nuclear safety enforcement experience. Contractor investigation, causal analysis, and corrective action processes are typically institutional in nature and cover both safety and security functional areas as they relate to managing events and deficiency resolution.

F-I. Investigation, Causal Analysis, and Corrective Action Process

F-I.A. Relevant Requirements and Other Regulatory Drivers

Specifically for nuclear safety, Part 830.122(c), criterion 3, *Management/Quality Improvement*, establishes DOE requirements for investigating identified nuclear safety

deficiencies, determining underlying causes, and developing and implementing effective corrective actions to both correct the deficiency and prevent recurrence. Additionally, Part 820, appendix A, *Nuclear Safety Enforcement Policy*, delineates incentives for contractors' timely and comprehensive corrective actions for noncompliances, including application of discretion and/or mitigation.

Although the worker safety rule does not mandate a quality improvement process, the enforcement provisions of Part 851, and its Enforcement Policy in appendix B, establish regulatory drivers through crediting contractors' timely and comprehensive corrective actions as one of the factors in applying enforcement discretion and possible mitigation. The preamble to Part 851 also notes that for contractor violations indicative of egregious and/or general performance failures (which may be manifested by recurrent deficiencies and violations), contract penalties may be applied.

When the Office of Enforcement notes general deficiencies during its investigation activities or observes recurring problems and repetitive events, the Office cannot make a favorable judgment regarding compliance with the QA Rule requirements or granting discretion or mitigation as delineated in the above enforcement policies. It is hoped that contractors will evaluate and improve their processes in these areas and avoid these types of deficiencies. The information presented here is not intended to establish new requirements or to serve as a comprehensive guide on the approach to causal analysis or corrective action management. General program guidance has

already been developed by the Department⁸ and a variety of industry groups, such as the Institute for Nuclear Power Operations (INPO). The following areas are discussed here because they represent common deficiencies.

F-I.B. General Principles

The Office of Enforcement generally expects that a contractor conducting an investigation/causal analysis will ensure that the personnel who conduct the investigation are adequately trained and qualified, that the investigation includes appropriate scope and depth, and that corrective actions are timely and clearly relate to identified causes. This expectation applies both to contractor investigations of events and to investigations of safety/security issues identified as a result of more proactive means (e.g., assessments).

Consistent with Part 830.7, the level and effort of the contractor investigation and corrective actions should be commensurate with the significance and complexity of the problem—that is, a graded approach should be applied. For example, identification of apparent causes may be an appropriate endpoint when investigating less-significant problems, while a full root cause analysis would be appropriate for more significant or complex issues. As one point of reference, many contractors use NTS reportability as one of several criteria for determining whether to perform a root cause analysis or a less-rigorous apparent cause analysis.

⁸ See DOE G 414.1-2A, *Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1*; DOE-NE-STD-1004-92, *Root Cause Analysis Guidance Document*; DOE 231.1-2, *Occurrence Reporting Causal Analysis Guide*; DOE G 225.1A-1, *Implementation Guide for use with DOE O 275.1, Accident Investigation*.

F-I.C. Scope of Investigation

Once a deficiency or quality problem has been identified, it must be fully evaluated and characterized so that it can be corrected. As part of its review of a contractor's investigation of a nuclear, worker safety, or security problem, the Office of Enforcement typically questions whether the investigation included the following elements:

- Extent-of-condition (EOC) review.
- Precursor or historical review (including the effectiveness of prior corrective actions).
- Evaluation of assessment performance.

1. Extent-of-Condition Review

Once a significant quality problem has been identified, an EOC review should be performed to determine the full extent and generic implications of the problem—for example, determining whether the same problem/condition exists elsewhere (transportability of condition) and whether the same root or underlying causes of the problem/condition may be affecting performance in other applications (transportability of cause). Areas to be covered as part of an effective EOC review vary with the specifics of the identified problem, but generally include the following:

- Looking for the same problem in applications, locations or facilities other than where originally found.
- Looking for other manifestations of the identified root cause or underlying causes of the problem.

- Looking for similar or related problems, or problems that can be anticipated based on the identified problem.
- Reviewing prior applications of the deficient process or procedure to see whether earlier deficiencies had gone unnoticed.

The approach used in conducting an EOC review may also vary with the details and significance of the identified problem (i.e., a graded approach). Typically, an EOC review includes a series of focused field observations or assessments in conjunction with document reviews; a simple review of site trending data or quality problem tracking systems rarely provides the specificity needed to adequately assess the scope of the problem.

The most common performance deficiency in this area is the simple failure to do an EOC review for deficiencies with a clear potential for generic applicability. In addition, contractors sometimes simply search event databases for similar prior events or for general negative performance trends, and call such searches “extent of condition” reviews. Although the Office of Enforcement understands that database reviews have value (e.g., as a precursor/historical review), they do not constitute an effective EOC review. Inappropriate use of this terminology may give senior management false confidence that an identified problem is limited in scope.

2. Precursor/Historical Review

A contractor’s investigation and analysis of an identified quality problem should include a review to determine whether the same or similar problem has occurred previously. This

determination addresses both the problem condition and the underlying causes to determine whether the problem is recurrent. If a quality problem is determined to be recurrent, the contractor’s analysis should determine why prior corrective actions were not effective in preventing recurrence. The results of that evaluation should be factored into the corrective actions developed for the current event or problem. Unlike an EOC review, a precursor or historical review is retrospective in nature and can usually be conducted effectively using site database information on events, assessment results, etc.

3. Evaluation of Assessment Performance

Over the past two years, the Office of Enforcement has increasingly focused on the implementation and effectiveness of contractors’ assessment programs in improving nuclear safety performance. The Office has concluded that self-identification through implementation of an effective internal assessment program (rather than by reacting to events) is a cost-effective way to improve nuclear safety, worker safety, and classified information security performance, and that contractors should strive to implement an assessment-driven (rather than event-driven) nuclear safety, worker safety, and classified information security programs.

Consequently, when conducting an event investigation, the Office of Enforcement typically asks whether the subject safety or security noncompliance should have reasonably been identified through the contractor’s assessment program. Based on the initial answers, follow-up questions can help identify deficiencies in assessment scheduling, quality, or corrective action development and implementation. The

Office of Enforcement recommends that, where appropriate, contractors perform a similar evaluation as part of their investigation of an event or other nuclear safety, worker safety, and security problems.

F-I.D. Causal Analysis

An effective causal analysis is essential in developing appropriate corrective actions for an identified nuclear safety quality or a classified information security problem. Numerous causal analysis techniques and methodologies are currently used within the DOE contractor community. The Office of Enforcement has no preference, assuming that each is used in an appropriate fashion by trained and qualified personnel.

1. Depth of Analysis

The depth of the contractor's causal analysis should reflect the significance and complexity of the nuclear safety quality problem/incident of security concern or event under analysis. Some problems may be easily understood, while others may require considerable in-depth analysis.

Based on review of a large number of contractor causal analyses, the Office of Enforcement considers the most frequent deficiency in this area to be the tendency for analyses to be truncated before getting to underlying issues; that is, they do not go "deep" enough. In particular, the Office of Enforcement has found that contractors often end their analyses at some failure condition (e.g., failure to follow procedures, inadequate training, inadequate administrative controls) and then identify this condition as the root or underlying cause. Although convenient for binning and

trending purposes, these failure conditions do not always represent satisfactory endpoints. A more detailed causal analysis should go further and ask why the procedure was not followed, why the training was inadequate, or why there was an inadequate administrative control.

2. Cultural/Organizational Factors

"Worker failure to follow procedures" is often cited as an underlying cause, with corrective actions focusing on retraining or disciplining the worker or revising the procedure or process. Although such actions may be appropriate in some cases, contractors should also investigate whether organizational and management issues contributed to the failure. The cultural or organizational factors that may underlie worker procedural compliance issues can include the following:

- Perceived differences in management's actions versus their words.
- Local supervisory influences contrary to management's stated expectations.
- Emphasis on production or schedule.
- Inconsistent application of standards across the institution.
- Longstanding organizational practices conflicting with procedures and becoming the default process.
- Examples set by fellow workers.
- Desire for a successful experiment or evolution.

A comprehensive investigation of a nuclear safety

problem/incident of security concern should attempt to identify all the particular influences that caused the problem, including the management or supervisory influences that affect workers' behavior. These underlying factors may be difficult to identify or "get to" in an investigation and may require a senior-level effort, special expertise, or a number of one-on-one interviews.

3. Breadth of Analysis

The Office of Enforcement has also noted that some causal analyses do not identify all significant issues associated with an event. For example, the Office is typically just as interested in the reasons why a longstanding nuclear safety noncompliance persisted without being identified as in the specific causes of the original noncompliance. Often, such questions are not asked as part of the causal analysis, which tends to focus on the specific failure condition.

F-I.E. Corrective Actions

The Office of Enforcement evaluates contractor corrective action plans (CAPs) as part of the routine review of submitted NTS and ITAC reports during program reviews and as part of an investigation into a nuclear safety or security problem. The Office of Enforcement uses the general criteria outlined below to evaluate corrective actions, and also relies on the judgment of cognizant DOE/NNSA representatives when evaluating the adequacy of contractor corrective actions:

- Clear linkage to causal analysis – identifying whether the contractor has developed corrective actions for all root and significant contributing/underlying causes identified through

the causal analysis process.

- Appropriateness of corrective actions – verifying that stated corrective actions make sense and appear appropriate for the problem being addressed (i.e., behavioral or culture issues are not being addressed by a procedure revision) and that deliverables are clearly stated and achievable.
- Timeliness of corrective actions – verifying that schedules for corrective action completion reflect an appropriate priority and do not extend out past a reasonable timeframe. The Office of Enforcement expects that any delays in corrective action completion will be justifiable and limited in number and extent.
- Verification of effectiveness – determining whether the contractor included verification of effectiveness (described below) as a planned corrective action for significant or complex nuclear safety or security problems.

Several contractors conduct "effectiveness verification" as a corrective action for significant nuclear safety issues. This verification, typically performed several months after the other corrective actions are completed, is intended to assess workplace performance in the subject area and to determine whether the corrective actions have been effective. Effectiveness verifications can also be performed as an element of the independent assessment process.

The Office of Enforcement views the practice of conducting verification assessments as a positive one that should reduce the incidence of recurrent events. For nuclear safety noncompliances reported to the NTS, the contractor may choose whether to list the planned verification assessment as one of the NTS report's formal corrective actions (which may involve keeping the NTS report open for a longer period of time) or to

track it separately. Implementing a verification assessment approach does not alter the Office of Enforcement's expectation that the contractor and local DOE personnel verify completion of corrective actions before closing an NTS report.

F-II. Case Examples

Some of the specific deficiencies in this area are illustrated in examples available on the Office of Enforcement website:

- In cases where enforcement action was taken, those that cite the QA Rule *Quality Improvement* section generally involve conditions where the investigation, causal analysis, and/or corrective action processes were inadequate.
- The transmittal letter for enforcement action cases may identify deficiencies in the investigation, causal analysis, and/or corrective actions, and also may affect considerations of mitigation.
- The transmittal letter or the PNOV may note the recurring nature of the event or underlying problems, thus indicating deficiencies in the contractor's investigation, causal analysis, and corrective action processes.
- Program review reports may also note deficiencies in corrective action processes.

Appendix G - Contractor Assessment Program Weaknesses

G.1. Background

10 CFR Part 830.121(a) requires that contractors conducting activities that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the quality assurance (QA) criteria in Part 830.122. Part 830.122(i) identifies criteria specific to the conduct of management assessments, and Part 830.122(j) identifies criteria for independent assessments. Both assessment functions are required but, where appropriate, must be implemented in a graded approach consistent with Part 830.7. Additionally, in the worker safety area, failure to discover problems (e.g., by having an ineffective assessment process) can lead to loss of mitigation in an enforcement action.

Supplemental DOE guidance specific to assessments is set out in DOE Guide 414.1-1A, *Management Assessment and Independent Assessment Guide*. DOE Guide 414.1-1A provides significant detail and guidance on assessment program purpose, objectives, and implementation. In addition, the Energy Facility Contractors Group (EFCOG) has issued an assessment guide, *Implementing the Assessment Process at the Department of Energy Facilities*, that describes the types of assessments, steps in the assessment process, obstacles to implementing an effective assessment program, and ways to overcome these obstacles. The EFCOG assessment guide can be found at

efcog.org/wg/paaa/documents.htm

When conducted effectively, contractor assessment activities are part of a significant performance feedback loop, allowing the proactive identification and correction of safety deficiencies that might otherwise result in significant events. However, over the past several years, DOE enforcement actions have indicated a need for improvement in the conduct of contractor assessment programs, including:

- A lack of assessment activity in significant safety-related areas.
- Ineffective assessments, as evidenced by the absence of assessment findings in areas where programmatic problems have been disclosed through other means (e.g., operational history, events).
- Weaknesses in the effective correction and closure of assessment issues, resulting in recurrent and longstanding deficiencies.

During investigations of potential regulatory noncompliances, the Office of Enforcement typically reviews contractor assessment performance and results as they specifically relate to the subject area of the investigation. The Office of Enforcement will continue its emphasis on evaluating the implementation of contractor assessment programs as described in the section G-3 below. In addition, through the use of program reviews, the Office of Enforcement will seek to measure contractor performance in transitioning to an assessment-driven culture by focusing on contractor assessment initiatives aimed at improving the ability to proactively identify conditions adverse to quality. The emphasis here is on continuous assessment process improvement and not

on contractor “binning” of regulatory noncompliances to demonstrate reaching of a numerical percentage.

G.2. Management and Independent Assessment (M&IA) Programs Review Criteria

The Office of Enforcement intends to use the M&IA review criteria listed in section G.3 as an internal guide during evaluations of contractor assessment program implementation in order to promote consistency. These criteria largely reflect relevant Part 830.122 requirements, logical extensions of those requirements, or the evaluation of contractor performance against their applicable procedures. The criteria do not reflect supplemental DOE or external guidance relative to M&IA programs, and the Office of Enforcement will not use such guidance to evaluate contractor programs except as it is incorporated into contractor QA program (QAP) documentation. This evaluation approach merely reflects the Office of Enforcement’s regulatory perspective and should not be viewed as encouragement to contractors to limit their programs.

G.3. Criteria for Evaluating M&IA Program Implementation

The Office of Enforcement will increase its emphasis on evaluating contractor assessment program compliance by:

- Broadening the scope of routine noncompliance investigations to include increased evaluation and follow-up of contractor assessment program deficiencies.
- Continued monitoring of contractor reporting information, with increased attention to assessment- or corrective action-related items.

- As necessary, conducting contractor M&IA program compliance reviews (in response to negative performance indicators or DOE request).
- Reviewing the NTS database to evaluate progress in shifting from an event-driven to an assessment-driven culture.
- Determining to what extent specific assessment program improvement initiatives have been undertaken to drive assessment program improvement.

Consistent with the Part 830 scope and the Office of Enforcement’s jurisdictional authority, the Office of Enforcement’s review activities are directed toward evaluating the compliance of contractor M&IA program activities with Part 830.122 M&IA nuclear safety requirements for those facilities and activities subject to the requirements. Enforcement action for identified noncompliances will be pursued as appropriate, consistent with the specifics of the noncompliance and in full consideration of any mitigating factors.

The review criteria are intended to promote consistency, not to represent new or supplemental requirements. Contractor compliance will be evaluated directly against applicable Part 830 criteria, the contractor’s documented QAP, and associated policies and procedures.

The following review criteria have been developed to support Office of Enforcement evaluations of contractor implementation of the M&IA requirements of Part 830.122. Sections G.3-I through III contain general programmatic criteria that may be used during any review; section G.3-IV contains more focused criteria and is intended for use (along with applicable general criteria from G.3-I

through III) during an investigation of a specific event or noncompliance.

The contractor's documented QAP describes how the contractor will satisfy Part 830.122 QA criteria consistent with the graded-approach provisions of Part 830.7. Thus, the following criteria should be adjusted as necessary to reflect the specific commitments and provisions of the subject contractor QAP.

G.3-I. Programs and Procedures

- A. Verify that the contractor's QAP documentation describes how the contractor meets the M&IA criteria of Part 830.122 and that the QAP description reflects current conditions, referenced procedures are correct, etc.
- B. Verify that the contractor's management assessment (MA) and independent assessment (IA) processes are adequately described in approved procedures or instructions. Determine whether the procedures adequately address:
 - Organizational responsibilities.
 - Assessment prioritization, planning, and methodology.
 - Training/qualification requirements.
 - Reporting and records.
 - Assessment follow-up actions.
- C. Verify that the contractor's process for quality problem resolution and corrective action is described in formal procedures. Determine whether the procedures adequately address:
 - Organizational responsibilities.
 - Problem/deficiency significance evaluation.
 - Responsibilities and criteria for conducting causal determinations.
 - Corrective action development and approval.
 - Documentation of disposition and resolution.
 - Corrective action closeout.
 - Verification of effectiveness.
- D. Verify that the group responsible for performing IAs is reasonably and obviously independent from, and has no direct responsibility for, the work being assessed. Also verify that the IA group is assigned appropriate authority to perform their assessment function.
- E. Verify that a process has been established to ensure that IA assessors are appropriately trained and qualified and knowledgeable in the areas to be assessed.
- F. Verify that the MA program/procedures require the direct participation of management-level individuals in the conduct of MAs. (Unless defined differently in contractor procedures, "management-level" or "management" includes second-level supervision and higher.) Specific support activities (e.g., data collection) may be delegated to staff, but managers are expected to be directly involved in the process, and the resulting MAs should represent the evaluation and conclusions of management.

- G. Verify the contractor's progress in shifting from an event-driven to an assessment-driven culture.
- H. Verify the extent to which specific assessment program improvement initiatives have been undertaken to drive assessment program improvement.

G.3-II. MA Implementation

- A. Select at least two MA assessment units (e.g., facilities, operational divisions) and review the current MA schedule and completion status. Verify that procedural expectations for scope and scheduling are met and that management processes are assessed. For assessments that were not completed, evaluate the rationale for not completing them.
- B. Select examples of completed MAs for detailed review. This review should include the assessment report, supporting documentation as necessary, any associated corrective action plan, and selected corrective action closure documentation. The review should:
 - Verify that the assessment was planned, conducted, and reported in accordance with procedural requirements.
 - Verify through review and interview that management was involved in completing the assessment (involvement may include participation in data collection or evaluation of results).
 - Verify that personnel performing the assessment were trained in the assessment process and knowledgeable of the program, system, or process being assessed.
 - Verify that quality problems identified during the assessment were evaluated and that significant problems were entered into a formal corrective action system consistent with site procedures.
- Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal analyses evaluate the extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.
- Verify that corrective actions are assigned to specific "owners," have associated milestone dates, and are being completed/closed in a timely fashion.
- Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine whether adequate evidence exists to support closure.
- C. Review additional sources of performance information (e.g., prior or subsequent MAs, external assessments, and occurrence reports) for one of the assessment units discussed in item G.3-II.B above. Determine whether the subject MA results are consistent with other indicators of performance and whether findings identified during the subject MA represent longstanding or recurring problems.
- D. Review MA program documentation to determine whether the contractor includes methods in addition to assessments (e.g., event review, performance indicators, etc.) in its overall MA strategy. In such instances, for one of the assessment units discussed in G.3-II.B above, determine through personnel interviews and review of selected documentation whether:
 - MA methods are consistent with applicable procedures.

- Identified quality problems are appropriately tracked, controlled, and resolved consistent with procedures.

E. Based on interviews with management representatives and review of MA results (from G.3-II.B above), evaluate the effectiveness of the MA process in identifying and correcting problems that hinder the organization from achieving its objectives.

G.3-III. IA Implementation

A. Review the current IA schedule. Verify that procedural expectations for scope and scheduling are being met. The IA schedule should demonstrate that assessments are being performed to measure item and service quality; to measure the adequacy of work performance; and to promote improvement.

Although the Office of Enforcement's emphasis in this area should be on evaluating performance against the contractor's procedural requirements, the Office of Enforcement reviewer should consider the following during review of the IA schedule:

- The scheduling process should consider such factors as risk, time since last assessment, operational activities during the assessment period, feedback from trending, events, and other assessments.
- The schedule should show that significant facilities, operations, and functional areas are assessed on a periodic basis.
- The IA schedule (or individual assessment scope) should

reflect the observation/evaluation of work activities and practices.

B. Review the completion status of the IA schedule. For scheduled assessments that were not completed, evaluate the rationale for not completing.

C. Select several completed IAs for detailed review (assessments selected by the Office of Enforcement reviewer should reflect a mix of facilities and topic areas). The review should include the assessment report, backup assessment documentation as necessary, selected associated corrective action plans, and selected corrective action closure documentation. The review should:

- Verify that the assessments were planned, conducted, and reported in accordance with procedural requirements.
- Verify that assessors participating in the assessments were qualified in accordance with procedures and knowledgeable in the areas being assessed.
- Verify that assessment findings (i.e., quality problems, issues) were evaluated and significant findings were entered into a formal corrective action system consistent with site procedures.
- Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal analyses evaluate the extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.
- Verify that corrective actions are assigned to specific "owners," have associated milestone dates, and are being

- completed/closed in a timely fashion.
- Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine whether adequate evidence exists to support closure.
- D. Review additional sources of performance information (e.g., prior or subsequent IAs, external assessments, occurrence reports) for one of the assessed facilities or topic areas discussed in item G.3-III.C above. Determine whether the subject IA results are consistent with other indicators of performance and whether findings identified during the subject IA represent longstanding or recurring problems.
- E. Based on interviews with IA and line management representatives and review of IA results (from G.3-III.C above), evaluate the effectiveness of the IA process in identifying quality problems and promoting improvement.
- If prior assessments identified quality problems similar to those evident during the current investigation, determine the following through review and interview:
 - Whether effective causal analyses were performed for the prior quality problems consistent with procedural requirements.
 - Whether the identified corrective actions for the prior quality problems reflected the causes identified during the causal analysis and were effectively completed.
 - If no prior assessments were performed in the subject area of the investigation, determine whether the contractor has met procedural requirements for scope and scheduling, using the applicable review criteria G.3-II.A and III.A.

G.3-IV. Review as Part of Office of Enforcement Specific Investigation

As part of the investigation document request (or at the onset of the site visit), request any recent (within approximately 24 months) prior assessments that evaluated performance within the subject area of the investigation. Determine/perform the following:

- Review and evaluate the general adequacy of the assessments, using the applicable review criteria G.3-II.B or III.C.

Appendix H - Enforcement of QA Rule Applicability

Summary of Key Requirements and Interpretive Ruling Statements

10 CFR Part 830.120 states that the QA requirements of subpart A apply to contractor activities, including providing items and services that affect, or may affect, the nuclear safety of DOE nuclear facilities. In Ruling 1995-1, the DOE Office of General Counsel further clarified that the scope of the QA rule (currently subpart A), applies to all DOE activities that have the potential to cause radiological harm, in the present or future, other than those already explicitly excluded by the rule.

Part 830 allows requirements to be applied in a graded approach, such that work that poses a more significant hazard must have a greater level of control. It does not stipulate that work posing a lesser hazard does not require compliance with subpart A requirements. An appropriate level of work controls (planning, procedural controls, etc.)—training and assessment, for example—should be applied to ensure the activity is performed in a quality manner and does not adversely affect nuclear safety or materials.

Specific Applicability Issues

Attempting to limit QA requirements to safety basis facilities, equipment, and/or operations.

The Office of Enforcement has encountered some questions and confusion concerning the relationship of Part 830 subpart A QA requirements with subpart B requirements for developing a safety

basis for higher hazard facilities. In general, any language or site/facility specific requirements developed as part of or contained in existing safety basis documents cannot in and of itself further “narrow or limit” the applicability of subpart A rule requirements to only higher hazard facilities or activities.

Subpart A requirements apply to all nuclear facilities, in a graded approach, including those below the subpart B hazard category 3 threshold. Subpart B requirements, though, apply only to hazard category 1, 2 and 3 facilities. In the preamble to the 1994 QA final rule, DOE rejected comments that requested a threshold to exclude coverage of lower hazard facilities. In addition, DOE reaffirmed its intent to cover all facilities that involve radioactive material in such form and quantity that a nuclear hazard potentially exists. There have been a number of events and some enforcement cases with actual and potential radiological consequences to workers within the DOE complex that involved facilities and activities below subpart B nuclear hazard thresholds. Facilities with more limited quantities of nuclear material as well as activities such as waste handling, environmental remediation, decontamination, certainly can have the potential to cause radiological harm.

Noncompliance associated with proper work control is a common contributing cause for such events.

The Office of Enforcement has also encountered situations involving facilities that have a rule-required safety basis but for which site QA programs were inappropriately limited to a defined set of systems, equipment, or operations described within safety

basis documents (documented safety analyses and technical safety requirements). Such a limitation is inconsistent with the scope and requirements of the rule. In general, DOE enforcement actions have involved equipment/safety degradation or improper modification, maintenance, or operation of safety systems or features. However, several cases have also involved situations in which work not involving safety systems or features still had a potential nuclear safety implication, due to the location or nature of the work or the potential effects of some adverse event.

One specific example included a fire and explosion involving a canister of organic material that was left unattended in an oven. The activity did not directly involve any safety-related equipment described in the safety basis and did not involve any nuclear materials. The fire and explosion led to facility damage and had the potential for radiological harm if nuclear material had been in the area at the time of the event. Rule noncompliances associated with work control contributed to this event.

Another case involved the installation of drain sumps in a facility. The sumps were being installed to contain any fluid spills and to preclude releases that might violate environmental restrictions. The sumps were not a nuclear safety feature described in the safety basis, but were being installed in an area that contained switchgear, cabling, and power feeds for facility safety features. Further, the sump installation was not inside the boundaries of the nuclear facility but had the potential to cause loss of power to safety equipment for a nuclear facility. Noncompliances associated with work planning and control for this activity could negatively affect nuclear safety at this facility.

Attempting to limit QA requirements to work involving only a physical activity and/or direct handling of radiological material.

In its reviews, the Office of Enforcement has found certain contractors who considered Part 830, subpart A, to apply only to work activities involving a physical activity (e.g., turning a valve, modifying equipment). They did not consider examinations, diagnostic evaluations, planning, surveillance, or other such activities to be “work,” and thus did not apply subpart A requirements. No work planning, hazard evaluation, procedural controls, etc., were applied to such activities. In some of these cases, such “non-work” activities involved instances in which unexpected conditions occurred, and workers received radiological exposures and intakes.

Subpart A has no limitation that work must involve physical activity or hardware. Part 830 defines quality as “...the condition achieved when an item, service, or process meets or exceeds the user’s requirements or expectations.” Service is defined in Part 830 as “the performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.” Further, requirements set forth in the rule regarding record keeping, training, procurement, self-assessment, and independent assessment clearly do not require the presence of radioactive materials or “work” involving a physical activity.

Individuals who evaluate conditions, assess operations, inspect materials or equipment, evaluate problems, perform assessment activities, or conduct other like activities are also performing work. Such work falls under the requirements of Part 830 if it pertains to a nuclear facility in which a hazard potentially exists to employees

or the general public. Since the rule applies to design, manufacture, and assembly of items for use with radioactive materials and fissionable materials, it is clear that the rule applies to such activities even if no nuclear inventory is present.

The Office of Enforcement has also found the need, from time to time, to address a misconception that Part 830 QA requirements apply only to work that directly involves the handling of radiological material. Some implementation documents included language suggesting that work in a nuclear facility had to present the immediate potential for radiological harm to a worker for Part 830 to apply. As noted above, Part 830 contains no such limiting applicability for work that pertains to a nuclear facility.

Attempting to limit QA requirements to apply only when nuclear or radiological material is present in a facility.

Another applicability issue encountered by the Office of Enforcement involved the application of Part 830 QA requirements to a radiological facility only when the facility contained an inventory of radiological material. This practice was based on the premise that a facility was not designated as a radiological facility until it contained radiological materials that could pose a risk to workers. The concept of when a facility becomes a radiological facility is important in terms of establishing the application of Part 835. With respect to Part 830, subpart A, the phrase “radiological facility” versus “nuclear facility” has no relevance. Part 830 applies to nuclear facilities, and for the reasons noted above, use of a threshold (such as hazard category 3) of subpart B is not applicable to a threshold for application of subpart A. DOE’s Office of General Counsel Ruling 1995-1 (61 FR 4209, February 5, 1996), noted that “Part 830 covers activities where no nuclear material is present,

such as facilities that prepare non-nuclear components of nuclear weapons, but which could cause radiological damage at a later date.” (See 61 FR 4210.) Part 830 also relates to facilities that could pose a hazard to the public or the environment.

Part 830 unambiguously states that it applies to activities or operations that “[d]esign, manufacture or assemble items for use with radiological materials....” Such activities clearly fall under the requirements of the rule. The requirements of Part 830 can therefore apply to facilities and activities where no nuclear inventory is present.

Appendix I - Nuclear Weapons Program Enforcement Issues

The following guidance describes more specifically how the general enforcement process described in this *Overview* is applied to particular conditions in the nuclear weapons program area. Section I-I provides a brief background of rule requirements and a related legal interpretation by DOE's Office of General Counsel as they relate to nuclear weapons programs. Section I-II discusses the Office of Enforcement's general enforcement approach and the basis for making enforcement recommendations to the Administrator, National Nuclear Security Administration (NNSA). Section I-III addresses several specific topics concerning nuclear weapons-related issues.

I-I. Background and Current Rule Requirements

The original version of Part 830, with an effective date of May 5, 1994, excluded in Part 830.2(c) "activities conducted under the Nuclear Explosive and Weapons Safety Program relating to prevention of accidental or unauthorized nuclear detonations..." from the scope of the rule. Certain contractor personnel, DOE, and NNSA representatives inappropriately interpreted this language to exempt all routine and emergency nuclear weapons related activities.

In Ruling 1995-1 (61 FR 4209, February 5, 1996), the DOE Office of General Counsel (OGC) clarified this language as a narrow exclusion limited to those immediate actions necessary to prevent an accidental or unauthorized nuclear detonation. The OGC interpretation clarified that routine operations related to nuclear weapon programs were not excluded from the PAAA rules. On January 10, 2001, DOE published an amended Part 830 final

rule that removed the nuclear weapons exclusion effective April 17, 2001. Subsequent to its removal, the Office of Enforcement received additional requests for clarification concerning the enforcement of Part 830 with respect to nuclear weapon programs. The requests for clarification focused mainly on:

- Retroactive enforcement.
- NTS reporting of QA deficiencies.
- Emergency response.
- Offsite weapons activities.
- Contractor QA interfaces.
- Pre-design research and development (R&D) work.

I-II. General Enforcement Approach and Guidance

The Office of Enforcement will continue to enforce the provisions of Part 830 consistent with established enforcement policy and guidance. Nuclear facilities and activities that have the potential to cause radiological harm can be the subject of enforcement actions unless (A) specifically excluded by the rule or (B) specifically excluded through an approved exemption issued in accordance with Part 820. This definition includes NNSA facilities and activities that involve nuclear weapons and weapons related activities.

The Office of Enforcement anticipates, however, the use of broad discretion in its enforcement of Part 830 based on some unique

aspects involving nuclear weapon programs. For example, the Office of Enforcement anticipates little involvement in areas relative to nuclear weapons emergency response and activities on foreign soil. The application of this discretion is further discussed in section I-III.

The above described enforcement approach is consistent with the principles outlined in the memorandum of understanding (MOU) between the Administrator for the NNSA and the Assistant Secretary for Environment, Safety and Health, dated January 12, 2001. The MOU is available at the Office of Enforcement web page at

www.hss.energy.gov/Enforce/handbks.html

In consideration of both the rule's applicability and the above enforcement approach, NNSA contractors, in working with the NNSA, should establish which of their facilities and activities have the potential to cause radiological harm. Contractors should then ensure that those applicable facilities and activities comply with the requirements of Part 830. The Office of Enforcement does not expect that all elements of nuclear weapon programs fall under Part 830. For instance, components that are relied upon solely for nuclear weapon reliability would not necessarily be subject to PAAA rules. Conversely, nuclear weapon activities and components that are relied upon for nuclear or radiological safety or that contain radiological material most likely have the potential for radiological harm and thus would be subject to the rule.

The Office of Enforcement is also aware that NNSA has placed certain QA requirements in its contracts, including DOE Order 414 and the QC-1 requirements of NNSA/AL Supplemental Order

56XB. The Office of Enforcement expects that contractor processes intended to meet those QA requirements should be sufficient to demonstrate compliance with subpart A of Part 830. However, it is still incumbent on the individual NNSA contractors to review those programs and their implementation to ensure that they comply with subpart A.

I-III. Specific Enforcement Issues

A. Retroactive Enforcement

Most of the nuclear weapons stockpile was designed, manufactured, and placed into inventory prior to the effective date of the QA rule. If quality problems are discovered, how does the Office of Enforcement enforce the QA rule for these problems?

QA problems that are attributed to historical design and manufacturing activities conducted prior to the establishment of PAAA rules will not be subject to enforcement actions. This judgment also applies to quality problems associated with nuclear weapon facilities, activities, and components. By establishing an effective date for each of the PAAA rules, DOE's intent was not to "backfit" the requirements of the rules to these past activities. However, the following additional points should be recognized.

Both subparts A and B of Part 830 contain requirements that currently apply to nuclear weapon programs whether or not the weapons or facilities themselves were manufactured or constructed before the effective date of the rule. Part 830 requirements are intended to address the ongoing management and nuclear safety of nuclear weapons and facilities (storage, stockpile surveillance, maintenance, etc.) regardless of whether they came into existence prior to the rule.

For example, the quality improvement criterion of subpart A requires ongoing processes to detect and correct quality problems. The failure of an ongoing surveillance/maintenance program to identify and correct safety-significant quality problems associated with nuclear weapons or facilities that predate the rule could be subject to enforcement actions. Similarly, subpart B contains applicable requirements involving documented safety analysis (DSAs), technical safety requirements (TSRs), and USQ processes. These requirements also apply to nuclear weapon facilities and activities, regardless of their design or manufacture date.

The above enforcement discretion concerning legacy quality problems is consistent with the Office of Enforcement's approach to legacy contamination issues as outlined in section VIII.C, *Enforcement Approach to Discovery and Control of Legacy Contamination Issues*, of this document.

The following example situations are provided to help illustrate the above guidance.

Example 1: A specific software code was developed and used in the design or modeling of a weapon component in 1982. This component is currently in the stockpile. Is the responsible contractor required to go back and ensure that the software code meets current QA requirements?

No. The Office of Enforcement does not expect contractors to backfit quality requirements to processes and activities completed before the application date of the PAAA rules.

Example 2: A specific software code was used in the design or modeling of a component in 1982. This component is currently in

the stockpile. A contractor is continuing to use this same software code for maintaining or improving the component. Is the responsible contractor required to ensure that the software or the software-generated data meets the QA requirements of the rule?

Yes. If the component or activity has the potential to cause radiological harm or if it is used to prevent radiological harm, then the PAAA rules would apply since the software code or its generated data is being used for a current activity (i.e., maintenance or improvement).

Example 3: A component was designed and placed into production in 1982. It is being monitored by means of present-day surveillance activities to ensure that it continues to meet performance expectations. The monitoring activities detect a safety-significant quality-manufacturing defect with the potential to cause radiological harm. Are the contractor's monitoring and corrective action activities required to meet the QA requirements of the rule?

Yes. The monitoring and corrective action activities would be subject to PAAA rules and potential enforcement actions, including any failures to control and correct the safety-significant defects.

B. Emergency Response

An NNSA contractor may have to take certain actions during an emergency to prevent a nuclear detonation. These actions may not be in compliance with the QA rule. How will the QA rule be enforced?

The removal of the nuclear weapons exclusion from Part 830 (see section I-I) has resulted in questions on whether or not contractor emergency response actions could be subject to future enforcement actions. As stated in the preamble to the October 10, 2000, Interim Final Rule, the nuclear weapons exclusion was eliminated with the addition of subpart B. Specifically, subpart B added a “safe harbor” or process for contractors to integrate both nuclear safety and nuclear explosive and weapons surety program requirements in a single DSA. DSAs are intended to address nuclear hazard controls, including emergency response programs/requirements. The preamble also stated that any potential conflicts between the different sets of requirements should be resolved by way of a rule exemption in accordance with subpart E of Part 820.

The Office of Enforcement recognizes that in spite of the above expectations, the possibility (however unlikely) could still exist that NNSA contractors may need to take certain nuclear weapons-related emergency actions that do not comply with the rule. The primary reason for taking such actions would be to prevent an accidental or unauthorized nuclear weapons detonation and any corresponding harm to workers, the public, and the environment.

Since these types of emergency actions are intended to prevent imminent and significant harm to workers and the public, enforcement discretion would be appropriate. The Office of Enforcement would consider the following factors, similar to those outlined in Part 830.205(b) for DOE nuclear facility emergency response activities, when deciding to apply enforcement discretion:

- The actions taken were needed to prevent an accidental or

unauthorized nuclear weapons detonation and consistent with an overall intent to protect workers, the public, or the environment from imminent and significant harm.

- No other apparent and appropriate actions were available consistent with the requirements of Part 830 and corresponding implementing procedures, plans, and programs.
- The actions were authorized by the appropriate DOE/NNSA Senior Energy Official (SEO) as required.
- Follow-up corrective actions are taken as necessary to identify, report, and resolve the potential conflicts.

For noncompliances involving the above, the Office of Enforcement will limit its enforcement authority and refrain from initiating enforcement actions.

It should be noted that the Office of Enforcement does not intend to use its enforcement authority in a manner that inhibits or restricts contractor emergency actions essential for the protection of workers, the public, or the environment from imminent and significant harm. The Office of Enforcement also does not take enforcement action against an individual who may be involved with a PAAA noncompliance since the scope of DOE’s enforcement authority is limited to the “indemnified contractor,” which is a corporate entity. The exception would be a situation where criminal wrongdoing was evident.

The purpose of the enforcement program is to promote and protect the radiological health and safety of the public and workers. Consistent with the above, the Office of Enforcement will carefully consider the facts and will exercise appropriate enforcement discretion.

This enforcement discretion, however, does not relieve contractors of their contractual responsibilities for the management or technical support of NNSA radiological emergency response assets. It also does not relieve contractors of their responsibility to integrate both nuclear safety and nuclear explosives and weapons surety requirements under subpart B of the rule and to address any conflicts in accordance with subpart E of Part 820.

C. Contractor QA Program Interfaces for the Design-Manufacturing-Final Assembly Cycle

The Design-Manufacture-Final Assembly (D-M-FA) cycle for nuclear weapon programs can include different NNSA prime contractors for each phase of the process. Under this arrangement, prime contractors are required to provide specialized products and services for use by other prime contractors. These prime contractors do not have contractual relationships with each other governing the QA of such services and products. How does the PAAA enforcement policy address this arrangement?

Products developed and supplied for use among different NNSA prime contractors in general represent activities performed for the DOE/NNSA. Section 830.1 of the rule states “[t]his part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities.” These shared products, including technical services and weapon components, are thus subject to the requirements of Part 830.

The NNSA, through its contracts and directives, establishes

prime contractor roles and responsibilities for products used within the nuclear weapons D-M-FA cycle. Each prime contractor is therefore responsible for the quality of its NNSA-specified products used within the D-M-FA cycle, including the development of a QA program in accordance with Part 830.

Based on the above arrangements, the Office of Enforcement recognizes the potential for events to occur at one prime contractor site that discloses a potential rule noncompliance caused by a different prime contractor at another site. For example, a design flaw in a component could go undetected until the manufacturing phase of the D-M-FA cycle. As a result, the Office of Enforcement will consider the following before determining whether or not an enforcement action is appropriate and for which specific prime contractor(s).

- Where in the D-M-FA cycle did the quality noncompliance arise, and which contractor(s) was/were responsible for introducing and correcting the deficiency?
- Did the involved contractor(s) conduct the activities consistent with the requirements of the rule and their designated NNSA contractual responsibilities?
- Did the involved contractor(s) identify and voluntarily report any potential noncompliances consistent with established Office of Enforcement reporting guidance?
- Did the contractor discovering the issue notify other appropriate parties (other affected contractors and NNSA/DOE officials) in a timely manner and assist in the review and corrective actions, as appropriate?
- Did the contractor responsible for the noncompliances initiate prompt and effective corrective actions?

The Office of Enforcement also recognizes that in the contractor's delivery of products for use in the D-M-FA cycle, both formal and informal exchanges of technical support, information, and services do occur between prime contractors. In some cases, this technical exchange can have QA implications that can affect the nuclear safety of NNSA activities, including lessons learned or other similar quality-related information.

It is not the intent of the Office of Enforcement to implement its enforcement authority so as to discourage technical exchanges and communications that improve the quality of nuclear weapons services. However, because some of these technical services could significantly affect the nuclear safety of NNSA activities, contractors need to manage these services consistent with rule requirements. Contractors responsible for the generation and subsequent use of technical services must ensure they meet, in a graded approach based on safety significance, the requirements of their QA programs and the rule. This is required by the rule even if Part 830.122(g), *Criterion 7-Performance/Procurement*, is not applicable due to the lack of contractual processes between prime contractors.

The following example situations are provided to help illustrate the above guidance:

Example 1: A defect that involves nuclear safety requirements is identified in a weapon component at a NNSA production site. In evaluating the root cause of the defect, it is determined that the production site followed all quality system requirements and the deficiency was the result of a design developed by a national laboratory. In evaluating potential PAAA enforcement issues, the Office of Enforcement will address the following lines of inquiry:

- What was the root cause of the deficiency? Was there a failure of a contractor's quality system that allowed this failure and, if so, where did this failure occur?
- Did the production site appropriately identify the defect, perform appropriate root cause analysis, and communicate the deficiency to the design lab?
- Did the design lab perform appropriate root cause analysis, reporting, and corrective action?

If the answers to these questions confirm a failure at the design laboratory, any potential enforcement actions would be assessed against the design laboratory. The manufacturing site's quality system worked correctly in identifying the defect, and communication occurred between design and production contractors as desired by both NNSA and the Office of Enforcement.

Example 2: A defect that affects nuclear safety is identified in a component produced by a supplier subcontracted by an NNSA production site. A national laboratory provided the design requirements for the component. In evaluating the root cause of the defect, it is determined that the supplier produced the defect; however, the supplier's qualification and acceptance process was insufficient to prevent the defect.

In evaluating potential PAAA enforcement issues, the Office of Enforcement will address the following lines of inquiry:

- Was the design adequate? Was the design correctly provided to the NNSA production site?
- Did the production site effectively transmit design and production QA procurement requirements to the supplier?

- Was there a failure in the suppliers QA process that allowed the defective component to be purchased by the production site?
- Did the production site's quality acceptance process perform correctly in identifying the defect?
- Was there communication and cooperation between the design and production sites in identifying, reporting, and correcting the deficiency?

The Office of Enforcement could take enforcement action against the supplier for a failed quality control program, dependent on the responses to the above questions.

Example 3: A defect that affects nuclear safety is generated during the manufacturing process at a production site. The defect is not detected by the production site's QA program and the component is shipped to an assembly plant, where the defect is detected during assembly. The assembly plant follows their work direction in identifying the non-conformance to the production site.

In evaluating potential PAAA enforcement issues, the Office of Enforcement would evaluate the production site's quality system, the failure of the quality system to identify the defect, root cause analysis, and corrective actions taken subsequent the notification of the defective component. The Office of Enforcement would note that the assembly plant's QA program performed correctly in identifying the defect and in communicating the defect to the originator for corrective action.

D. NTS Reporting of QA Deficiencies

The nuclear weapons complex has established QA processes for identifying, documenting, evaluating, and reporting nonconforming items. Are all of these nonconformance reports (NCRs) considered to be PAAA NTS reportable noncompliances?

The Office of Enforcement recognizes that weapon programs have established processes to identify nonconformances to quality requirements. These processes identify quality deficiencies for weapon components and services concerning both product reliability (fit, form, and function) and nuclear or radiological safety. Consequently, only some of the NCRs may represent PAAA rule noncompliances and only a subset of these more significant noncompliances would meet the thresholds for PAAA NTS reporting.

Section IV. C. of this plan contains general NTS reporting guidance, and appendix A contains specific NTS reporting thresholds. Contractors responsible for reporting weapons-related noncompliance should refer to and use the above guidance and reporting thresholds. In determining whether or not an NCR (or any other type of deficiency/problem) represents a PAAA noncompliance that should be considered for NTS reporting, the screening should be consider whether:

- The NCR involves a component that has the potential for radiological harm, including specific weapon design or operational characteristics.
- The nonconformance deficiencies represent a noncompliance with a requirement of a PAAA rule.

- The noncompliance represents a programmatic or recurrence issue.
- The noncompliance meets any of the ORPS thresholds listed in appendix A of this plan.
- The noncompliance represents a willful or intentional violation of the rule.

Identified rule noncompliances that do not meet any of the NTS reportable thresholds noted in appendix A should be tracked locally and appropriately corrected, consistent with the contractor's issue/deficiency management processes and their own regulatory screening and reporting program.

Note: Safeguards and security classified information should not be included in the NTS report. The information in the NTS report should identify that a potential regulatory noncompliance has occurred, without compromising sensitive or classified information.

The following example situations are provided to help illustrate how NTS reporting interfaces with nuclear weapon program NCR processes.

Example 1: A reservoir vessel is produced to contain tritium gas in a weapon assembly. A nonconformance is detected during acceptance testing activities associated with the contractor's QC-1 program. The nonconformance involves an out-of-spec dimension that is an isolated case (i.e., not a reoccurring nor programmatic issue) that was detected by the contractor's QA program. Although the nonconformance is reported under the NNSA weapons QC-1 program, it would not be NTS reportable.

Example 2: The same reservoir vessel is produced as noted above to contain tritium gas in a weapons assembly. A nonconformance that could create a potential for tritium gas release to a worker or the atmosphere is detected by the contractor's QC-1 program. The nonconformance is repetitive in nature, indicating an ongoing concern with the QA of the seals. The nonconformance should be considered (using the screening criteria and reporting threshold guidance noted above) for regulatory noncompliance reportability in addition to any NCR.

E. Offsite Weapons Activities

NNSA contractor nuclear weapons program support may be required at department of Defense (DOD) facilities and within other countries where the NNSA contractor may have no control over the facilities or conditions. How will Part 830 be enforced in these situations?

In determining whether enforcement discretion would be appropriate, the Office of Enforcement considers two factors. First, Subpart B of Part 830 is limited to DOE facilities and, therefore, would not apply at non-DOE/NNSA facilities, including those operated by DOD or the government of another country. On the other hand, Subpart A of the rule is not limited to activities performed at DOE nuclear facilities. In the preamble (page 1811) of Part 830 Final Rule, dated January 10, 2001, DOE states the following in discussing its intent in choosing not to limit the applicability of the rule to "on-site activities":

"In adopting this option to cover offsite activities, we noted that the scope of the rule would apply not only to prime contractors responsible for a nuclear facility, but also subcontractors, suppliers, and other contractors including

those who provide items...or services... that affect, or may affect, the nuclear safety of DOE nuclear facilities.”

DOE’s OGC, in its Ruling 1995-1, provided the following interpretation:

“Although the requirements of Parts 830 and 835 apply to arrangements other than contracts, civil penalty assessments are authorized only for a ‘...person who may conduct activities under contract with the Department of Energy...’ and any subcontractor or supplier thereto. Civil penalties are not authorized for activities conducted under a cooperative agreement, grant, or work-for-others arrangement, as distinguished from a contract.”

The DOE Enforcement Policy of Part 820 appendix A, section IX, b. 9, *Exercise of Discretion*, states:

“DOE will not issue a Notice of Violation for cases in which the violation discovered by the DOE contractor cannot be reasonably linked to the conduct of that contractor....”

Based on the above, the Office of Enforcement has determined that it will generally refrain from issuing enforcement actions for Part 830 noncompliances involving offsite weapons support activities for the following reasons:

- Subpart B of the rule would not be applicable.
- DOE's original intent for expanding the scope of subpart A was to address offsite activities that could affect the nuclear safety of DOE facilities, not to regulate all offsite activities (such as work at non-DOE/NNSA sites involving other agencies or governments).

- The DOE OGC’s 1995-1 ruling prohibits the issuance of civil penalties involving cooperative agreements or work-for-others arrangements.
- Contractor support work at non-DOE/NNSA sites typically includes conditions that are beyond the contractor’s control.

F. Pre-Design R&D Work

During the R&D stage, conceptual designs are evaluated, and not all QA requirements are applied. At what point in the R&D design process will the Office of Enforcement start to enforce QA requirements?

Pre-design testing and engineering activities could have a significant impact on later design selection and its safety adequacy. Consequently, Part 830 addresses the QA of design items and processes, including pre-design selection activities. Specifically, Part 830.122(f)(5) states “[v]erify or validate work before approval and implementation of the design.” (It is recognized that not all QA requirements of the rule will apply to all of the varying types of pre-design testing and selection activities.)

Based on the above, there is no consistent or defining point in the design process for commencing implementation of the QA rule or enforcement actions. Contractors should therefore consider using a graded approach, rather than defining a specific point (e.g., design approval) for commencing QA rule implementation. The graded approach should be based on how the pre and post-design selection activities affect the safety adequacy of the final design.

Consistent with the above-described approach, the Office of Enforcement intends to investigate and issue enforcement

actions concerning only those design-related noncompliances that have safety-related consequences. Therefore, the Office of Enforcement generally limits its enforcement actions to noncompliances involving implemented designs (post-design selection failures). Even though an enforcement action may be issued for a post-design selection failure, a noncompliance could be cited based on a pre-design selection failure, such as that described in Part 830.122(f)(5) (see above).

Various design-related failures/deficiencies are discussed below, along with the Office of Enforcement's approach to assessing these events (in recognition of the above rule applicability and graded approach) for potential QA rule noncompliances and enforcement actions.

Post-design selection and implementation failures: A weapon component fails, and the component is one that is critical to preventing significant radiological harm. The component failure is attributed to an inadequate design caused by inadequate safety-related performance testing during the pre-design selection process. The Office of Enforcement would consider this type of failure for potential enforcement actions because the noncompliance involves a failure to verify/validate work (inadequate testing) prior to design approval, and the event consequences could be significant (significant radiological harm).

Pre-design selection component QA failures/deficiencies: Several prototype vessels are being considered for use in a future weapon to contain a radioactive gas. The components have different sealing designs and are subjected to leak testing using a surrogate non-radioactive gas. Several of the designs fail the leak test and do not meet the quality performance criteria

established for the test, so none of the failed prototype designs is selected for further use. The testing was conducted in a non-nuclear and non-radiological facility. The Office of Enforcement would not consider the above types of events for potential enforcement actions since the failed prototype activity was not part of the design process for components to be used in a nuclear weapon, facility, or activity.

Pre-design selection activity failures/deficiencies: Design R&D activities are conducted that involve neutron flux testing on prototype components using a research reactor. The described R&D activities would be subject to potential enforcement actions since the R&D involves nuclear activities with the potential to cause radiological harm (i.e., flux testing using a nuclear reactor).

Appendix J – Legacy Contamination

The concept of legacy, or pre-existing, contamination is neither defined nor discussed in Part 835 (neither the original nor the amended version). Further, Part 835, subpart A, contains no exclusions for pre-existing conditions (including legacy contamination). Consequently, any identified radioactive surface contamination (legacy or otherwise) above the applicable levels contained in Part 835, appendix D, for an unposted and uncontrolled area typically represents a noncompliance with Part 835 requirements. The specific noncompliance with Part 835 depends on the circumstances of the discovery. However, the following sections are generally applicable:

- 835.603(e) - Requires that Contamination Areas (see 835.2 definition) be posted.
- 835.1102(b) - Requires that areas where contamination levels exceed appendix D values be appropriately controlled.
- 835.1102(c) - Establishes control requirements for areas where fixed-only contamination levels exceed appendix D values.

Such discoveries may also represent a noncompliance with Part 830.122, *Quality Assurance Criteria*, depending upon circumstances and specific procedural requirements.

It should be recognized during evaluations of legacy contamination conditions that the appendix D values of Part 835, which trigger the above requirements, are applicable to surface contamination conditions only. They do not apply to situations in which an item or area is contaminated only in volume or by matrix (see note 1 to appendix D, also see the Part 835 preamble

comment on volumetric contamination in 58 FR 65475). Consequently, the discovery of an item incorporating legacy contamination by volume but not representing a surface contamination condition or hazard (such as contaminated flora, fauna, or some soils⁹) would not typically represent a Part 835 noncompliance. Nevertheless, such environmental contamination conditions must be appropriately controlled; it may also present other radiological hazards (such as direct radiation) that do require appropriate posting and control under Part 835.

In recognition of the specific circumstances that surround a legacy contamination discovery event, the Office of Enforcement generally does not pursue enforcement for a noncompliance identified in association with such events, subject to the following conditions:

- An effective radiological survey program is in place and functioning.
- Appropriate and timely corrective actions (such as posting, effective area control, and decontamination) are taken upon identification of the contamination.

⁹ For the case of volume-contaminated soil, the applicability of the Part 835, appendix D, levels are based on the potential to disperse contamination from the area in excess of these levels. If such a potential is likely, the area containing the soil should be posted and controlled as a Contamination Area. DOE relevant guidance is contained in Implementation Guide DOE Guide 441.1-9, *Radioactive Contamination Control Guide*, (6/99) and Article 238.3 of the DOE Standard DOE-STD-1098-99, *Radiological Control*, (12/04).

- It is unreasonable to expect the contamination to have been identified earlier through the radiological survey program, review of readily available historical information, or prudent response to previous contamination incidents.

Even though the condition may warrant Office of Enforcement discretion in terms of enforcement action, the condition may still qualify for reporting into the NTS. Contamination events (legacy or otherwise) should be screened and tracked in accordance with site regulatory screening and reporting program procedures. Typically, simple discovery-type events do not meet NTS reporting thresholds and should be entered into and tracked on contractor local noncompliance tracking systems. For contamination-related noncompliances that meet the thresholds of tables A-1 or A-2 of appendix A, a report should be made to the NTS regardless of whether the contractor chooses to apply the term “legacy.”