U.S. Department of Energy Orders Self-Study Program

DOE G 450.4-1B

INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE

ALBUQUERQUE OPERATIONS OFFICE

Change No: 0
DOE G 450.4-1B
Level: Familiar
Date: 6/15/01

DOE G 450.4-1B
INTEGRATED SAFETY MANAGEMENT SYSTEM (ISMS) GUIDE
FAMILIAR LEVEL

OBJECTIVES

Given the familiar level of this module and the resources listed below, you will be able to:

1. State the purpose of DOE G 450.4, ISMS Guide.
2. State the objectives of DOE G 450.4, ISMS Guide.
3. Discuss the general aspects of integration. Your discussion will include:
   - a definition of integration,
   - the factors that may affect the ISMS,
   - the layered structure that characterizes an ISMS,
   - the typical safety management programs for a Hazard Category 2 nuclear facility, and
   - the integration of risk.
4. State the core functions and guiding principles of the ISMS.
5. Given an example of an executed authorization agreement, determine if the agreement meets the requirements discussed in the Guide.
6. Discuss the attributes of ISMS documentation.
7. Discuss DOE and contractor activities associated with maintaining an approved ISMS.
8. Discuss the principles and attributes of safety management assessments.
9. Discuss the protocol for the review and approval of a safety management system description.
10. Discuss the feedback and improvement function in an ISMS.

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Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.

RESOURCES

DOE O 414.1A, Quality Assurance.
DOE O 425.1, Startup and Restart of Nuclear Facilities.
DOE O 430.1, Life-Cycle Asset Management and its associated guides.
DOE Order 5480.23, Nuclear Safety Analysis Reports.
DOE G 450.3-3, Tailoring for Integrated Safety Management Applications.
DOE G 450.4-1B, Integrated Safety Management System Guide, volumes 1 and 2, 3/1/01.
DOE M 411.1-1, Manual of Safety Management Functions, Responsibilities and Authorities (FRAM).
DOE P 411.1, Safety Management Functions, Responsibilities, and Authorities Policy.
DOE P 450.4, Safety Management System Policy.
DOE P 450.5, Line Environment, Safety, and Health Oversight.
DOE P 450.6, Secretarial Policy Statement, Environment, Safety, and Health.
DOE-DP-STD-3023-98, DOE Limited Standard, Guidelines for Risk-Based Prioritization of DOE Activities.
DOE/EH-0573, Environmental Management Systems Primer for Federal Facilities.
DOE-STD-1027, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports.
DOE-STD-1120, DOE Standard Integration of Environment, Safety, and Health into Facility Disposition Activities.
DOE STD-7501-95, Change 2, The DOE Corporate Lessons Learned Program.
10 CFR 820, Procedural Rules for DOE Nuclear Activities.
10 CFR 830, Nuclear Safety Management.
10 CFR 830.120, Quality Assurance.
10 CFR 835, Radiation Protection for Occupational Workers.
10 CFR 1021, National Environmental Protection Act.

48 CFR 970.1100-1, 970.5215-3, and 970.5223-1, Department of Energy Acquisition Regulation (DEAR).
48 CFR 970.5204-2, Laws, Regulations, and DOE Directives.
41 Unites States Code (U.S.C.) 253a, Public Contracts, Planning and Solicitation Requirements.
Federal Acquisition Regulation (FAR)15.605, Source Selection, Evaluation Factors and Subfactors.
ISO 14001, Environmental Management Systems.
Code of Environmental Management Principles for Federal Agencies (CEMP), U.S. EPA, September 1996.
How to Measure Performance, A Handbook of Techniques and Tools, U.S. DOE, TRADE 1995.

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INSTRUCTION

The familiar level of this module is divided into two sections that cover the two volumes of the Order. We have provided several examples throughout the module to help familiarize you with the material. The practice at the end of this module is required and will help prepare you for the criterion test.

Before continuing, you should obtain a copy of DOE G 450.4-1B, volumes I and II. Copies of these documents are available on the Las Alamos National Laboratory Web site at http://iosun.lanl.gov:1776/htmls/directives.html or through the course manager. It is not necessary to obtain copies of all the resources listed for this module. However, you should be familiar with these resources. You may need to refer to these documents to complete the examples, practice, and criterion test.

SECTION 1 – ISMS INTEGRATION AND PRODUCTS

PURPOSE

This Guide has two purposes. One purpose is to assist DOE contractors in developing, describing, and implementing an ISMS to comply with DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line Environment, Safety, and Health Oversight; DOE P 450.6, Secretarial Policy Statement Environment, Safety and Health; DOE P 411.1, Safety Management FRAM; and the following provisions of the DEAR:

- 48 CFR 970.5223-1, which requires integration of environment, safety, and health into work planning and execution;
- 48 CFR 970.5204-2, which deals with laws, regulations, and DOE directives; and
- 48 CFR 970.1100-1, which requires performance-based contracting.

A second purpose of this Guide is to assist DOE line managers and contracting officers (COs) who:

- provide ISMS guidance and requirements,
- review and approve ISMS products,
- verify implementation of the ISMS, and

- perform various integrating activities (e.g., planning, budgeting, review, approval, and oversight) that complement or are required for the ISMS.

OBJECTIVE

The objective of an ISMS is to incorporate safety into management and work practices at all levels, addressing all types of work and all types of hazards to ensure safety for the workers, the public, and the environment. In the ISMS Guide, the term "safety" is used to encompass environment, safety, and health.

GENERAL ASPECTS OF INTEGRATION

To develop and implement an ISMS, an organization must integrate safety into all aspects of work planning and execution. Integration means that all management systems and programs are designed to fit together to permit safe and efficient performance of work. Safety should be incorporated as a value into all business and operations systems.

Other factors that affect ISMS integration include:

- the relative responsibilities of DOE and contractor personnel;
- business processes, such as budget and resource allocation;
- the type of contract in place;
- the nature of the hazard; and
- the scope of the threat posed by the hazard.

All safety control measures, programs, and processes flow down and must be implemented at the appropriate work level to achieve adequate safety.

Figure 1 illustrates the layered structure that characterizes an ISMS. Each circle represents a single organizational level; that is, the institution or site level, the facility level, and the activity level. Individuals at each level of the organization play a role in work and safety planning. The ISMS core safety functions illustrated in figure 1 are integrated activities at each level of the organization.

- At the facility and activity levels, workers are essential in identifying and implementing controls and performing work.

- At the facility level, multiple activities are defined and the work is planned and integrated so as not to delay, interfere, or hinder other activities. The results of this lower-tier integration feed back to higher tiers in the line management chain for integration with other programs.
- At the institutional or facility level, the scope of work is defined using input from DOE (via contracts) and from the lower-level line managers and facility workers who have detailed knowledge of the work activities.

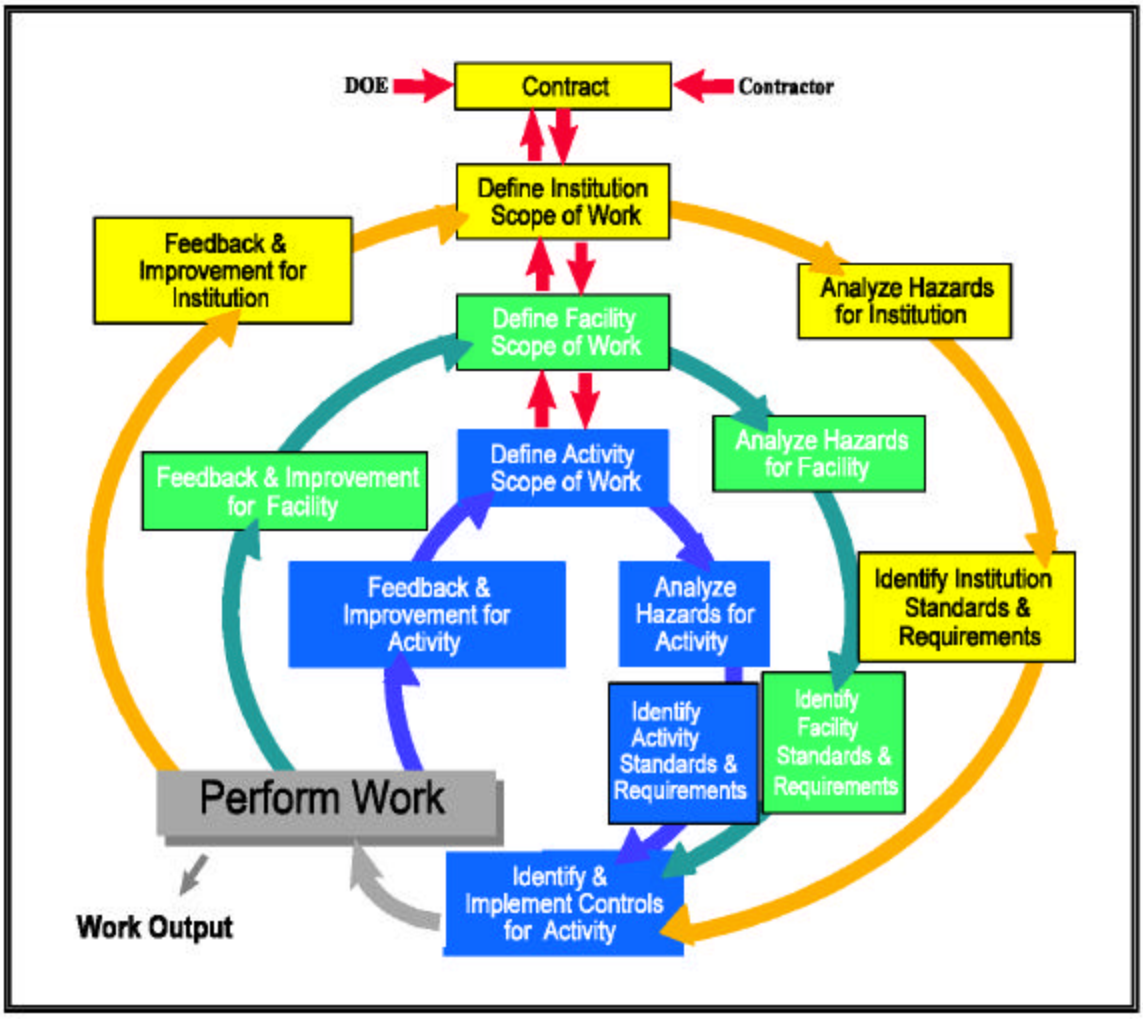


Figure 1. *An illustration of major interactions between organizational levels for the five SMS core functions.*

Figure 2 shows how site-wide activities overlay the facility, activity, and work for a Hazard Category 2 facility.

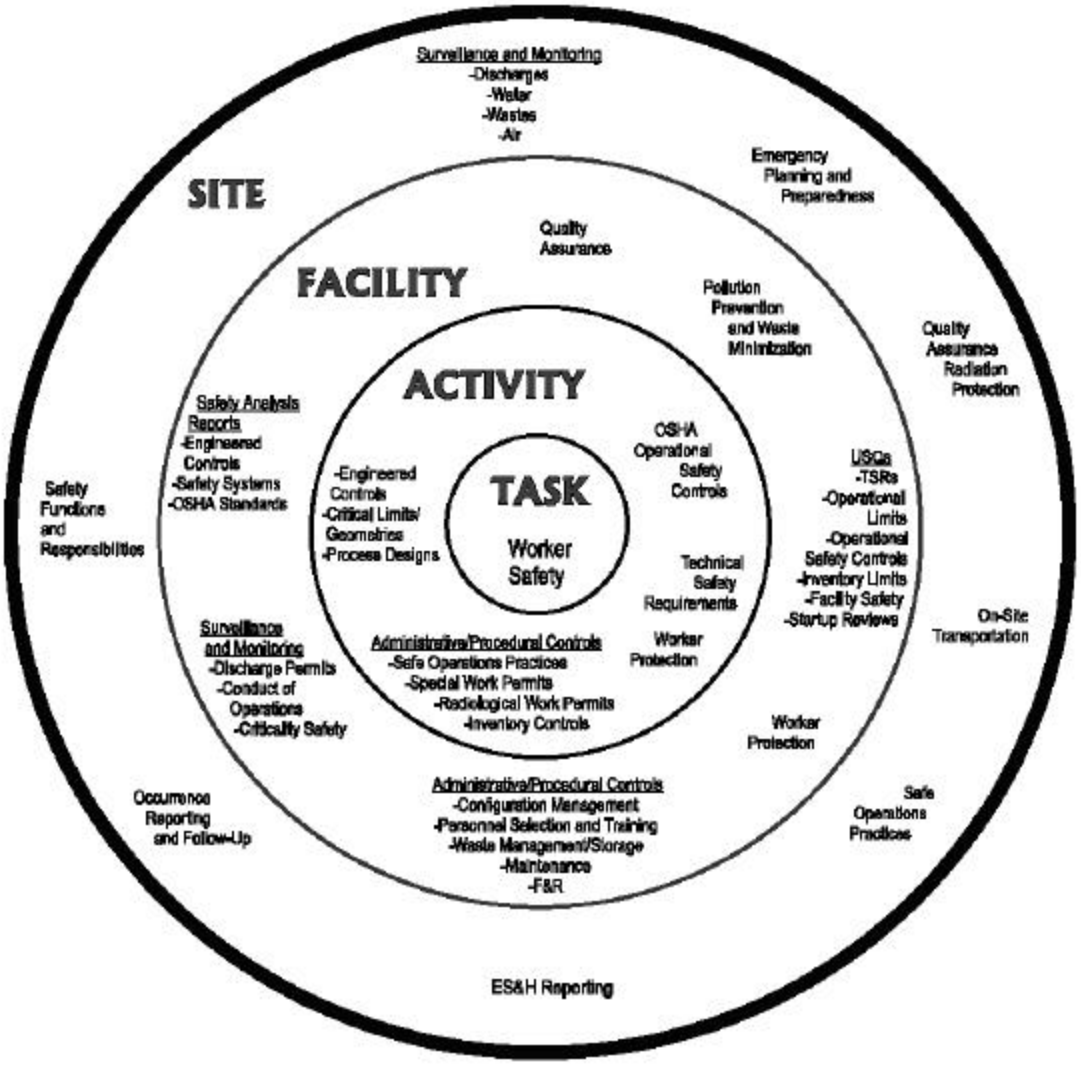


Figure 2*. An illustration of safety management programs and controls at various organizational levels for a Hazard Category 2 nuclear facility.*

INTEGRATION OF DOE AND CONTRACTOR ROLES

Another aspect of integration is the complementary nature of DOE and contractor responsibilities in ensuring integration of safety. Contractor responsibilities are typically defined in the DEAR contract requirements and are incorporated in the contract, corporate policies, and manuals. Application of these documents is outlined in the contractor's ISMS description.

Although the DEAR specifies some DOE responsibilities, most are described in the FRAM. Every organization in DOE is responsible for establishing a document specifying how its functions and responsibilities, as assigned in the FRAM, are discharged.

INTEGRATION OF SAFETY AND BUSINESS PROCESSES

Determining budget and resource allocations necessary to provide safe operations must be integrated with DOE's and the contractor's annual planning and budget cycle. A first step is to translate missions into work requirements in conjunction with the prioritization of budget and resources. By performing work analysis and budget formulation together, DOE can estimate the funding required for safety analysis and the control of hazards associated with the task.

INTEGRATION BY TYPE OF RISK AND HAZARD

Integration allows for the effective and efficient management of risk to workers, the environment, and the public. It is DOE line management's responsibility to ensure that contractors:

- develop and implement an ISMS tailored to the risk of the work and the associated hazards and
- develop and integrate their safety management systems with the business and operational systems throughout their organizations.

The integration process must address all hazards and the possible risks these hazards may present to workers, the public, and the environment. Individuals responsible for engineering the processes should work with multidisciplinary teams who have direct responsibility for analyzing hazards, identifying control measures derived from that

analysis, and ensuring those measures are effective. Similarly, individuals responsible for operations should have direct responsibility for the safety of those operations and should be given the resources to implement the necessary controls.

INTEGRATION OF RISK (WORKER, PUBLIC, AND THE ENVIRONMENT)

Systems for worker safety, industrial hygiene, medical services, radiation worker protection, safeguards and security, emergency response, emissions control, waste management, public safety, and environmental protection perform effectively and efficiently when they are integrated.

An ISMS provides the structure by which specific activities can be carried out by different organizations while adopting a uniform approach to protecting the workers, the public, and the environment. At the same time, an ISMS allows an organization the flexibility to adapt and improve systems without jeopardizing the needs, priorities, and missions of other, interfacing organizations.

Worker Safety

When worker safety is managed as a vital and valued part of an ISMS, managers and workers gain ownership in the process. Consequently, work can be conducted safely and work processes can be continuously improved. To be successful, however, a viable worker safety system requires commitment from managers and meaningful involvement of workers.

Public Safety

Integrating public safety into operations requires increased and intentional management awareness and commitment. Work planning must include the consideration of its possible impact on public safety. Every impact that is identified must be managed as a hazard to worker safety would be managed, and subjected to the same responsibility and accountability as part of an integrated safety management system.

Environmental Protection

Threats to the environment are addressed through environmental assessments (EAs) or environmental impact statements (EISs), which are required by NEPA (National Environmental Protection Act, 10 CFR 1021).

Environmental management systems (EMSs) used by the federal government should be integrated with the ISMS. An EMS is that part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy. A discussion of EMSs is provided in DOE/EH-0573, Environmental Management Systems Primer for Federal Facilities.

An EMS provides the structure by which specific activities can be carried out efficiently and in a manner consistent with important organizational goals; an EMS also allows an organization the flexibility to adapt the system to its needs and priorities.

The EMS approach has its genesis in the same movement that created the quality management systems traditionally applied to manufacturing. The two predominant EMS documents are the CEMP and ISO 14001, Environmental Management Systems.

CEMP was developed by the Environmental Protection Agency (EPA) in response to Executive Order 12856, Federal Compliance with Right-to-Know Laws and Pollution Prevention Requirements, signed on August 3, 1993. EPA patterned the CEMP on the common critical elements of a comprehensive management system tailored to the environmental activities of an organization. CEMP uses a construct of five broad principles and underlying performance objectives as the basis for Federal agencies to move toward responsible environmental management. CEMP principles help ensure environmental performance that is proactive, flexible, cost-effective, integrated, and sustainable.

ISO 14001 provides a comparable EMS construct that is being implemented throughout the world. The guiding principles and core functions of an ISMS correspond to the elements of an EMS.

ISMS DEVELOPMENT AND IMPLEMENTATION PROCESSES AND PRODUCTS

DOE and the contractor should follow the steps outlined in the Guide to develop, review, approve, implement, and monitor an ISMS that is fully integrated with the work.

DEVELOP AND DOCUMENT THE ISMS ACCORDING TO THE REQUIREMENTS IN THE DEAR

The process for developing and documenting an ISMS is specified in the DEAR, 48 CFR 970.5223-1. It includes the following provisions:

- Each contractor manages and performs work according to a documented ISMS that fulfills all conditions in 48 CFR 970.5223-1(b) and (c).
- Each contractor submits its ISMS documentation to the CO for review and approval.
- The ISMS documentation shall also describe how the contractor will measure the system's effectiveness.
- The ISMS is integrated with the contractor's business processes for work planning, budgeting, authorization, execution, and change control.

REVIEW AND APPROVE THE ISMS AS REQUIRED BY THE DEAR AND ACCORDING TO THE DOE RESPONSIBILITIES IN THE FRAM

DOE personnel must review and approve ISMSs according to the DEAR 48 CFR 970.5223-1(e) and the FRAM. The process for implementing review and approval is discussed in chapter III, section 3, and in Appendix E of the Guide. Additionally, the Office of the Deputy Assistant Secretary, Oversight (EH-2), performs oversight of DOE safety management functions.

EVALUATE THE ISMS IMPLEMENTATION

The contractor should ensure that its approved ISMS description has been implemented. This is done with the CO-implemented review and approval. Additional ISMS reviews are done according to DOE P 450.5, Line Environment, Safety, and Health Oversight. DOE evaluates implementation of the ISMS according to the DEAR and the FRAM. This

evaluation is an effective process for ensuring the contractor's ISMS is integrated and working as described in the ISMS documentation.

MONITORING AND ANNUAL UPDATING OF THE ISMS ACCORDING TO THE REQUIREMENTS IN THE DEAR

On an annual basis, the contractor shall review and update, for DOE approval, its safety performance objectives, performance measures, and commitments consistent with and in response to DOE's program and budget execution guidance and direction.

Work processes and organizational safety management performance should be measured and evaluated continuously to ensure that line management is aware of the contractor's compliance with the documented ISMS. Accordingly, DOE and contractor organizations perform management and independent assessments using quantitative and/or qualitative information obtained from a variety of sources. Because such evaluations are conducted at all organizational levels, they contribute to safety management integration. Improvement actions identified are shared with similar organizations and are tracked throughout implementation to determine if they are yielding the anticipated improvements. Evaluation reports that document the process followed, the results, and measurements indicating the success of the improvements, are parts of the ISMS.

TAILORING THE ISMS

Because work can range in complexity and hazard potential from high-hazard operations in major facilities to much simpler tasks, DOE safety management directives are structured to address a variety of hazardous operations. Tailoring is directed at developing safety controls to fit the hazards and the work. Through tailoring, existing guidance and safety management processes can be selectively applied to planned work activities to meet applicable, enforceable requirements while adequately protecting health, safety, and the environment. The DEAR environment, safety, and health (ES&H) clause states that administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work and associated hazards. To meet this requirement, DOE and contractor personnel at all levels should not only tailor their ISMSs, but should also evaluate the effectiveness of their work management systems to continuously improve system performance.

Work management systems must deal effectively with a full spectrum of work types and work activities. A successful ISMS should ensure high-quality work and compliance with predetermined performance expectations, while continuously ensuring that work is conducted in an environmentally sound, safe, and healthy way.

DOE G 450.3-3, Tailoring for Integrated Safety Management Applications, provides guidance for tailoring an ISMS and its core functions.

Note: You do not have to do example 1 on the following pages, but it is a good time to check your skill and knowledge of the information covered. You may do example 1 or go to section 2.

EXAMPLE 1

Using the familiar level of this module and the resources, complete the following exercises.

1. State in your words the purpose and objective of DOE G 450.4.

2. List three factors that affect ISMS integration.

3. Define integration as it applies to an ISMS.

Note: When you are finished, compare your answers to those contained in the example 1 self-check. When you are satisfied with your answers, go to section 2.

EXAMPLE 1 SELF-CHECK

1. State in your words the purpose and objective of DOE G 450.4.

   This Guide has two purposes. One purpose is to assist DOE contractors in developing, describing, and implementing an ISMS to comply with DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line Environment, Safety, and Health Oversight; DOE P 450.6, Secretarial Policy Statement Environment, Safety and Health; DOE P 411.1, Safety Management FRAM; and the following provisions of the DEAR:

   - 48 CFR 970.5223-1, which requires integration of environment, safety, and health into work planning and execution;
   - 48 CFR 970.5204-2, which deals with laws, regulations, and DOE directives; and
   - 48 CFR 970.1100-1, which requires performance-based contracting.

   A second purpose of this Guide is to assist DOE line managers and COs who:

   - provide ISMS guidance and requirements,
   - review and approve ISMS products,
   - verify implementation of the ISMS, and
   - perform various integrating activities (e.g., planning, budgeting, review, approval, and oversight) that complement or are required for the ISMS requirements.

   The objective of an ISMS is to incorporate safety into management and work practices at all levels, addressing all types of work and all types of hazards to ensure safety for the workers, the public, and the environment. In the ISMS Guide, the term "safety" is used to encompass environment, safety, and health.

2. List three factors that affect ISMS integration.

   - The relative responsibilities of DOE and contractor personnel
   - Business processes such as budget and resource allocation
   - The type of contract in place

- The nature of the hazard
- The scope of the threat posed by the hazard

3. Define integration as it applies to an ISMS.

   Integration means that all management systems and programs are designed to fit together to permit safe and efficient performance of work.

SECTION 2 – ISMS CORE FUNCTIONS AND GUIDING PRINCIPLES

This section describes the seven guiding principles and five core functions of the ISMS.

GUIDING PRINCIPLES 1, 2, AND 3

The following three guiding principles relate to all five core functions:

- line management responsibility for safety,
- clear roles and responsibilities, and
- competence commensurate with responsibilities.

These interrelated guiding principles help ensure the management structure has personnel who focus on the safe accomplishment of mission, understand their assignments, and can carry out the core safety management functions correctly and efficiently.

To be used effectively, these principles depend on management commitment and employee involvement. Management commitment can be demonstrated by the following actions:

- Management communicates the documented ISMS and policy statements throughout the organization.
- Managers are held accountable for safety performance.
- Managers are visibly present, addressing safety issues.
- Managers invite and encourage employees at all levels to participate in development and implementation of the ISMS.
- Managers emphasize the importance of individual accountability for performing work safely.

LINE MANAGEMENT RESPONSIBILITY FOR SAFETY

The Guide discusses responsibility for safety for DOE's and the contractor's line management.

DOE Responsibilities

The FRAM specifies the DOE safety management functions, with clear lines of responsibility and authority that are necessary to:

- define essential safety management functions;
- ensure compliance with legal and contractual requirements; and
- implement the standards to provide assurance that workers, the public, and the environment are adequately protected.

Line management includes any management level in the line organization that is responsible and accountable for directing and conducting work.

Contractor Responsibilities

Contractor line management is responsible for ensuring that work is performed in a manner that ensures adequate protection for employees, the public, and the environment. Line management includes those contractor and subcontractor employees managing or supervising employees performing work.

CLEAR ROLES AND RESPONSIBILITIES

DOE Responsibilities

The FRAM addresses the second guiding principle, Clear Roles and Responsibilities, as follows:

- Clearly delineate management and safety responsibilities for approving the contractor's ISMS and other binding agreements that implement the ISMS.
- Clarify the roles, responsibilities, lines of authority, and delegations between Headquarters and field organizations.
- Define functional relationships and responsibilities among DOE line, support, oversight, and enforcement organizations.
- Address the coordination of line management direction from multiple program offices at a single site.

Contractor Responsibilities

The DOE quality assurance rule (10 CFR 830.120) applies to contractors operating DOE nuclear facilities. In addition, DOE O 414.1A, Quality Assurance, is a contractual requirement for many DOE contractors. The CFR and the Order contain specific requirements for documenting the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The contractor's description of its ISMS organization should clearly define roles and responsibilities by specifying how contractor functions are to be carried out and identifying who has the responsibility and authority to carry out those functions. Additionally, the description should address contractor flow down to subcontractors and suppliers, which is required by DEAR 970.5223-1. Contractors are responsible for ensuring subcontractors are held accountable for ES&H requirements by:

- specifying ES&H requirements pertinent to the work scope in the request for proposals,
- specifying ES&H requirements in the contract language,
- providing daily oversight of the subcontractor's performance of work by a subcontract technical representative,
- ensuring that safety and health representatives oversee the work site,
- providing site-specific training to subcontractors, and
- ensuring that safety professionals review and approve all safety plans and hazard communication programs before the start of any project.

COMPETENCE COMMENSURATE WITH RESPONSIBILITIES

DOE Responsibilities

The FRAM addresses the third guiding principle, Competence Commensurate with Responsibilities, by assigning each DOE element the responsibility for ensuring that its employees are qualified to perform their assigned functions. The Assistant Secretary for Management and Administration (MA-1) is assigned responsibility for assisting DOE line managers in recruiting and retaining highly qualified technical personnel.

Contractor Responsibilities

Federal Acquisition Regulation (FAR) 15.605 and 41 United States Code (U.S.C.) 253a require that evaluation factors be used to select DOE contractors. FAR 15.605 also cites management capability and personnel qualifications as factors that must be evaluated.

Accordingly, contractor management determines the basis for selecting individual qualifications for specific position/job responsibilities. Qualifications and capabilities are provided via position and job descriptions, résumés of key personnel, or other, similar descriptions.

CORE FUNCTION, 1 DEFINE THE SCOPE OF WORK, AND GUIDING PRINCIPLE 4, BALANCED PRIORITIES

DOE and the contractor identify and prioritize work and allocate resources. The contractor's role in this core function is to translate broad missions into specific work packages. DOE provides performance expectations through strategic plans, goals, and objectives.

A fundamental objective of Core Function 1, Define the Scope of Work, is to identify the scope, schedule, and costs of activities required to achieve DOE missions and expectations in a safe and environmentally sound manner.

DESCRIBING THE WORK

The responsible manager is accountable for understanding as completely as possible the work to be done through every phase of the work cycle:

- Inception
- Development and planning
- Work conduct
- Shutdown

DOE and contractor line management should establish formal processes for translating DOE mission statements into a scope of work. These processes should be used to establish expectations for satisfactorily accomplishing the work, prioritizing tasks, and allocating resources. DEAR 970.5223-1(b)(4) requires resources to be effectively allocated to address ES&H, programmatic, and operational considerations to ensure that DOE attends to its most significant hazards first, in a cost-effective manner.

ESTABLISHING PRIORITIES

Protecting the public, workers, and the environment is a top priority whenever the Department plans and performs work. Critical to this objective is providing adequate resources and ensuring that those resources are effectively allocated. Each organizational

level should establish a method for ensuring a proper balance among competing priorities of the organization.

In addition to Guiding Principle 4, Balanced Priorities, which demonstrates the Department's focus on prioritization, DEAR 970.5223-1(b)(4) provides guidance for balancing priorities, as does DOE-DP-STD-3023-98, DOE Limited Standard, Guidelines for Risk-Based Prioritization of DOE Activities.

CORE FUNCTION 2, ANALYZE HAZARDS

The objective of hazards analysis is to develop an understanding of the potential for the hazard to affect the health and safety of the worker, the public, and the environment. The analysis includes two steps:

- identifying and categorizing the hazard, and
- analyzing accident scenarios related to hazardous work.

Two types of analysis methods commonly used by industry for evaluating hazards at the facility and task level are the process hazard analysis (PHA) and the job hazard analysis (JHA). A JHA is a basic and widely used tool for analyzing and reviewing operations and procedures to identify potential worker protection hazards and deficiencies and can satisfy a significant portion of the worker-protection hazard-identification requirements at most workplaces. These hazard analyses are performed by experienced teams of hazard analysts, facility and systems engineers, process operators, human factors engineers, and facility workers. These may include safety professionals and technicians in specialties such as hazard analysis, radiological protection, chemical process safety, industrial hygiene, and occupational safety. Regulatory and contractual requirements applicable to the work and the complexity and hazard of the work will dictate the methods the contractor uses to analyze hazards. This illustrates the importance of the relationship between the core functions of defining the scope of work and analyzing hazards, which lead to Core Function 3, Develop and Implement Controls.

CORE FUNCTION 3, DEVELOP AND IMPLEMENT CONTROLS; GUIDING PRINCIPLE 5, IDENTIFICATION OF SAFETY STANDARDS AND REQUIREMENTS; AND GUIDING PRINCIPLE 6, HAZARD CONTROLS TAILORED TO WORK BEING PERFORMED

The terms and conditions that define DOE safety expectations for its contractors are set forth as contract requirements. DEAR 970.5204-2 requires the contractor to comply with the requirements of applicable federal, state, and local laws and regulations in developing and implementing controls. DOE has identified safety requirements in rules and Orders and has developed technical standards, guides, and manuals.

IDENTIFICATION OF APPROPRIATE STANDARDS

ES&H requirements appropriate for work conducted by a contractor may be determined using a DOE-approved process to:

- evaluate the work and the associated hazards;
- identify an appropriate set of standards, practices, and controls.

When such a process is used, the set of ES&H requirements must be reviewed for adequacy and approved by the CO. These approved processes may also be used to identify standards that are specific to facilities or activities. Approved controls for establishing ES&H requirements include the following:

- incorporation of a Standards/Requirements Identification Document into the contract,
- use of the Work Smart Standards Processes,
- compliance with DOE directives and other applicable laws and regulations.

A multidisciplinary hazard analysis team should tailor the set of standards that apply to the work at each management level. These standards should be commensurate with the hazards involved, per Guiding Principle 5. To achieve this objective, DOE and contractor line management identify laws, statutes, and federal regulations that apply. DOE and contractor line management should establish any additional requirements required to ensure adequate safety. These requirements may be derived from DOE directives, DOE technical standards, or national consensus standards.

The ISMS should also incorporate a process to identify engineering, administrative, and personal protective equipment controls and pollution prevention/waste minimization options. These controls should be tailored to the work and the associated hazards, according to Guiding Principle 6. The controls should encompass all aspects of the work and each phase of work performance. Emphasis should be on designing the work and/or controls to reduce or eliminate the hazards and to prevent accidents and unplanned releases and exposures. Operation-specific controls tailored to the hazards become contractual terms and conditions for performing the work. DOE and contractor agreement on the safety envelope is required as a condition for authorizing operations to proceed.

Once a set of controls has been established, processes should be provided for maintaining work performance within the safety envelope. A process to review, approve, and provide change control of the safety envelope should exist.

CORE FUNCTION 4, PERFORM WORK, AND GUIDING PRINCIPLE 7, OPERATIONS AUTHORIZATION

PERFORM WORK

DOE and the contractor identify and implement safety controls before starting to work. Once work begins, it is performed according to those safety controls. DEAR 970.5223-1(b)(7) requires that DOE and the contractor establish and agree on the conditions and requirements for operations. These conditions and requirements are included in the contract. The formality and rigor of the review process and the extent of documentation and level of authority for agreement should be based on the hazard and complexity of the work.

DOE O 425.1, Startup and Restart of Nuclear Facilities, provides readiness guidance for nuclear facilities. An independent assessment or DOE review should be required. Internal or external oversight groups, review teams, and audit organizations should evaluate the process to identify and correct deficiencies. The process should ensure corrective actions are effective in establishing a state of readiness. Examples of methods used by DOE and contractors to confirm readiness include readiness assessments (RAs), operational readiness reviews (ORRs), and Title III inspections. Guiding Principle 7 and the DEAR require that conditions must be agreed on and established before operations are started.

These agreed-upon conditions and requirements are contractual and binding on the contractor. The extent of documentation and level of authority for agreement shall be tailored to the complexity and hazards associated with the work and shall be established in an ISMS.

The QA Rule, 10 CFR 830.120, Quality Assurance, and DOE O 414.1A, Quality Assurance, requires that work be performed according to established technical standards and controls. For certain site-wide systems and activities, such as fire protection, emergency planning, and operator training, readiness may be confirmed periodically.

Authorize Work

DOE and the contractor should formally agree on the need for authorization agreements for those nuclear and significant hazard facilities that must perform work safely without any undue risk to the worker, the public, and the environment. The contractor's ISMS should identify the roles of the contractor and DOE in authorizing work at appropriate levels. Understanding DOE and contractor roles with respect to authorizing work and changes to the work is essential for successful implementation of the ISMS. The following discussion on authorization protocol and authorization agreements provides elementary information and guidance for consideration in the development of contractor ISMSs.

Authorization Protocol

The DOE FRAM defines authorization protocols as those processes used to communicate acceptance of the contractor's integrated plans for hazardous work. Such protocols are expected to range from preperformance review and approval by DOE of detailed safety-related terms and conditions for performing work (authorization agreement) to less rigorous oversight and postperformance assessment of the contractor's work.

These protocols should be included in the contractor's ISMS description and should clarify the understanding and agreements between the contractor and the Department in performing hazardous work.

Authorization Agreement

An authorization agreement is a contractually binding agreement between DOE and the contractor for predetermined hazardous facilities, tasks, or activities. The DOE FRAM defines an authorization agreement as a documented agreement between DOE and the contractor for high-hazard facilities, incorporating the results of DOE's review of the contractor's proposed authorization basis for a defined scope of work. The authorization agreement contains essential terms and conditions under which the contractor is authorized to perform the work. Any changes to these terms and conditions would require DOE approval. The need for an authorization agreement depends on the organization and adequacy of the existing, contractually binding documentation. The Department and the contractor should ensure that the ISMS includes procedural mechanisms that trigger a review to determine the necessity of having, revising, or eliminating an authorization agreement.

Sample Format and Content for Authorization Agreements

The following sample format and content may be useful for documenting an authorization agreement.

Scope of the Agreement

This section should describes the work being authorized and the facility or facilities where the work is to be performed. It should be consistent with the work analyzed in the authorization basis and the controls established.

DOE Basis for Approval

This section should include the basis for DOE approval to perform the work and the basis for its conclusion that the work defined in the agreement can be performed without undue risk to the worker, the public, and the environment. This section should include the essential reviews and assessments that form the basis of DOE approval. Typical examples include DOE issuance of a safety analysis report (SAR); review and approval of a SAR; reviews and approvals of technical safety requirements (TSRs), ORRs, or assessments; approval of the list of requirements required by the DEAR laws

clause; and approval of the contractor's ISMS description according to the DEAR ES&H clause.

Listing of Documents that Constitute the Authorization Basis

This section should include a summary listing of essential documents such as SARs, the basis for interim operation, NEPA documentation including EIS, and environmental permits.

Terms and Conditions

This section should specify contractor commitments to assure DOE that the authorized work will be performed safely. The process used to keep the authorization agreement current should be described. Essential terms and conditions requiring DOE review and approval need to be identified in this section. This may include specific implementation procedures or manuals of practice. Other terms and conditions may only require DOE notification and review if deemed appropriate. Examples of terms and conditions include the following:

- controls identified in TSRs;
- commitments to a configuration management program, including an unreviewed safety question (USQ) process;
- commitments to a process for reporting noncompliances with established controls or terms of the authorization agreement. This process would include any special actions to be taken if an unplanned event were to occur.

Contractor Qualification

This section should make a positive statement about DOE's confidence in the contractor's ability to safely perform the work identified in the agreement.

Special Conditions

This section should cover any other special conditions that DOE wants to make contractually binding. Such conditions may include aspects of environmental management, safeguards and security, and protection of property.

Effective Date and Expiration Date

This section should include the duration of the agreement and the schedule for re-negotiation, review, or extension.

Statement of Agreement

This section would include signatures of the agreeing parties and the dates with the typed names below the signature line.

Exceptions (if required)

This section would identify any specific exceptions or unusual circumstances that should be noted. For example, at Rocky Flats, authorization agreements might address appropriate liability and the understanding between DOE and the new contractor regarding less than fully analyzed bases for controls.

Sample Authorization Agreements and Checklists

Samples of authorization agreements are on the ISMS home page (http://tis-nt.eh.doe.gov/ism). A sample checklist for authorization agreements is included in the Guide, volume I, in section 5.3.

CORE FUNCTION 5, FEEDBACK AND IMPROVEMENT

Feedback and improvement complete the ISMS loop by connecting practical experiences of work conducted to planning for future work. The feedback and improvement function is intended to:

- identify and correct processes or deviations that lead to unsafe or undesired work outcomes,
- confirm that the desired work outcomes were obtained safely, and
- provide managers and workers information to improve the quality and safety of subsequent similar work.

Note: You do not have to do example 2 on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do example 2 or go to section 3.

EXAMPLE 2

1. List the ISMS core functions and guiding principles.

2. State the objective of a hazards analysis.

3. Describe an approved process for establishing ES&H requirements as discussed in section 4.1 of the Guide.

Note: When you are finished, compare your answers to those contained in the example 2 self-check. When you are satisfied with your answers, go to section 3.

EXAMPLE 2 SELF-CHECK

1. List the ISMS core functions.

   - Define the scope of work
   - Analyze hazards
   - Develop controls
   - Perform work
   - Feedback

2. State the objective of a hazard analysis.

   The objective of a hazard analysis is to develop an understanding of the potential for the hazard to affect the health and safety of the worker, the public, and the environment.

3. Describe an approved process for establishing ES&H requirements as discussed in section 4.1 of the Guide.

   - Incorporation of a Standards/Requirements Identification Document into the contract
   - Use of the Work Smart Standards Processes
   - Compliance with DOE directives and other applicable laws and regulations

SECTION 3 – ISMS DEVELOPMENT, IMPLEMENTATION, REVIEW, AND APPROVAL

This section provides guidance on development, implementation, review, and approval of an ISMS. This guidance is based on the ISMS policies, the DEAR, and the FRAM.

CONTRACTOR ACTIONS TO DEVELOP AN ISMS

The existing ISMSs used by DOE and its contractors include a number of sound procedures and manuals of practice that have been proven over many years. DOE does not intend the DEAR clauses to change these proven safety practices. The objective is to provide the contractor with tools to improve the integration of these practices and ensure that the seven ISMS principles and five core functions provide the foundation for safety management practices.

EVALUATION OF EXISTING SYSTEMS

Experience has demonstrated the value of reviewing the existing procedures and manuals before instituting any changes or attempting to describe how the existing ISMS satisfies the DEAR requirements. The contractor should first identify the complete set of safety programs at the facility or site. These programs are typically described in facility- or site-wide policy statements and are implemented using facility- or site-wide procedures and/or manuals of practice. The following procedures and programs should be identified as part of this initial effort:

- Defining work plans
- Identifying hazards
- Defining and implementing hazards controls
- Developing and implementing operating procedures
- Performing work
- Monitoring and assessing performance for improvement

Subsequently, the facility- or operation-specific manuals of practice should also be identified for major facilities with procedures and practices unique to their operations.

GAP ANALYSIS

As the complete set of programs is identified, it is necessary to objectively analyze the programs to determine which of the seven guiding principles and five core functions are addressed by the various procedures and manuals of practice. Accordingly, ISMS developers use a gap analysis to ensure integration and to identify missing or weak elements.

IMPLEMENTATION

This section lists several functions in the FRAM that DOE and the contractor must perform to support implementation of an ISMS. Additional information is available in the FRAM and section 3.1 of the Guide.

DOE ACTIONS REQUIRED TO SUPPORT IMPLEMENTATION OF ISMS

Core Function 2, Analyze Hazards

Identify and Analyze Hazards (FRAM 9.3.1)
Categorize Hazards (FRAM 9.3.2)

Core Function 3, Develop Controls

Identify Standards and Requirements (FRAM 9.4.1.1)
Identify Controls to Prevent/Mitigate Hazards (FRAM (9.4.2)
Establish Safety Controls (FRAM 9.4.3)
Implement Controls (FRAM 9.4.4)

Core Function 4, Perform Work

Confirm Readiness (FRAM 9.5.1)
Perform Work Safety (FRAM 9.5.2)

Core Function 5, Feedback and Improvement

Collect Feedback Information (FRAM 9.6.1.1 and 9.6.1.2)
Identify Improvement Opportunities (FRAM 9.6.1.3)
Make Changes to Improve (FRAM 9.6.2)

CONTRACTOR ACTIONS TO IMPLEMENT ISMS

Preparing ISMS Documentation

The DEAR requires that the ISMS be documented. To a large extent, the required documentation may consist of the contractor's corporate procedures and manuals of practice used to perform work. Additionally, a database may also be compiled based on information from the existing procedures and manuals of practice and a gap analysis.

Generally, the ISMS description identifies existing policies, procedures, manuals of practice, and other contractor ISMS mechanisms. Additionally, many contractors have found it beneficial to provide details on the overall ISMS philosophy or vision, the implementation mechanisms, and the integrating mechanisms. Most contractors have organized their ISMS descriptions to reflect the core functions and guiding principles.

Identifying and Describing Procedures and Manuals of Practice

As part of the ISMS implementation process, the contractor should review and evaluate existing policy manuals, procedure manuals, and workplace instructions. Some of these will be site-wide documents while others will be specific to a facility or work activity. The documentation of interest includes business procedures and practices that allocate resources and prioritize work and instructions to protect the public, worker, and environment. This set of documentation currently exists at most sites and facilities, but may not be readily identified with the DOE functions and principles required in an ISMS.

Describing Integrating Mechanisms

Documented procedures and practices do not inherently produce the integration that DOE expects. A number of mechanisms may be incorporated into the ISMS to encourage integration. Specific business and work procedures may be used to support the integration. Some organizations use regularly scheduled subject area meetings at various levels of the

organization to encourage integration and information exchange. Such councils can be part of the documented business practices in the ISMS. Other integration mechanisms may include site-wide maintenance manuals, site-wide safety meetings, and safety boards. Reviews and assessments, programmatic and site-wide, and feedback of lessons learned to all programs are mechanisms that contribute to integration. Although DOE-STD-1120 is written for disposition activities, it provides guidance and examples for integrating planning, hazards analysis, and controls, and the methodology is applicable to other parts of the facility life cycle.

Contractors with complex nuclear facilities have found it necessary to form integrating mechanisms to meet the intent of the ISMS Policy. They have established boards or panels that report to line management and have the responsibility to provide advice, expertise, and/or approval as appropriate on ES&H integration issues. Some contractors have found it useful to pilot new integrating mechanisms at one facility to work the bugs out before implementing it site-wide.

ISMS ATTRIBUTES

The attributes listed below summarize DOE expectations for the overall performance and documentation of the contractor's ISMS.

- The ISMS is consistent with the DOE Policies, DEAR Requirements for Integrated Safety Management, and direction from the heads of contracting activities (HCA) to the contractor.
- The ISMS description indicates how the contractor will evaluate and improve the effectiveness of the ISMS.
- The ISMS description indicates how performance objectives and performance measures are established in response to DOE program and budget guidance.
- The contractor directs, monitors, and verifies implementation of the ISMS as described in the system description.
- Implementation and integration expectations and mechanisms are evident throughout all organizational functions and across all organizations from the site to the individual activities.

- The contractor has assigned responsibilities and established the mechanisms to ensure that the ISMS is maintained and that the annual update information is prepared and submitted.

EXPECTATIONS AND ATTRIBUTES OF ISMS DOCUMENTATION

This section describes the expectations and attributes of a contractor's ISMS for the benefit of those who must prepare the ISMS documentation and for reviewers who must evaluate the adequacy of the ISMS. The list of expectations provides summary descriptions of ISMS performance with respect to the ISMS core functions and principles. The attributes identify specific criteria that can be used to guide development and evaluation of an ISMS.

Responsibilities for review and approval of ISMS are specified in DOE M 411.1-1, Safety Management Functions, Responsibilities, and Authorities, which makes the HCA responsible for approving the ISMS description and revisions. HCA responsibilities are normally assigned to the manager of the cognizant DOE operations office, who is generally known as the approval authority.

EXPECTATIONS FOR CORE FUNCTION 1, DEFINE SCOPE OF WORK, AND GUIDING PRINCIPLE 4, BALANCED PRIORITIES

DOE establishes a set of processes to ensure that the scope of work is adequately reviewed and that interactions with the contractor proceed efficiently and effectively.

Translate Mission into Work

An ISMS should include a process to identify the activities necessary to accomplish the assigned mission and a process to develop these activities into discrete tasks. DOE uses strategic plans, goals, objectives, and mission statements to define the contractor's broad work assignments. The contractor uses these assignments to prepare its work.

Set Expectations

An ISMS should include processes for establishing performance goals that address safety objectives and the work assignments for the site. Such processes should include DOE budget execution guidance and employee performance reviews and appraisals.

Provide for Integration

The DEAR ES&H clause [48 CFR 970.5223-1(b)(6)] and DOE P 450.4, Safety Management System Policy, require the integration of environment, safety, and health functions and activities including pollution prevention and waste minimization into work planning and execution. Integration should be evident throughout all organizational functions at all organizational levels from the site to the individual activity.

Prioritize Tasks and Allocate Resources

An ISMS should include processes for prioritizing and allocating work. To establish balanced priorities, a formal method should be employed (see chapter II, section 2 of the Guide). The necessary criteria for a quality risk-based prioritization method are described in DOE-DP-STD-3023-98, Guidelines for Risk-Based Prioritization of DOE Activities.

EXPECTATIONS FOR CORE FUNCTION 2, ANALYZE HAZARDS

In addition to the hazard identification and analysis performed to support line management, safety-related training and heightened safety awareness through structured worker programs should enable each worker to identify hazards in the workplace. It is important that workers know where to go and what to do should a new hazard be identified. Environmental, safety, and health professionals and line supervisors must be visible and available to assist workers in better understanding hazards in the workplace. Administrative controls should be established through the application of safe work standards and/or agreed-upon requirements to keep the workplaces safe. Workers must question their understanding of what the hazard controls are in each work area so that they fully understand the measures taken for their protection.

Identify Hazards

An ISMS includes processes for identifying hazards (e.g., nuclear, industrial, fire, external events, construction, environmental impact, etc.).

Analyze Hazards

DOE and other regulatory requirements are implemented as appropriate to the work, the type of hazard identified, and the magnitude of its risk.

Hazard analysis methods address all types of hazards (e.g., nuclear, industrial fire, external events, natural phenomena, construction, chemical, etc.).

Hazard analysis methods are applied to all types and stages of work (e.g., design, construction, normal operations, surveillance, deactivation, maintenance, facility modification, decontamination and decommissioning, etc.).

Categorize Hazards

An ISMS should include a process for categorizing hazards, such as that defined in DOE-STD-1027, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports; DOE O 430.1, Life-Cycle Asset Management and its associated guides; and DOE-STD-1120, DOE Standard Integration of Environment, Safety, and Health into Facility Disposition Activities, to provide special hazard identification and analysis methods that apply to facility disposition activities.

EXPECTATIONS FOR CORE FUNCTION 3, DEVELOP/IMPLEMENT HAZARD CONTROLS; GUIDING PRINCIPLE 5, IDENTIFICATION OF SAFETY STANDARDS AND REQUIREMENTS; AND GUIDING PRINCIPLE 6, HAZARDS CONTROLS TAILORED TO WORK BEING PERFORMED

Before work is performed, the associated hazards are evaluated and DOE and the contractor agree on a set of ES&H requirements that will provide adequate assurance that the public, the workers, and the environment are protected.

Identify Standards and Requirements

An ISMS should include processes to establish the set of ES&H requirements for the work consistent with the requirements of the DEAR (see 10 CFR 830.120, Quality Assurance). The process for identifying ES&H requirements should be one of the existing, accepted approaches. If a method or approach other than an existing, accepted one is proposed, the contractor should provide a description for DOE review and approval. The use of applicable laws, statutes, federal rules, national consensus standards, DOE directives, and DOE technical standards is described in chapter II, section 4.1 of the Guide.

Identify Controls to Prevent or Mitigate Hazards

An ISMS should include a process for identifying and tailoring administrative controls, safety controls, safety programs, and other conditions that affect work performed (Guiding Principle 6). The processes should use information obtained in the hazard analysis and define the requirements for each phase or discrete task of the planned work. Controls developed at the site level should be used as the basis for facility controls. DOE-STD-1120, DOE Standard Integration of Environment, Safety, and Health into Facility Disposition Activities, describes the process of developing detailed, task-level controls from the generic, site-level controls.

Establish Safety Controls

An ISMS should include a process to establish and document engineered controls, administrative controls, safety controls, safety programs, and other conditions that affect the work to be performed.

Implement Controls

An ISMS should provide a method to implement the controls identified at every level of work and hazard. The method should ensure that the controls remain in effect so long as the hazard is present. The method documents the procedures used by workers.

EXPECTATIONS FOR CORE FUNCTION 4, PERFORM WORK, AND GUIDING PRINCIPLE 7, OPERATIONS AUTHORIZATION

Confirm Readiness

An ISMS should include a process to confirm that the facility or process and the operational work force are in an adequate state of readiness before authorizing the work.

Operations Authorization

An ISMS should include a method for gaining authorization to conduct operations. Provisions should be included to grant operations authorizations for each level of effort at the site, facility, activity, or process. Such provisions or procedures may include an ORR, approval to resume operations following a weekend shutdown, and authorization to start individual procedures or work items using controls such as work clearance permits, shift orders, or shift manager's control. An ISMS should also include a method for updating and configuration control of the operations authorization documentation, such as authorization agreements, permits, and SARs.

Perform Work Safely

An ISMS should include processes for ensuring that safety requirements are integrated into work performance. Processes should be adequate to ensure that work is performed within the controls that have been developed and implemented. Controls may include site or facility commitments, such as conduct of operations and maintenance programs; worker safety programs; specified safety systems; or specific controls in work permits. The controls may be specified in site-level programs or facility-specific authorization basis documents. An ISMS should include provisions to ensure that ongoing work continues to be performed within the specified and agreed-upon controls.

Performance Measures

An ISMS should include a process to identify performance measures and indicators, including safety performance measures for the work.

EXPECTATIONS FOR CORE FUNCTION 5, FEEDBACK AND IMPROVEMENT

All aspects of an ISMS should be subject to continuous improvement through an assessment and feedback process that should function at each level of work and at every stage in the work process. To determine adequacy in execution of the ISMS, DOE and the contractor should establish and agree upon a set of objectives and criteria. When used in determining if implementation of the ISMS is adequate, these agreed-to objectives and criteria may support a determination of contractor fees. These objectives and criteria may also be useful in identifying those day-to-day performance indicators that can assist in continually evaluating the effectiveness of the ISMS. The feedback and improvement process includes the following:

- Feedback information on the effectiveness of the ISMS and the adequacy of controls is gathered.
- Opportunities for improving work execution and planning are identified and implemented.
- Line and independent oversight is conducted.
- Regulatory enforcement actions occur, as required.

Identify Improvement Opportunities

An ISMS should evaluate feedback and oversight information. Such an evaluation should include processes for translating this operational information into recommendations for improvement and processes for translating lessons learned from onsite and from other sites into recommendations for improvement. An ISMS description should include a worker suggestion program for improving safety.

Make Changes to Improve

An ISMS should contain processes for management to consider recommendations for improvement, including worker suggestions. The process should include provisions for translating feedback from assessments, lessons learned programs, external oversight and enforcement, and other inputs into improvements.

Oversight and Enforcement

An ISMS should include processes for oversight by contractor management. Interfaces for communication with external oversight organizations should also be included.

EXPECTATIONS FOR GUIDING PRINCIPLE 1, LINE MANAGEMENT RESPONSIBILITY FOR SAFETY, AND GUIDING PRINCIPLE 2, CLEAR ROLES AND RESPONSIBILITIES

At every level of control, line management must be responsible for safety. Clear and unambiguous roles and responsibilities should be defined and maintained at all levels in the organization defined by the ISMS description. All aspects of work identification, planning, and execution should be under the control and responsibility of line management. Support organizations, such as ES&H or human resources, must have clearly defined roles and responsibilities that ensure work is performed safely.

EXPECTATION FOR GUIDING PRINCIPLE 3, COMPETENCE COMMENSURATE WITH RESPONSIBILITY

All organizations and activities in the ISMS should be evaluated to ensure that personnel have the experience, knowledge, skills, and abilities necessary to discharge their assigned responsibilities. Accordingly, the ISMS description should establish core competencies for support and line workers and managers. Additionally, the ISMS description should define personnel performance expectations and provide for training needs and performance evaluations to determine if expectations are met.

OVERSIGHT

ISMS-related assessments need to verify that safety obligations are being met. DOE P 450.5, Line Environment, Safety, and Health Oversight, provides the fundamental framework for the Department's expectations for DOE line management ES&H oversight. The Policy notes that the use of contractor self-assessment programs is the cornerstone for this oversight. However, there are additional regulatory and DOE independent oversight activities that contribute feedback on the adequacy of the ISMS. The initial ISMS review and approval required in the FRAM is the first in a continuing series of independent DOE oversight activities.

OVERSIGHT AND ENFORCEMENT

The FRAM establishes the following requirements for DOE's oversight and enforcement role. Like other parts of the ISMS, it depends on the contractor to provide an organization and documentation that supports DOE completing its required functions.

Section 9.6.3.1 requires the field element manager (FEM) to ensure that oversight personnel have unfettered access to information and facilities, consistent with safety and security requirements.

Section 9.6.3.1 requires EH-2 to perform independent oversight of line management to assess success of the DOE ISMS and supporting programs for doing work safely and report the results of independent oversight activities to the Secretary, Congress, Cognizant Secretarial Officers (CSO), FEMs, and the contractors.

Section 9.6.3.2 requires the FEM to perform management assessments of contractors to evaluate their success in doing work safely, to review their performance against formally established ES&H performance indicators, and to take appropriate action.

Section 9.6.3.3 requires the FEM to monitor contractor actions to report nuclear safety violations to the Office of Enforcement (EH-10) for review under the provisions of 10 CFR 820, Procedural Rules for DOE Nuclear Activities. The FEM and the CSO must refer violations to EH-10 for review under the provisions of 10 CFR 820 where appropriate.

Section 9.6.3.3 requires EH-10 to investigate noncompliances with nuclear safety rules, to assess the level of violation of noncompliances, and to issue notices of violations where appropriate. EH-10 is also required to establish, maintain, and implement a noncompliance tracking system for self-reporting by contractors. EH-10 must also issue civil penalties where appropriate and refer violations to the Justice Department for criminal review where appropriate. The Secretary shall receive appeals and grant or deny them.

CONTRACTOR IMPLEMENTATION

DOE P 450.5, Line Environment, Safety, and Health Oversight, describes a transition process for DOE field element oversight as effective contractor self-assessment programs

are established. The DOE field, in this case, focuses more on maintaining operational awareness of contractor work activities and reviews performance against formally established ES&H performance indicators, using contractor self assessments. The contractor organization and documentation should be structured to support these DOE functions.

In its requirements for describing the ISMS, the DEAR references performance objectives and performance measures. The DEAR also tasks contractors to describe how they will measure the effectiveness of the ISMS and ensure a process of continuous improvement. Performance objectives and performance measures have been linked to the contract, budget, and DOE program execution guidance. Most contractors have found it necessary to establish important performance indicators to assess the effectiveness of their ISMSs. These indicators should result in a set of metrics that demonstrate the status of the safety management programs and the overall effectiveness of the ISMS. Circumstances at each site will cause some of the metrics to be unique although others will be common to all sites. The activities listed below are useful in developing ISMS performance measures and indicators.

- DOE and the contractor should define and document the mechanisms for developing and maintaining ISMS performance objectives and criteria. From these objectives and criteria, an appropriate set of assessments, performance measures, and performance indicators can be derived. The resulting data can be used to adjust the ISMS mechanisms. If serious deficiencies with the performance indicators are uncovered, a new performance objective and related performance measures and indicators should be established.
- DOE and the contractor should agree on the tools and measures to promote effective implementation of the ISMS. These measures are reviewed annually and modified to reflect improved performance. For more detailed information on developing performance measures, see How to Measure Performance, A Handbook of Techniques and Tools, U.S. DOE, Trade, which may be downloaded at http://www.llnl.gov/PBM/handbook.
- DOE Headquarters Program Secretarial Officers' line organizations should develop performance criteria that can be linked to their field organizations. All facilities

should be able to roll up their site-specific and mission-specific performance criteria into the top-level criteria.

Note: You do not have to do example 3 on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do example 3 or go to section 4.

EXAMPLE 3

1. Discuss how the DEAR and the FRAM are associated with ISMS.

2. Discuss how a gap analysis is used to determine if the guiding principles and core functions are addressed in the ISMS.

3. Discuss the DOE actions that are required to develop hazard controls.

Note: When you are finished, compare your answers to those contained in the example 3 self-check. When you are satisfied with your answers, go to section 4.

EXAMPLE 3 SELF-CHECK

1. Discuss how the DEAR and the FRAM are associated with ISMS.

   The DEAR contains ISMS rules and regulations for the contractor. The FRAM contains ISMS rules and regulations for DOE personnel.

2. Discuss how a gap analysis is used to determine if the guiding principles and core functions are addressed in the ISMS.

   ISMS developers use the gap analysis to ensure integration and to identify missing or weak elements. However, if the missing or weak element is deemed important, corrective action should be taken to provide revised documentation that will permit implementation of the necessary ISMS element.

3. List the DOE actions that are required to develop hazard controls.

   - Identify standards and requirements.
   - Identify controls to prevent or mitigate hazards.
   - Establish safety controls.
   - Implement controls.

SECTION 4 – MAINTAINING AN APPROVED ISMS

This section provides guidance to DOE and its contractors for keeping an approved ISMS effective through continuous improvement actions and for describing the actions needed to develop and respond to DOE's annual program and budget execution guidance.

The contractor and DOE are responsible for ensuring that an approved ISMS is controlled by an effective feedback and improvement process. The ISMS should remain current and reflect changes in the mission, program objectives, and budget direction from DOE.

The DEAR, 48 CFR 970.5223-1 (d) and (e), requires DOE and contractor actions to continuously maintain the integrity of ISMS and to generate revisions as scheduled by the contracting officer.

CONTRACTOR ANNUAL AND CONTINUOUS ACTIVITIES

- Review the status of post-facility ISM verification activities.
- Select appropriate performance measures and indicators.
- Improve the adequacy and effectiveness of the ISMS in response to DOE oversight and contractor self-assessment.
- Submit ISMS revisions.
- Establish an effective ISM system feedback and improvement process.

DOE ANNUAL AND CONTINUOUS ACTIVITIES

- Establish dates for discussions and revisions to the system.
- Develop program and budget execution guidance.
- Provide direction to the contractor concerning environment, safety, and health performance objectives and performance measures.
- Assess DOE's performance in compliance with organizational and departmental ISMS requirements.
- Oversee the contractor's ISMS and the review and approval of the contractor's annual ISMS revisions and the environment, safety, and health performance objectives, performance measures, and commitments.

ADDITIONAL CONSIDERATIONS

Conditions and considerations that could lead to a partial or complete re-verification of the contractor's ISMS or its implementation might include:

- a change of contractor resulting in a significant revision to the ISMS description;
- a situation in which the assessment results of an evaluation identifies safety problems, a series of safety problems occur, problems are found in readiness reviews, or other indicators call the adequacy of the system or related processes into question;
- a major change of mission at a particular site or facility; and
- changes to applicable federal, state, and local laws and regulations or DOE directives.

CONTRACTOR ISMS UPDATING AND MAINTENANCE ACTIVITIES

Contractor Activities to Sustain, Measure, and Update a Satisfactory ISMS

The contractor is required to develop environment, safety, and health performance objectives, performance measures, and commitments, and to update them on an annual basis. The contractor is also required to measure the ISMS's effectiveness and to identify and allocate resources to meet the objectives and performance commitments, and maintain the integrity of the system. This effort should continue to improve safety management. If the results of this activity require changes to the ISMS, the contractor should address those changes and submit them to DOE for approval. The following types of activities may be considered:

- Evaluate the effectiveness of the performance objectives, performance measures, and commitments. Determine reasons for success or failure of those commitments.
- Review occurrence reports and corrective actions for ISMS improvement opportunities.
- Review facility data and identify environment, safety, and health issues to develop improvements required in the ISMS.
- Review worker or operator suggestions from the Employee Concerns Program and employees' organizations.

- Review the DOE program and budget execution guidance and direction.
- Review changes to laws, regulations, and directives.

When the contractor's ISMS is updated, the update should document:

- contractor performance against the previous year's safety commitments;
- contractor commitments designed to achieve safety performance objectives and performance measures for the upcoming fiscal year; and
- resources necessary to meet environment, safety, and health program minimum requirements.

Through this process, the ISMS annual update is responsive to DOE budget guidance and direction contained in the Unified Budget Call that is issued annually by the DOE Chief Financial Officer, and Lead Program Secretarial Office.

Introduction of a Major New Facility or Major Mission Change in an Existing Facility

New facilities or major mission changes will need to be integrated into the ISMS. A new facility or program may require a significant revision to a site or facility ISMS to respond to new hazards or potential environmental impacts. If the new facility or process does not fit in the existing ISMS, the contractor should update the ISMS. Once the revised ISMS is approved, the contractor is expected to implement the revisions. Additionally, the contracting officer should develop a DOE review plan that includes appropriate verification elements to ensure that an updated, viable, and effective ISMS is in place before work is authorized.

Changes to Laws, Regulations, and Directives

The DEAR (48 CFR 970.5204-2) requires that environmental, safety, and health requirements be established and identified in the contract as List B. These requirements are established either by the DOE contracting officer or by a DOE-approved process that is described in the ISMS and used to develop a set of standards, practices, and controls, which are then incorporated into the contract. This List B must be kept current. The DOE procurement executive expects the HCA to ensure that the contracting officer reviews and

updates List B at least annually concurrent with the annual work scope and performance measure negotiations. Changes to DOE directives or federal, state, and local laws and regulations may require changes to the ISMS description and implementation.

DOE REQUIRED ACTIVITIES RELATED TO ISMS CONTINUAL EVALUATION AND ANNUAL UPDATING

The DEAR and DOE policies assign numerous requirements to DOE field and Headquarters elements to sustain the ISMS in the DOE complex. The policies include DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line Management, Safety And Health Oversight; DOE P 450.6, Secretarial Policy Statement, Environment, Safety, and Health; and DOE P 411.1, Safety Management Functions, Responsibilities, and Authorities Policy. The DOE ISMS annual and continuous activities are:

- the development and promulgation of budget and budget execution guidance and direction to the contractor concerning safety performance objectives, performance measures, and ISMS revisions;
- the assessment/self-assessment of DOE's performance in compliance with organizational and departmental ISMS requirements and expectations; and
- the oversight of a contractor's ISMS implementation and performance.

CONSIDERATIONS FOR PERFORMING ANOTHER VERIFICATION

The following circumstances are examples of those that might result in a need for a re-verification.

- loss of confidence in the adequacy of the existing ISMS
- change of contractor

AIDS FOR CONDUCTING ANNUAL REVIEWS OF AN ISMS

The following continuing core expectation (CCE) statements can be used to aid in developing an evaluation of the ISMS. This list may be used by contractors and DOE.

- CCE -1. The annual updates in response to budget execution process are completed. DOE direction is provided as part of the annual program and budget execution guidance. The contractor updates the safety performance objectives, performance measures, and commitments so that they reflect and promote continual improvement and address major mission changes. The ISMS is updated and submitted for the contracting officer's approval.
- CCE -2. System effectiveness is satisfactory. Safety performance objectives, performance measures, and commitments are met or exceeded, and they are revised as appropriate for the next year.
- CCE -3. Work activities reflect effective implementation of the functions of ISMS. Work is defined. Hazards are identified. Actions to prevent or eliminate the hazards are taken. Controls are developed and implemented. Work is properly authorized. Work is accomplished within controls. Appropriate worker involvement is a priority.
- CCE -4. Contractor and DOE implementing mechanisms continue to support the principles of ISMS. Promulgated roles and responsibilities are clear. Line management is responsible for safety. Required competence is commensurate with responsibilities, and the technical and safety system knowledge of managers and staff continues to improve.
- CCE -5. Contractor and DOE budget processes ensure that priorities are balanced. Budget development and change control processes ensure that safety is balanced with production.
- CCE -6. An effective feedback and improvement process is functioning at each level of the organization.
- CCE -7. List B is reviewed and updated annually.
- CCE -8. Performance objectives and criteria guidance for contractor and DOE assessments focus the reviews on the adequate implementation of the core functions and the principles of ISMS.
- CCE -9. Relevant records reflect an improving ISMS.

- CCE -10. DOE ISMS procedures and mechanisms are in place to ensure that work is authorized and performed safely.
- CCE -11. DOE ISMS procedures and mechanisms are in place to ensure that hazards are analyzed, actions to prevent or eliminate the hazards are taken, controls are developed, and feedback and improvement programs are in place and effective.

DOE REQUIREMENTS FOR SUSTAINING ISMS AND CONDUCTING ANNUAL REVIEWS

An important element of the budget guidance and development process is the annual updating of the ISMS. The following requirements are related to sustaining ISMS and conducting annual reviews.

- DEAR 48 CFR 970.5223-1(e) requires that the contractor review and update its safety performance objectives, performance measures, and commitments consistent with and in response to DOE's program and budget execution guidance and direction.
- FRAM section 9.2.4 requires that the FEM review and support development of performance objectives and related CSO priorities.
- FRAM section 9.1.5 requires the CSO and the FEM to interact during the annual budget process to ensure balanced priorities.
- FRAM section 9.2.1 specifies that each field element is expected to develop appropriate documents delineating its plan of work, including scope, schedule, and funding allocations for each fiscal year.
- DOE P 450.5, Line Environment, Safety and Health Oversight specifies that the Department and contractor line work together to develop ES&H performance objectives, measures, and expectations tied to Departmental strategic goals, objectives, performance goals, and objectives of the ISMS. Mutual agreement is reached on expected ES&H performance. The measures found in this documented agreement are a part of the annual assessment.
- DOE O 425.1A, Startup and Restart of Nuclear Facilities, requires that the ORR team comment on the ISMS.

Assessment and Self-Assessment of DOE's Performance

DOE P 450.5, Line Environment, Safety, and Health Oversight, assigns Headquarters' line management with ES&H oversight functions of the DOE field elements. These oversight functions include:

- monitoring field element performance;
- participating in field element appraisals, assessments, surveillance, or walkthroughs; and
- conducting onsite reviews of field element performance, including verification of their appraisals of the contractor.

DOE Oversight of a Contractor's ISMS Implementation and Performance

DOE has a significant role to play through the oversight and assessment process to ensure that the contractor's ISMS remains effective and robust. An important element of achieving the measurable and sustained results is DOE's oversight and assessment of the contractor's ISMS.

DOE P 450.5, Line Environment, Safety, and Health Oversight, describes the steps to ensure that the contractor's ES&H self-assessment program is in place. Before the contractor achieves the required self-assessment program, DOE's oversight of the contractor's operation is more frequent and more intense. As an effective contractor self-assessment program is established, DOE oversight changes to operational awareness through evaluation of ES&H performance measures and indicators, required readiness reviews, ISMS documentation reviews, authorization basis documentation reviews, implementation reviews, and periodic appraisals. Additionally, DOE EH-2 conducts independent evaluations of contractors and DOE line implementation of ISMS and reports their findings to DOE cognizant line managers, Program Secretarial Officers, and the Secretary of Energy. Line management is responsible for developing approved corrective action plans in response to DOE EH-2 findings.

DEAR 48 CFR 970.5215-3 is the conditional fee clause that includes minimum requirements for ES&H. To comply with the specified contract clause, DOE will conduct oversight and focused evaluations of the contractor's ISMS. The results are used to determine the ISMS effect on the fee.

The FRAM defines the following oversight and assessment requirements for DOE.

- FRAM 9.4.2.1 and 9.4.2.2 require the FEM to direct the contractor to prepare documentation for controls for the prevention and mitigation of hazards. Review the adequacy of the controls and their documentation. The FRAM also specifies that the FEM provide line management oversight and ensure that hazards mitigation programs and controls are implemented.
- FRAM 9.4.3.1 requires the FEM to direct preparation of the authorization basis and associated safety documentation and oversee implementation by the contractor.
- FRAM 9.4.4 requires the FEM to monitor the proper implementation of controls, including contractor processes for USQs, configuration management, and compliance with the TSRs.
- FRAM 9.5.2 requires the FEM to perform line management oversight of contractors' worker, public, environment, and facility protection programs and to maintain day-to-day operational oversight of contractor activities at applicable facilities through DOE facility representatives (FRs).
- FRAM 9.5.3 requires the FEM to ensure that contractors implement quality assurance programs.
- FRAM 9.6.3.1 requires the FEM to perform management assessment of contractors to evaluate their success in doing work safely and appraise performance of the contractor against formally established ES&H performance measures, and take appropriate action.

Change No: 0
DOE G 450.4-1B
Level: Familiar
Date: 6/15/01

SECTION 5 – G 450-4-1B, VOLUME II, APPENDIXES

This section covers volume II of the Guide. Volume II consists of seven appendixes, labeled A through G. Appendix A is a glossary of some of the terms used in the Guide and is a valuable reference when answering questions in the practice or criterion test that ask for definitions of terms or concepts. Appendix B is a list of resources associated with ISMS. Appendix C has been superseded by revisions to chapter III and appendixes E and F. Appendix F is a collection of topics addressed in ISMS description documents. You should review these appendixes. In this module, we will concentrate on appendixes D, E, and G.

APPENDIX D, DISCUSSION OF SAFETY MANAGEMENT ASSESSMENT

INTRODUCTION

The purpose of this appendix is to provide supplemental guidance for the use of assessments in ISMSs.

The feedback and improvement safety function is directly dependent on the effectiveness of assessments. To effectively accomplish the objectives of an assessment program, the assessment process needs to do more than develop a list of deficiencies. The process must produce a robust, rigorous, and credible assessment that is acceptable to DOE and the contractor. The results can be used with confidence to accomplish the following:

- Identify areas that do not meet the requirements.
- Prioritize those problems identified using a prioritization system based on each problem's importance in the execution of ISMS policies.
- Correct problems and follow up to help ensure that the problems assessed and prioritized for correction have been corrected, and that the correction has been effective enough to result in sustained, long-term improvement.
- Share significant assessment issues and identified strengths and successes with other organizations.

TYPES OF ASSESSMENTS

An assessment program must be developed within the framework of DOE P 450.5, Line Environment, Safety and Health Oversight; 10 CFR 830.120, Quality Assurance; and DOE O 414.1A, Quality Assurance.

There are many different types of, and purposes for, individual assessments conducted in DOE and contractor organizations. Some assessments evaluate compliance with the law and contract requirements, while others seek areas for improvement beyond simple compliance. Some assessments evaluate a product or service while others evaluate the organization's management system and its ability to yield the desired products and services. Some assessments are required by DOE and external regulations. Others are required by DOE directives as implemented at a site or facility through contracts.

Other types of assessments include:

- assessments conducted by EH-2;
- assessments associated with the administration of the Price-Anderson Amendments Act (PAAA);
- routine and frequent performance assessments conducted in DOE facilities by FRs; and
- verification that ISMS requirements are implemented, which is a specific type of assessment associated with the establishment of an ISMS.

PRINCIPLES OF THE ASSESSMENT EFFORT

As stated in DOE P 450.5, Line Environment, Safety, and Health Oversight, the contractor and DOE have the following common principles:

- Work together to develop ES&H performance objectives, measures, and expectations that are tied to Department strategic goals and objectives and performance goals and objectives of the ISMS elements.
- Work together to develop contract performance measures and performance indicators that are linked to the DOE ISMS.

- Work together to develop a high level of performance assurance that results in improved ES&H performance.

ATTRIBUTES OF ASSESSMENTS

The introduction to this appendix briefly discusses the attributes of assessments. Those attributes are:

- identification of problems and issues,
- prioritization of issues found with respect to significance,
- correction of identified issues, and
- promulgation of lessons learned from the identified issues and problems at other sites and facilities when doing so will add value to the complex.

Appendix D provides additional information about these attributes.

Identification of Problems and Issues

Most assessments are scheduled so that those doing the assessments can prepare for the assessment, and those being assessed can arrange the facility's schedule to accommodate the assessment and minimize the impact on facility work. Because all assessments may affect a facility's ability to do work, the impact of the assessments should be minimized wherever and whenever possible.

Additionally, there is a distinct advantage to conducting some assessments on an unannounced basis. It is only human nature to want to do well during any evaluation. Consequently, strong efforts to prepare for an assessment are not unusual. Conversely, it is probable that there may be a natural relaxing of performance after an assessment is completed. The possibility of unannounced assessments will help to minimize the potential for reduced performance, especially if some unannounced assessments are periodically conducted. The routine day-to-day assessments of performance by facility managers at any level and by DOE FRs similarly need to be sufficiently random to prevent complacency in a facility. If a manager or FR always does the same thing when he or she spends time in the facility or if those people only conduct their assessments during the normal work day, Monday through Friday, the workers in the facility may assume that

areas not being assessed or efforts ongoing on back shifts, weekends, or holidays are not as important to assessors. Consequently, workers may tend to emphasize effective safety performance only in those places and during those times that their management or local DOE personnel emphasize. Data derived from such observations will be a very valuable input to the assessment process.

Assessors must also be knowledgeable in the areas they assess. They need to understand the requirements applicable to the areas they are assessing. These assessors also need to have technical competence in the areas being assessed. Assessors who are not knowledgeable of the requirements to be evaluated and how to assess professionally will more than likely be ineffective.

In conducting most assessments, it is essential that the evaluation be based on identified requirements and not the assessor's expectations. Assessors who have their own agenda, used instead of the identified requirements, cause a counterproductive diversion of effort.

Prioritization of Deficiencies

Once a deficiency has been formally identified as significant enough to be processed for correction, it should be assigned a priority for attention consistent with its significance. Either the organization doing the assessment or the one being assessed may assign the priority. If one of these two organizations disagrees on the priority assigned, a means should be available to resolve this difference.

Problem Correction

Many sites and facilities use an issues management or deficiency-tracking scheme to manage the correction of identified problems, whether those problems are identified by the contractor, DOE locally or externally, or other assessment and oversight organizations such as EH-2.

At some sites, facility managers and their staffs use the tracking system daily to monitor the status of the highest-priority deficiencies. Responsible managers should review the highest-priority deficiencies most frequently and all deficiencies periodically depending on the assigned priority. This management technique helps facility management and staff

focus on what is needed to correct the problems identified and helps them determine what assets are needed to do the job. It also helps those responsible for the facility to be acutely aware of the safety status of the facility.

Sharing of Significant Assessment Issues

The results of assessments that contain significant issues and problems of general applicability should be shared with other parts of the organization and with other organizations in the DOE complex to preclude those problems from occurring elsewhere. As appropriate, the process used to correct the problem should also be shared.

An excellent example of feedback concerning operational issues with respect to DOE nuclear facilities is the "Operating Experience Weekly Summary" published by the Office of Nuclear and Facility Safety. This document provides descriptions of the problem reported, some analysis of previous problems that were similar, and descriptions of some actions that were used to correct the problem and prevent recurrence.

APPENDIX E, ISMS EVALUATION GUIDANCE

This appendix describes a protocol for the review and approval of documented safety management system descriptions associated with defense nuclear facilities and provides an overview of some of the more significant lessons learned as the assessment process has matured. Conducting an ISMS evaluation is a significant event and thorough planning efforts are required to achieve success. Sites and facilities have found that they must devote significant management attention to preparing for and conducting these evaluations. Line managers, the majority of safety management personnel, and facility operations, maintenance, and health and safety support personnel are involved in preparing for and/or supporting the review. ISMS evaluations significantly affect the normal routine. Senior management support is essential to success.

ROLE OF THE APPROVAL AUTHORITY

The process of evaluating ISMS programs is described as verification or as the assurance that ISMS is implemented. DOE M 411.1, Manual of Safety Management Functions, Responsibilities and Authorities, assigns responsibilities to approve the safety management system description and revisions to the HCA. The HCA or approval authority is normally the manager of the cognizant DOE operations office. The term "approval authority" will be used in the following discussions. To carry out these responsibilities, the approval authority must decide if a team review is needed and, if a team is needed, select members of the review team. The approval authority selects the team leader from a list approved by the Deputy Secretary. In addition to this guidance, the team leader and the assembled team should use the ISMS Verification Process, Team Leader's Handbook (DOE SAFT-0065), to plan for and conduct the ISMS verification.

The approval authority should emphasize to the contractor the importance of having a complete, defensible ISMS before the verification review is scheduled. Having incomplete or missing documentation when the team begins its review only delays the process and wastes valuable resources. Additional details of the role of the approval authority during the verification process are provided in Appendix 4 of the Team Leader's Handbook.

ROLE OF THE ISMS VERIFICATION TEAM

The ISMS verification team's primary purpose is to review the adequacy of the ISMS and its implementation to provide a recommendation to the approval authority. A secondary purpose is to evaluate the role of DOE in supporting the contractor's ISMS. The review should confirm the capability of DOE and the contractor to implement all aspects of the ISMS as described in DOE policies, the DEAR, and the FRAM.

CONCEPT OF THE REVIEW

The verification team is required to establish a tailored process to determine the adequacy of the documented ISMS, evaluate the success of the ISMS implementation, and provide a recommendation to the approval authority.

Phase I is a review of the ISMS documentation. Phase II is a review to verify that the ISMS has been satisfactorily implemented. To be successful, Phase I should extend to the procedures, policies, and manuals of practice used to implement safety management. The review should evaluate how these procedures, policies, and manuals of practice have been implemented at the upper levels of management and should also include detailed discussions with key management personnel who are assigned safety management responsibilities. The primary goal for the review is to provide a recommendation to the approval authority as to whether the ISMS documentation should be approved. To reach that conclusion, the team must develop a complete understanding of the safety management programs and determine that, when implemented, they will satisfy DOE requirements for ISMS and will adequately manage the safety aspects of the work and operations.

The form of the ISMS description is flexible and should identify all safety management plans, programs, and manuals of practice. The identified documents should be available for review. Review of these documents and determination of their adequacy forms the essence of the Phase I review.

The Phase II review, which should be accomplished following review and approval of the ISMS documentation, is a review of the implementation of that ISMS. This is normally accomplished by sampling various facilities and programs to determine that the safety management system outlined in the ISMS is being effectively carried out.

The verification team leader should prepare a review plan. An essential part of preparing the review plan is developing detailed, site-specific criteria review and approach documents (CRADs). These documents establish the initial scope of the ISMS verification and provide guidance to the ISMS verification team members. The CRADs serve to focus the initial investigation. The review plan also serves as the primary means to communicate to the inspected contractor and DOE office the breadth and scope of the review. Sample CRADs and a completed ISMS assessment form from an example verification are included in appendix E of the Guide. Further detailed information concerning these subjects is contained in the Team Leader's Handbook. ISMS descriptions, verification reports, and other significant information addressing the planning, scheduling, and accomplishing of ISMS evaluations may be viewed on the ISMS home page (http://tis-nt.eh.doe.gov/ism). You should review these documents to prepare for the criterion test for this module.

INTEGRATED SAFETY MANAGEMENT CORE EXPECTATIONS

The following core expectations were developed from the requirements the DOE policies and the requirements of the DEAR and from the fundamental attributes that support the implementation of ISMS. These core expectations can serve as the basis for developing the CRADs. The following core expectations are annotated as being applicable to Phase I and Phase II. Phase I core expectations are used to evaluate the adequacy of the safety management documentation and the establishment of these programs at the site or corporate level. Phase II core expectations are used to evaluate the status of implementation at the facility, activity, or process level. Additional information regarding these expectations is available in section 2.1 of the Integrated Safety Management System Guide, volume 2.

PHASE I ISMS CORE EXPECTATIONS

The ISMS documentation is consistent with DOE P 450.4, Safety Management System Policy, the DEAR, and the guidance provided to the contractor by the approval authority.

DOE and the contractor effectively translate mission into work, set expectations, provide for integration, and prioritize and allocate resources.

An ISMS should include methods for identifying, analyzing, and categorizing hazards.

The ISMS should include methods for establishing and maintaining an agreed-on set of safety standards before work is performed.

Contractor policies, procedures, and documents are established and are adequate for the work or process to be performed safely.

The ISMS should be continuously improved through an assessment and feedback process that should be established at each level of work and at every stage in the work process.

The ISMS should establish that at every level of control, line management must be responsible for safety. Clear and unambiguous roles and responsibilities should be defined and maintained at all organizational levels.

The ISMS should ensure that personnel are competent commensurate with their responsibility for safety.

The DOE approval authority should have a set of processes that interface efficiently and effectively with the contractor organization.

PHASE II ISMS CORE EXPECTATIONS

An integrated process has been established and is used to identify and prioritize specific tasks, mission process operations, modifications, and work items.

The full spectrum of hazards associated with the work or task has been identified, analyzed, and categorized. Those individuals responsible for the analysis of the environmental, health and safety, and worker protection hazards are integrated with those personnel assigned to analyze the processes.

An integrated process has been established and is used to develop controls that mitigate the identified hazards present in a facility or activity. The set of controls ensures adequate protection of the public, the worker, and the environment and is established as agreed on by DOE.

An integrated process has been established and is used to effectively plan, authorize, and execute the identified work for the facility or activity. Workers and management demonstrate a commitment to ISMS.

An integrated process has been established and is used that ensures that continuous improvement mechanisms are in place.

Clear and unambiguous roles and responsibilities are defined and maintained at all levels in the facility or activity. Facility or activity line managers are responsible and accountable for safety. Facility or activity personnel are competent commensurate with their responsibility for safety.

DOE ISMS procedures and mechanisms should ensure that work is formally and appropriately authorized and performed safely. DOE line managers should be involved in the review of safety issues and concerns and should have an active role in authorizing and approving work and operations.

DOE ISMS procedures and mechanisms ensure that hazards are analyzed, controls are developed, and that feedback and improvement programs are in place and effective. DOE line managers are using these processes effectively, consistent with FRAM requirements.

CONDUCTING THE REVIEW

The quality of the ISMS evaluation is determined by a variety of factors. The team selected must have the required expertise or must be trained accordingly. Team member activities must be carefully planned and coordinated so that the full scope of the review is accomplished. The review sequence must be planned to efficiently accomplish the review within the prescribed time.

TEAM SELECTION

Selection of the proper team is an important element in conducting a successful ISMS verification. The following team member experience is beneficial:

- expertise in a functional area;
- site experience (especially familiarity and understanding of site programs);
- assessment experience (assessments/audits/ORRs/RAs);
- ISMS training (knowledge of ISMS Policy, Guide, and Team Leader's Handbook); and
- familiarity with DOE FRAMs.

Additional details on the important attributes of the team members are provided in Sections 5.5.2 and 6.3.2.2 of the Team Leader's Handbook.

Consideration of the size of the team is an important decision. Too large a team makes coordination difficult. From the perspective of recent site ISMS reviews, a team of 15-18 was determined to be required for the Phase I review. A Phase II review of one of the facilities at this site required a team of 7-8. The complexity of the site and facility and hazards involved should be instrumental factors in determining team size.

TEAM ASSIGNMENTS

To conduct the review efficiently, it is useful to delineate related safety management and support programs in discrete groups called functional areas. By establishing these groupings, personnel can be assigned team responsibilities in designated review areas for which they have the required expertise. Functional areas used in past reviews have been synthesized in the ISMS Team Leader's Handbook into distinct Phase I and Phase II areas that can be further synthesized for combined Phase I/ Phase II verifications. These include the following:

Phase I

- Business, Budget, and Contracts
- Hazards Identification and Standards Selection

- Management
- DOE

Phase II

- Operations and Implementation
- Subject Matter Experts (SMEs)
- Hazards Identification and Standards Selection
- Management
- DOE

Within Phase II it has been necessary to include SMEs to ensure that specific safety management functions are effectively addressed. SMEs may include experts in the following disciplines:

- Criticality safety
- Fire protection
- Industrial hygiene and safety
- Radiation protection
- Security
- Training and qualification
- Maintenance and work control
- Quality assurance
- Configuration management
- Environmental compliance

REVIEW SEQUENCE

The sequence for conducting the review should be carefully considered. The following is a typical chronology of a 4-week review sequence used for a Phase I ISMS verification at a major DOE site. A Phase II verification sequence would be similar, but generally could be accomplished in fewer days on site.

- An initial site visit by the team leader is conducted before the start of the review to meet site personnel responsible for ISMS and discuss the conduct of the review.

- A 3-day site visit before the review is used to train the team, explain the verification methodology, and develop the CRADs to be used for the review.
- The review commences with a 1-week period allotted for contractor and DOE management briefings to the team. The goal is to allow the contractor to fully explain the status of ISMS. Following these presentations, the team develops a list of personnel to be interviewed and records requested for review. The briefings are considered essential for the team to enable them to fully understand the safety management programs. The quality of the briefings is important. The contractor's expertise in providing the necessary information, with the correct amount of detail, is important to ensure the team has enough information to enable them to efficiently conduct the review. If conducted correctly, these briefings provide instant feedback about the strengths and weaknesses of the ISMS.
- A 1-week period is allotted for the actual review. This review occurs 2 weeks following the contractor briefings. The report is written the following week before the team departs the site.

COMBINED PHASE I AND PHASE II REVIEWS

The approval authority may elect to direct a combined Phase I and Phase II review at sites or facilities with a mature ISMS effectively in place. While this appears to be a timely way to accomplish the verification, a combined review can be complicated and difficult to coordinate. Combined reviews conducted to date have shown that it is important to carefully factor into the decision the size and complexities of hazards and the maturity of the existing safety management system. If it is still considered proper to combine the two phases into one review, the following comments should be carefully considered:

- The review of the ISMS description and the review of manuals of practice must be carefully coordinated with the review of the implementation of the ISMS mechanisms.
- The verification team should be well experienced. It is beneficial to assemble a team that has had some experience in conducting both phases of ISMS verifications.

- The verification team should have many opportunities to review the ISMS description, verification plan, and supporting documentation well ahead of the scheduled verification.
- Ample time should be provided to allow the team to study the documentation, ask questions, and receive answers and clarification of their issues and concerns before starting the review.

APPENDIX G, FEEDBACK AND IMPROVEMENT MECHANISMS

The feedback and improvement function closes the ISMS loop by connecting the practical experiences of work to the planning for future work. This appendix provides supporting details and examples of typical feedback and improvement mechanisms and discusses how these mechanisms are implemented at the activity, facility, and institutional levels in DOE and its contractor organizations.

DESCRIPTION OF FEEDBACK AND IMPROVEMENT MECHANISMS

The following are examples of various feedback and improvement mechanisms that are used in DOE.

Government Performance and Results Act and Performance-Based Management

DOE seeks to improve program management and execution and promote the comparison of results achieved with costs incurred by implementing the Government Performance and Results Act of 1993 (GPRA). The Department responded to GPRA by developing a strategic plan, setting performance goals, and measuring program performance against these goals. Annual performance plans, performance agreements with the president, and accountability reporting complete the cycle of GPRA documents produced by the Department.

The Department considers performance-based management as a strategic management tool. Performance-based management includes the following actions:

- identifying what needs to be accomplished,
- determining performance objectives,
- delegating authorities to the level closest to that at which the work is to be performed,
- deciding what to measure and the appropriate data collection methods,
- establishing challenging and realistic performance expectations,
- maintaining operational awareness,
- collecting performance data,

- assessing actual performance against expectations, and
- using the results to improve performance.

Lessons Learned

The DOE Society for Effective Lessons Learned Sharing (SELLS) is a champion for the generation and dissemination of lessons learned across DOE. More information about SELLS is available at http://tis.eh.doe.gov/ll/. Lessons learned programs should search the local organization's data generation and analysis mechanisms for recurring trends or good practices with broad organizational implications. Lessons learned programs should also search beyond the local organization for experiences of other DOE facilities and sites, private industry, and other governmental organizations involved with similar work, hazards, or technical components. Internal and external experience should be analyzed for local implications and communicated to relevant local audiences to aid in the performance of future work.

DOE STD-7501-95, Change 2, The DOE Corporate Lessons Learned Program, provides guidance for the development and operation of DOE-wide lessons learned programs. The standard describes lessons learned programs for DOE and contractor organizations to facilitate improvement at all organizational levels and for all work activities in the ISMS functions. Robust lessons learned programs play an important role in continuous improvement and provide a valuable source of information for confirming the ISMS and preparing the annual ISMS update as required by DEAR 48 CFR 970.5223-1 (d) and (e).

Sources of Lessons

Contractors can generate lessons learned data by studying information from the sources in table 1.

Table 1. Sources of Lessons Learned

INTERNAL SOURCES	EXTERNAL SOURCES
Process data	DOE line ES&H oversight
Environmental monitoring data	DOE independent oversight
Peer technical/safety monitoring	DOE PAAA enforcement
Management assessments	DOE Inspector General
Independent assessments	Customers and suppliers
Walk-arounds	External regulators
Supplier quality evaluations	Safety boards
Receipt inspections	Professional/technical societies
Worker experience reports	Peer/industry organizations
Occurrence reports	Stakeholders and community advisory boards
Accident investigation reports	
Emergency exercises or drills	

Lessons Learned Data Application

Headquarters, field, and contractor elements have flexibility to implement lessons learned in a manner appropriate for their organizations.

Defense Programs (DP)

The Office of Defense Programs has previously prepared and issued a report titled "DP Facilities Semi-Annual Occurrence Summary Report." This report reviews and highlights all occurrence reporting and processing system (ORPS) reports screened for DP purposes. The report also summarizes information obtained from the DOE quality assurance working group, SELLS, and DP field and contractor lessons learned programs. DP has produced the "Facilities Semi-Annual Occurrence Summary Report" to assist line managers in their safety management responsibilities.

Environmental Management Programs

The Office of Environmental Management (EM) maintains a Lessons Learned Program that is part of the DOE Corporate Lessons Learned Program. In April 1992, the U.S. General Accounting Office published a report titled "More Can Be Done to Better Control

Environmental Restoration Costs." One of the recommendations in this report was that the DOE Office of Environmental Restoration (EM-40) implement a lessons learned program to avoid repeating mistakes and to share successful work practices. EM-40 responded by initiating a three-phased process to develop a lessons learned program, including research and program development, and implementation. Shortly after the research and scoping phase was completed, DOE established a process improvement team to develop a crosscutting DOE-wide Lessons Learned Program. The team was chartered to develop an infrastructure for effectively sharing lessons learned across the DOE complex.

Assessments

A common feedback mechanism used for improvement across DOE is assessment. Assessments use a formal process to evaluate work or organizational performance to determine if requirements, outcomes, and expectations are being met. Assessments are performed by those people responsible for the work performance or by individuals independent from responsibility for the work.

Safety Performance Measures

The Deputy Secretary's memorandum "Implementation of Integrated Safety Management Performance Measures," dated 12-23-99, established performance standards and systems requested by the Secretary to hold federal personnel and contractors accountable for effective and timely implementation of an ISMS. These standards and systems fall into three categories:

- Federal personnel accountability
- Implementation milestone completion
- Effective ISMS implementation

Federal Personnel Accountability

Federal management personnel performance standards include the following ISM performance language (or equivalent language to meet the intent):

> *The Federal Manager has taken the necessary initiatives to implement fully the principles of the Department's Safety Management System Policy in programs for which the Manager is responsible. This includes the demonstration of an appropriate emphasis on ensuring the technical competence of the federal staff associated with those programs and the conduct of effective oversight of the accomplishment of related work products and schedules.*

This statement provides a standard to which DOE managers are accountable for implementing the safety management system policy.

Corrective Actions

Corrective action is an improvement mechanism used to document, track, and verify corrections in instances where expectations are not met. Such instances are often referred to as errors, deficiencies, nonconformances, defects, or other similar terms. Nonconformance to expectations may be detected in hardware, software, or in the performance of work.

EXAMPLES OF FEEDBACK AND IMPROVEMENT MECHANISMS IMPLEMENTED AT VARIOUS ORGANIZATIONAL LEVELS

The feedback and improvement mechanisms of lessons learned, assessment, corrective actions, and performance indicators are tailored for the particular work to be done, the hazards associated with the work, and the organizational level at which the work is performed. The following sections contain examples of how these mechanisms are implemented within activity, facility, and institutional levels of DOE and DOE contractors.

Work Task Feedback

As work is accomplished, workers identify and report opportunities for improvement, deficiencies, or conditions adverse to quality. These worker-identified changes surface during post-job briefings or via suggestion box programs. This information is received through a variety of mediums, such as work requests, nonconformance reports, problem reports, work process improvement suggestions, and employee concern reports. Work process improvements at this level often require minimal effort to realize and can be effected in a short time. Evaluation of issues raised at this level focus on the immediate cause and on action to correct the immediate issue. However, the evaluation may also lead to actions to prevent recurrence, site-wide ISMS improvements, and lessons learned for broader application.

Facility Feedback Assessment

Facility assessments are conducted to:

- determine whether the management systems, processes, procedures, and practices support the facility's ability to perform work safely;
- identify opportunities for improvement; and
- detect and correct errors.

Assessments of this type tend to focus on how the work is being done, versus what work needs to be done. They may be performed by the workers or by personnel independent from the work. Assessments of this type assess supplier and subcontractor capability to provide acceptable items and services. Several DOE contractors have established Facility Evaluation Boards that report to senior management and independently assess the safety performance at a facility.

DOE Field Office Line Management Oversight

Field office oversight focuses on the performance of individual facilities. The mechanisms typically used to perform this oversight include:

- operational awareness;
- review against established performance measures and performance indicators;
- reviews and assessments, such as required readiness assessments, operational readiness reviews, ISMS verification reviews, and authorization basis document reviews; and
- appraisals.

DOE O 414.1A, Quality Assurance, requires DOE to conduct independent assessments of contractor performance. The Order also requires DOE organizations to assess their work performance and management systems. As compared to contract management and enforcement, this level of feedback is more direct and timely, and therefore more useful to the contractor. Line management oversight at the field office level is a primary means for providing routine feedback on the contractor's performance.

DOE Contract Management and Enforcement

DOE contract management and enforcement are closely related to field office line management oversight, but focus on the formal contractual relationship between DOE and its contractors. Contract management and enforcement are used to clarify expectations and to monitor performance to the terms of the contract. DOE and its contractors reach agreements about mission and safety expectations. Each contract establishes the formal framework for safety and performance management by means of the safety management clause, the laws clause, the list of applicable rules and Orders, and the conditional payment of fee clause. In response to DOE direction, the contractor provides its annual plan, including performance objectives, performance measures, and commitments. DOE reviews and approves the contractor's ISMS description and initial implementation and periodically reviews ongoing implementation through a variety of feedback mechanisms. DOE performs an annual performance appraisal and provides annual performance awards where contractual agreements have been made. DOE may also reduce or eliminate award

fees where safety performance is not acceptable. DOE may choose to replace the contractor in severe cases of poor safety performance.

DOE PAAA Enforcement

DOE contractors responsible for nuclear and radiological facilities are subject to the regulatory requirements of 10 CFR 830 and 835 (PAAA rules). The PAAA enforcement program provides assurance to Congress and the public that DOE-owned facilities are being operated safely. The 1988 PAAA extended indemnification to DOE operating contractors. At the same time, Congress required DOE to undertake enforcement actions against those contractors who violate nuclear safety rules. DOE contractors, and their subcontractors and suppliers as covered by the Act, are subject to civil penalties for violations of applicable DOE nuclear safety rules. The PAAA enforcement program provides for discretion in pursuing enforcement actions where contractors demonstrate initiative in safety management performance, self-identification of deficiencies, self-reporting, and prompt and comprehensive corrective actions. PAAA enforcement is administered by DOE's Office of Enforcement and Investigation, which establishes PAAA enforcement policies and procedures, investigates potential violations, and initiates and resolves enforcement actions, as warranted. In contrast to contract management/enforcement, PAAA enforcement is performed independently of line management and provides added assurance to Congress and the public that DOE contractors are meeting DOE's nuclear safety requirements.

DOE Headquarters Line Management Oversight

DOE Headquarters focuses, from a corporate level, on the performance of individual sites and facilities and on complex-wide programs. The focus of this level is on whether the DOE field elements are performing work safely.

The principal mechanisms used by Headquarters are:

- monitoring field element and contractor performance through review of existing feedback information;
- participating in field element appraisals, assessments, surveillance, and walkthroughs;

- conducting on-site reviews of field element performance, including verification of their appraisals of the contractors; and
- for-cause reviews, as necessary.

DOE Internal Independent Oversight

The Department's Office of Oversight (EH-2) is responsible for DOE's internal independent ES&H oversight function. The Office of Independent Oversight and Performance Assurance (OA) is responsible for DOE's internal independent security and emergency management oversight function. These offices provide information and analysis needed to ensure that the Secretary, Department, contractor managers, and the public have an accurate, comprehensive understanding of the effectiveness, vulnerabilities, and trends of ES&H, security and emergency management policies and programs. The independent oversight functions are independent of DOE's line program offices in that they have no responsibility for operations or programs, policy development, or assistance to line managers. This independent oversight complements line management oversight efforts conducted according to DOE P 450.5, Line Environment, Safety, and Health Oversight. Benefits of effective independent oversight include objective, unbiased evaluations from a complex-wide perspective; an unbiased source of information on safety effectiveness for Department senior managers; and increased confidence and credibility with outside constituents. Major vehicles for internal, independent oversight of ES&H include evaluations, special reviews, special studies, and type-A accident investigations.

External Oversight

External oversight is established independently of the Department through federal and state statutes. The purpose of these oversight bodies is generally to provide the public and workers with assurance that they are being properly protected from environmental, safety, and health hazards. In most cases, external oversight applies to DOE and other federal and industrial organizations within their jurisdiction. In some cases, Congress has established a DOE-specific external oversight body, such as the Defense Nuclear Facilities Safety Board (DNFSB). The DNFSB's mandate is provided by its enabling statute, 42 U.S.C. 2286, which directs the Board to:

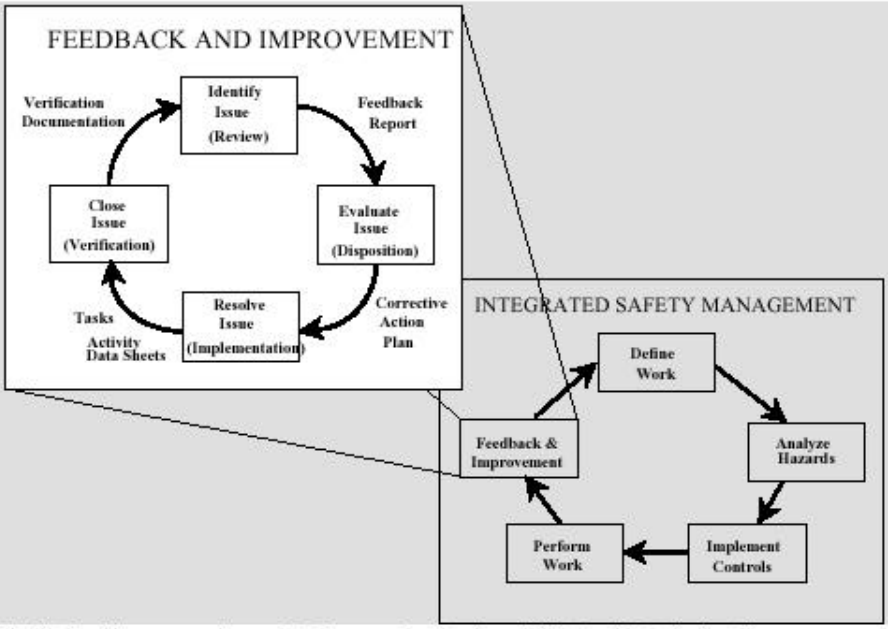
- review and evaluate the content and implementation of the standards,

- investigate events or practices,
- review the design and construction of new facilities,
- analyze facility design and operational data, and
- provide a meaningful opportunity for public participation in the recommendation process.

RESOLUTION OF SAFETY ISSUES IDENTIFIED BY DOE INDEPENDENT OVERSIGHT OFFICES

The following summary describes the major process steps, requirements, functions, responsibilities, and authorities defined in DOE O 414.1A, Quality Assurance, and provides guidelines for their implementation. The generalized feedback and improvement process is illustrated in figure 3.

Generalized Feedback and Improvement Process Framework
Applied to Safety Issue Resolution



Feedback and improvement is one of the five core safety functions of ISM. Specific feedback and improvement processes can and do vary based on the specific source and type of feedback information. Regardless of the specific feedback mechanism, this core safety function is accomplished through the following generalized steps.

Identify Issues. Feedback information is collected from a variety of sources, including management self-assessments, line management oversight, independent oversight, and external oversight. Assessments, appraisals, analyses, evaluations, reviews, and other feedback mechanisms provide clear, factually accurate information, issues, and areas for improvement.

Evaluate Issues. Cognizant line managers evaluate identified issues and determine appropriate corrective actions, if any, including plans, schedules, and relative priorities compared to other ongoing safety improvements. Dispositions include cause identification, actions to address the immediate issue, actions to prevent recurrence, and lessons learned for broader application.

Resolve Issues. Cognizant line managers implement corrective actions to resolve issues as determined by issue dispositions. Action status is tracked and reported to ensure timely and adequate issue resolution.

Close Issues. Cognizant line managers complete corrective actions and verify completion. This verification should be performed as an Independent Assessment per DOE O 414.1A, Section 4b(3)(b). Issues are closed by line management upon determining that the original issue has been effectively resolved by the actions taken.

Figure 3. *Generalized Feedback*

Note: You do not have to do example 4 on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do example 4 or go directly to the practice.

EXAMPLE 4

1. Provide three examples of how the results of a safety management assessment are used.

2. Discuss the role and responsibilities of an approval authority.

3. State the purpose of criteria review and approach documents.

Note: When you are finished, compare your answers to those contained in the example 4 self-check. When you are satisfied with your answers, go on to the practice.

EXAMPLE 4 SELF-CHECK

1. Provide three examples of how the results of a safety management assessment are used.

   - Identify areas that do not meet the requirements.
   - Prioritize those problems identified.
   - Correct problems.

2. Discuss the role and responsibilities of an approval authority.

   - Approve the safety management system description and revisions.
   - Decide if a team review is needed.
   - Select members of the review team and the team leader.

3. State the purpose of criteria review and approach documents.

   Establish the scope of the ISMS verification and provide guidance to the ISMS verification team members.

Change No: 0
DOE G 450.4-1B
Level: Familiar
Date: 6/15/01

PRACTICE

This practice is required if your proficiency is to be verified at the familiar level. The practice will prepare you for the criterion test. You may need to refer to the Orders and resources to answer the questions in the practice correctly. The practice and criterion test will also challenge additional analytical skills that you have acquired in other formal and on-the-job training.

1. To whom does DOE G 450.4-1B, Integrated Safety Management System Guide, apply?

2. Describe the two predominant environmental management system documents.

3. Discuss how management commitment to ISMS is demonstrated.

4. Discuss the purpose of a job hazard analysis.

5. Define List A and List B as related to ISMS requirements.

6. Define authorization protocols.

7. State four reasons for conducting assessments.

8. State the purpose of an ISMS verification team.

9. Discuss three of the nine core expectations for a Phase I ISMS.

10. List the four steps in the feedback and improvement function.

Note: The course manager will check your practice and verify your success at the familiar level. When you have successfully completed this practice, go to the general level module.

Change No: 0
DOE G 450.4-1B
Level: General
Date: 6/15/01

DOE G 450.4-1B
INTEGRATED SAFETY MANAGEMENT SYSTEM GUIDE
GENERAL LEVEL

OBJECTIVES

Given the familiar level of this module, an executed authorization agreement, a scenario, and an analysis, you will be able to:

- evaluate an authorization agreement; and
- state which requirements, sections, or elements of DOE G 450.4-1B apply to the situation described in the scenario.

Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.

RESOURCES

DOE Orders Self Study Program, DOE G 450.4-1B, Integrated Safety Management System Guide, Familiar Level, 6/15/01.
DOE O 414.1A, Quality Assurance.
DOE O 425.1, Startup and Restart of Nuclear Facilities.
DOE O 430.1, Life-Cycle Asset Management and its associated guides.
DOE Order 5480.23, Nuclear Safety Analysis Reports.
DOE G 450.3-3, Tailoring for Integrated Safety Management Applications.
DOE G 450.4-1B, Integrated Safety Management System Guide, volumes 1 and 2, 3/1/01.
DOE M 411.1-1, Manual of Safety Management Functions, Responsibilities and Authorities (FRAM).
DOE P 411.1, Safety Management Functions, Responsibilities, and Authorities Policy.
DOE P 450.4, Safety Management System Policy.
DOE P 450.5, Line Environment, Safety, and Health Oversight.
DOE P 450.6, Secretarial Policy Statement, Environment, Safety, and Health.
DOE-DP-STD-3023-98, DOE Limited Standard, Guidelines for Risk-Based Prioritization of DOE Activities.
DOE/EH-0573, Environmental Management Systems Primer for Federal Facilities.
DOE-STD-1027, Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports.
DOE-STD-1120, DOE Standard Integration of Environment, Safety, and Health into Facility Disposition Activities.
DOE STD-7501-95, Change 2, The DOE Corporate Lessons Learned Program.
10 CFR 820, Procedural Rules for DOE Nuclear Activities.
10 CFR 830, Nuclear Safety Management.
10 CFR 830.120, Quality Assurance.
10 CFR 835, Radiation Protection for Occupational Workers.
10 CFR 1021, National Environmental Protection Act.
48 CFR 970.1100-1, 970.5215-3, and 970.5223-1, Department of Energy Acquisition Regulation (DEAR).
48 CFR 970.5204-2, Laws, Regulations, and DOE Directives.

41 Unites States Code (U.S.C.) 253a, Public Contracts, Planning and Solicitation Requirements.
Federal Acquisition Regulation (FAR)15.605, Source Selection, Evaluation Factors and Subfactors.
ISO 14001, Environmental Management Systems.
Code of Environmental Management Principles for Federal Agencies (CEMP), U.S. EPA, September 1996.
How to Measure Performance, A Handbook of Techniques and Tools, U.S. DOE, TRADE, 1995.

INTRODUCTION

The familiar level of this module introduced DOE Guide 450.4-1B, Integrated Safety Management System Guide. The Guide offers flexible guidance to help organizations comply with the policies, the law, and the Manual of Safety Management Functions, Responsibilities, and Authorities. In the general level of this module, students are asked to apply the information contained in the familiar level and the listed resources to a series of questions related to the guide. Students are asked to review an authorization agreement using a checklist and decide if the agreement meets the requirements. Students are also asked a series of questions related to a scenario that will test their knowledge of the Integrated Safety Management System Guide. Students are not required to complete the example. However, doing so will help prepare for the criterion test.

Note: You do not have to do the example on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do the example or go on to the practice.

EXAMPLE

A review team has been assigned to verify that the authorization agreement that begins on the next page adequately addresses the following issues:

- Scope of the agreement
- DOE basis for approval
- Listing of documents that constitute the authorization basis (AB)
- Terms and conditions
- Contractor qualifications
- Special conditions
- Effective and expiration dates
- Statement of agreement
- Exceptions

Read the authorization agreement and review the guidance in section 5.2, volume 1, chapter II of the Integrated Safety Management System Guide. Then determine if the team's analysis of the agreement is correct.

BUILDING 418 AUTHORIZATION AGREEMENT

The purpose of this authorization agreement is to adopt the AB for Building 418 and to authorize the performance of activities in that building.

DOE recognized that:

- Building 418 was over 20 years old and had system deficiencies from its original intended design capability,
- there was incomplete knowledge and limited reliable/retrievable data regarding its systems and components,
- some complex systems and components required priority upgrades to perform the interim storage mission according to the implementation program plan for DNFSB Recommendation 94-3,
- the planned complex mission differs from its original design purpose, and
- additional upgrades were expected from the preparation of a new authorization basis document.

Based on these conditions, a new authorization basis document titled Basis for Interim Operation (BIO), Building 418, was developed. The following documents were used as references to prepare that document:

- DOE-STD-3011-94, Guidance for Preparation of DOE Order 5480.22, Technical Safety Requirements (TSRs) and DOE Order 5480.23, Nuclear Safety Analysis Reports Implementation Plans; and
- DOE STD-3009, Preparation Guide for DOE Nonreactor Nuclear Facility Safety Analysis Reports.

The BIO, Building 418, is the focus of this agreement.

With respect to Building 418, DOE and the contractor agree as follows:

- All BIO activities and operations conducted will be accomplished according to the applicable control set requirements established in the AB. These control set requirements are adequate to perform the general and current operations enveloped

by the analysis in the AB. During the course of BIO implementation, any additional controls and TSRs that may be needed to perform planned activities safely will be developed and evaluated according to the Activity Control and Nuclear Safety Programs described in the AB.

- The AB contains a graded set of requirements consistent with the requirements in DOE Order 5480.23. The requirements are suitable for implementing integrated safety management for Building 418 and its planned mission, including storage of special nuclear material until 2002. System evaluation reports support the BIO and document the means of ensuring compliance with the functional requirements of Building 418's safety systems, structures, and components. Adherence to these requirements is required by the TSRs.
- Applicable federal and state law, including implementing regulations, and all contractual requirements regarding Building 418 remain in force. The safety management controls in site program plans as referenced in chapter 3 of the BIO will enhance the contractor's ability to meet the safety management requirements contained in the Orders and directives listed in section J, attachment F, of contract #DE-AC34-95RF00825.
- Building 418's BIO supersedes previous AB documents. Existing Unreviewed Safety Question Determinations (USQDs) were reviewed to determine the valid compensatory measures that must be in place to meet the requirements of the proposed control set. Open USQDs and those that may be generated during implementation of the BIO will be addressed in updates to the AB, as necessary.
- Building 418's TSRs and controls will be kept current by the contractor. These controls will include an annual review. The contractor's evaluation will be used to add new activities or to make changes to existing activities identified in the AB.
- Controls in the AB will be implemented in a phased manner as described in the BIO implementation plan. The AB for BIO activities will be unambiguous at all stages during the phased implementation. For each phase, a readiness determination will be performed according to established site protocol that implements DOE O425.1, Startup and Restart of Nuclear Facilities. As of August 1, 1998, the BIO will be the AB of record for all activities conducted in Building 418.
- The contractor and DOE conclude that Building 418's BIO adequately documents the operating safety basis and contains controls that will provide reasonable

assurance that the work activities described in the AB can be conducted without endangering the environment or the health and safety of the workers or the public. The BIO review report developed by the review team using DOE-STD-1104, Review and Approval of Final Safety Analysis Reports, documents the technical bases for approval of the BIO and the TSRs.

- Building 418's safeguards and security plan provides specific direction for related activities and operations in Building 418.

This authorization agreement is effective for implementation as of August 1, 1998, and will remain in effect through the life of contract, unless extended in writing by both parties.

The team's analysis verified that all issues were addressed in the agreement.

Take some time to review the agreement and the team's analysis. Then decide if the team's conclusion is correct. If not, identify which issues were not included. Write your answer below and then compare your answer to the one contained in the example self-check.

EXAMPLE SELF-CHECK

Your answer does not have to match the following exactly. To be considered correct, your answer must convey at least the following.

The team's analysis is incorrect. The agreement does not clearly define any special conditions, nor does it identify any exceptions. The guidelines state that each issue must be addressed. Issues that do not apply must be identified as not applicable.

This practice is required if your proficiency is to be verified at the general level. If you are to be qualified as a facility representative, the practice will prepare you for the criterion test. You will need to refer to the Guide to answer the questions in the practice correctly. The practice and criterion test will also challenge additional analytical skills that you have acquired in other formal and on-the-job training for the facility representative position.

PRACTICE

Review the scenario below and answer the questions that follow the scenario.

SCENARIO

A spread of radiological contamination occurred in a facility's sub-basement. The radiological operations manager was performing a follow-up on a contaminated drum that was in the radiological buffer area. The radiological operations manager determined that recovery contamination surveys needed to be performed, and dispatched a radiological control technician (RCT) to the area to perform the surveys. While the RCT was performing the contamination surveys, an employee entered the area. The RCT checked the shoes of the employee; up to 780 dpm of alpha contamination was discovered on the employee's shoes. Personnel were relocated from the area and surveyed. No other contamination was detected. The affected area was posted as a contaminated area. The building implemented incident command and additional surveys were performed. The surveys revealed contamination levels of 200,000 dpm of alpha contamination in the room, and 2500 dpm of alpha contamination were also discovered in adjoining rooms. These rooms were posted as airborne radioactivity areas. Further investigation discovered a pin-size hole in the bottom of the contaminated drum. An employee moved a drum containing >200 grams of Pu from Room A to Room B located on the ground floor of the facility. When the drum was moved to the airlock, contamination surveys were taken as required before the drum could be released out of the area. Contamination surveys taken indicated loose contamination levels of alpha contamination on the bottom and sides of the drum. The operators moved the drum back into Room A, but then decided that the contaminated drum could not be left in Room A because the room was not designated as a contamination area. The operators decided to move the drum into the hallway, through Room C and into Room D. It was later determined that Room D was not posted to allow the storage of this type of drum. Contamination surveys were performed. The surveys revealed 726 dpm of

alpha contamination in Room A, which was then posted as a contaminated area. No contamination was discovered in the hallway. Although the intent of the operators was to secure the drum, their actions complicated the situation, which resulted in several errors. Movement of the drum was not overseen by an RCT nor was the shift manager notified of the upset condition. This resulted in a failure to stabilize the situation and establish a more controlled response, and a loss of work control.

Evaluations were conducted, and the affected area was posted as a contaminated area. The building implemented incident command, and additional surveys were performed to identify the contamination source.

A cause analysis of the incident was performed, and the following problems were identified.

- When the supervisor performed the pre-evolution briefing for moving the drums, there was a failure to recognize that one of the drums to be moved contained > 200 grams of Pu.
- The supervisor failed to review the Nuclear Material Drum Transfer Report (NMDTR), which clearly showed that one of the drums would require another surveillance to ensure criticality compliance with the movement. Failure to recognize this requirement resulted in not including the drum on the material move sheet, which is approved by radiological operations and the shift manager.
- Had the evolution supervisor properly and correctly identified the drum and conducted the appropriate surveillance measures, the identified controls would have been in place before the evolution. Because the shift manager was not informed of the situation at the onset or of the upset conditions, there was an inability to respond and establish command and control over an evolution that was out of control.

QUESTIONS

1. Which of the ISMS core functions would have been helpful in reducing the potential for this accident to occur?

2. Develop an action plan that would prevent similar occurrences.

Note: The course manager will check your practice and verify your success at the general level. When you have successfully completed this practice, the course manager will give you the criterion test.