

## ATTACHMENT

### **Fiscal Year 2011 Annual Integrated Safety Management System and Quality Assurance Effectiveness Review Declaration Guidance**

#### **Office of Environmental Management**

#### **1.0 Objectives**

One of the strategy's in Goal 5 of the Office of Environmental Management's (EM) Journey to Excellence Roadmap is to "Develop a concise statement that defines EM's vision that can be used to improve the effectiveness and focus of EM's annual ISM validation." This statement is the overlying principle for this year's guidance for the EM Declaration for Integrated Safety Management System (ISMS) as follows: As an institution, EM has over a decade of experience with implementation of ISMS and Quality Assurance (QA) Effectiveness Reviews. The ISMS guidance and subsequent integrated ISMS and QA declarations are an important tool in advancing EM's Journey to Excellence and our collective goal for continuous improvement in planning, management, and execution of day-to-day mission activities.

This document presents EM Fiscal Year (FY) 2011 Annual ISMS and QA Effectiveness Review Declaration guidance. The purpose of this document is to ensure a consistent and systematic approach for EM DOE field offices to perform annual ISMS and QA effectiveness reviews and prepare an annual declaration of the status of ISMS and QA implementation using the results of this review. Furthermore, it provides criteria for annual ISMS and QA Declaration submittals from field offices.

#### **2.0 Introduction**

The annual ISMS and QA effectiveness reviews are essential elements of ISMS and QA implementation that promote continuous improvement. These annual effectiveness reviews are expected to be completed using existing programs and processes designed to meet Department of Energy (DOE) Order (O) 210.2A, *DOE Corporate Operating Experience Program*, DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, DOE O 414.1D, *Quality Assurance*, and DOE O 450.2, *Integrated Safety Management*. These DOE directives have been revised to a succinct set of requirements and will ultimately include separate guidance documents. These revised directives focus on top-level requirements designed to give flexibility on how to implement them; however, these revisions must not be considered as direction to reduce the rigor and effectiveness of DOE and contractor ISMS and oversight programs currently in place. With safety as a core value, EM remains committed to continued development and implementation of the robust mechanisms and processes outlined in the original/predecessor directives.

DOE effectiveness reviews are to be conducted using Contractor Assurance Systems, self-assessments, line management operational awareness and oversight mechanisms,

performance measurement and analysis against established Performance Objectives, Measures, and Commitments (POMCs), Operating Experience Program, and other feedback and performance mechanisms. Elements of these reviews are ongoing throughout the year, and should culminate in a review report that supports an annual ISMS summary evaluation. DOE managers will supplement the use of existing mechanisms with targeted ISMS reviews or full ISMS re-verifications when the DOE manager believes there are indications of serious performance issues related to implementation of ISMS functions or principles. The purpose of these annual effectiveness reviews is to:

- 1) Determine the effectiveness of the implementation of the ISMS Description and QA Program (QAP) in supporting the safe conduct of quality work; and
- 2) Identify weaknesses to focus attention on corrective and improvement actions.

DOE field offices must plan and conduct full ISMS verifications for new prime contractors and for existing contractors when determined necessary by the DOE manager to ensure continued effectiveness or evaluate corrective actions. Field managers should consider the scope and periodicity of assessment activities by external groups in determining whether a full verification is needed. Tailoring the scope of the verification to focus on areas that have not received recent attention or are known to need verification of improvement actions is a good practice.

Consistent with the EM Corporate QAP, EM-QA-001, dated November 2008, DOE field offices are required to perform independent assessments of QAP implementation effectiveness with a scope and frequency that is graded and based on the status of prior quality performance and any third-party QAP certification. Once the need, scope, and frequency are identified, ISMS re-verifications and QA independent assessments should be scheduled as part of the DOE and/or contractor's oversight schedule.

The annual declaration should address all five criteria discussed in section 3. The declaration should also include an ISMS Description update, if necessary. Annual update of the ISMS description is not required if no substantial changes are deemed necessary. In such cases, a statement to this effect should be included in the ISMS declaration report.

The EM DOE field offices are responsible for performing and using the results of ISMS and QA effectiveness reviews to prepare an annual declaration of the status of ISMS and QA implementation, and submit to EM Headquarters (HQ) by December 30, 2011. As such, the effectiveness reviews and any required ISMS targeted reviews, verifications or re-verifications should be planned to meet this deadline. In addition, field managers should provide contractors timely direction on how to support the 2011 annual effectiveness review activities, solicit approval of the FY 2012 POMCs, and develop the Declaration.

### **3.0 Criteria for Annual ISMS and QA Effectiveness Reviews and Declaration**

The Annual Effectiveness Report and Declaration provides an opportunity for each field manager to objectively review, analyze, evaluate safety and quality performance, and formally document his/her assessment of the effectiveness of implementing ISMS at their site(s) including reporting progress against POMCs established during the previous year. The declaration serves a critical role to identify opportunities for continuous improvements in execution of EM programs. Declarations must be supported by objective evidence, such as: safety and quality performance metrics and trending data; results from ISMS targeted reviews or verifications, assessments, surveillances, management walkthroughs, event and accident investigations; and documented effectiveness of corrective actions taken to improve deficiencies or adverse safety and/or quality performance. The requirements for QA are included in the EM Corporate Quality Assurance Program, EM-QA-001, dated November 2008.

The field offices should submit annual declarations to EM HQ based on the results of their effectiveness reviews. The ISMS effectiveness review is primarily meant to be a DOE activity that uses information from existing line oversight processes and the contractor's assurance system. Contractor documents supporting the effectiveness review and declaration conclusion may be referenced in the declaration submittal, but should not be attached to the submittal. Contractor supporting documentation should be made available upon request if needed for HQ review.

The annual declaration submittal should address the following five criteria:

#### **Criterion 1: DOE Operational Awareness, Oversight, and Contractor Assurance System(s)**

The timeliness and effectiveness of field office line management oversight and operational awareness of potential project specific safety and quality issues is critical to prevent and minimize risks to executing EM mission within agreed upon cost and schedule. Three key opportunities for improving field line management oversight and operational awareness are: 1) use of technically consistent and documented Criteria Review and Approach Documents (CRAD) to evaluate contractor performance including services and products provided by subcontractors, fabricators, and suppliers; 2) persistent senior management follow-up to ensure the effectiveness of issues management process including timely completion of corrective action plan commitments; and 3) use of technically qualified staff to conduct the oversight and performance analyses.

Using DOE O 226.1B and DOE O 450.2 as benchmarks, describe:

- a. Assessment of maturity and effectiveness of Contractor Assurance System(s) in proactively identifying, evaluating, and addressing issues or concerns before they become self-identifying through occurrences or serious accidents or found by DOE oversight activities.

- b. Effectiveness of field office operational awareness and oversight of contractor and subcontractor activities.
- c. Plans/schedule for conducting full ISMS verification for new contractors (as required by DOE O 450.2 and supporting guidance) or ISMS targeted reviews of contractors as determined by the field managers.
- d. Self-assessment of the effectiveness of field line management and operational awareness of contractor issues and risks to ensure performance.

### **Criterion 2: Quality Assurance Plan (QAP) Implementation**

Using the *Office of Environmental Management Quality Assurance Program*, EM-QA-001, dated November 2008, and the guidance provided in the *Protocol for EM Review/Field Self-Assessment of Site-Specific Quality Assurance Programs/Quality Implementation Plans*, dated February 2010, provide the following: (note: the referenced documents are available online at <http://www.em.doe.gov/Pages/qualityassurance.aspx>):

- a. An evaluation of the effectiveness of QA program implementation by the Federal field office, prime contractors (including construction and operating projects), and a summary of subcontractors.
- b. A status of actions to address issues identified during the Phase 2 QAP/QIP implementation reviews.
- c. A discussion on how DOE EM field elements ensure that all work performed by the subcontractors/vendors is consistent with the applicable requirements of prime contractor's QAP/QIP. As part of this evaluation, specifically discuss how DOE assures that contractual quality requirements are flowed-down to all levels of work including prime contractors, subcontractors, and vendors. Also discuss the effectiveness of the suspect/counterfeit item program and how DOE assures such items are not introduced to safety related equipment.
- d. A completed EM Corporate QA Performance Metrics table for the Federal office and prime contractors.

### **Criterion 3: Activity Level Work Planning and Control, Job Hazard Identification and Analysis, and Development of Hazard Controls**

Using the Work Planning and Control Program Guidelines (Office of Safety and Security Program memorandum to the field, dated April 7, 2010) or other EM CRADs that address the EM guidance as a minimum, as well as work planning metrics, assess the effectiveness of work planning and control for each contractor. Throughout most of calendar year 2011, URS Corporation has undertaken an initiative to develop a work planning and control standard, in coordination with DOE and the Defense Nuclear Facilities Safety Board that could be used at sites in which they have a lead role. In July 2011, URS approved the standard and directed that its sites perform assessments to identify how their programs compare against the standard and how they would address

any identified gaps. This standard, identified in section 7.0, References, may have some utility in performing these reviews.

#### **Criterion 4: Nuclear Safety Culture and Establishment of Safety Conscious Work Environment**

All aspects of a nuclear safety culture should be evaluated using the structure of the Energy Facilities Contractor/DOE ISMS Safety Culture Focus Areas and Attributes (Energy Facilities Contractor Operations Group Document *Assessing safety culture in DOE facilities, 01/23/2009*).

Place emphasis on evaluating the ISM supplemental safety culture principle regarding organization learning for performance improvement. The two supplemental topics under organizational learning for performance improvement and their associated Lines of Inquiry (LOI) are discussed below. For the LOI, additional resources are identified below in the footnote.

##### **Organizational Learning for Performance Improvement**

The organization demonstrates excellence in performance monitoring, problem analysis, solution planning, and solution implementation. The organization encourages openness and trust, and cultivates a continuous learning environment.

##### **Safety Conscious Work Environment/Environment for Raising Concerns – LOI include:**

- Evaluate whether an environment exists in which employees feel free to raise concerns to their management, their customers, DOE or external regulators, without retaliation; and employees are encouraged to raise such concerns (*draft DOE G 450.4-1c, Att. 9, item 1 and 4; NRC Safety Culture Policy item 6; NRC Inspection Manual 310 06-03; INPO Principle 3*)<sup>1</sup>.
- Evaluate whether behaviors and interactions encourage free flow of information related to nuclear safety issues, differing professional opinions, and employee concerns and their prompt resolutions (*draft DOE G 450.4-1c, Att. 9, item 2 and 4; NRC Safety Culture Policy item 8 and 9; NRC Inspection Manual 310 06-03.a and b; INPO Principles 3 and 6*).

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<sup>1</sup> Draft DOE G 450.4-1C, *Integrated Safety Management System Guide* (2011); U.S. Nuclear Regulatory Commission (NRC) *Final Safety Culture Policy Statement* (June 2011), the NRC Inspection Manual Chapter 0310, *Components Within Cross-Cutting Areas* (February 2010), and the Institute of Nuclear Power Operations (INPO) *Principles of a Strong Nuclear Safety Culture* (2004).

**Preventing, Detecting, and Mitigating Perceptions of Retaliation – LOI include:**

- Evaluate whether the organization has an existing policy prohibiting harassment and retaliation for raising nuclear safety concerns and it is enforced (*draft DOE G 450.4-1c, Att. 9, item 1 and 4; NRC Safety Culture Policy item 6; NRC Inspection Manual 310 06-03 a and b; INPO Principles 3 and 6*).
- Evaluate whether all persons are aware that harassment and retaliation for raising safety concerns will not be tolerated (*draft DOE G 450.4-1c, Att. 9, item 1 and 4; NRC Safety Culture Policy item 6; NRC Inspection Manual 310 06-03 a and b; INPO Principles 3 and 6*).
- Evaluate how employees perceive how well their Differing Professional Opinion and employee concerns were handled (*draft DOE G 450.4-1c, Att. 9, item 1 and 4; NRC Safety Culture Policy item 6; NRC Inspection Manual 310 06-03 a and b; INPO Principles 3 and 6*).

These LOIs should facilitate the assessment of the maturity of the nuclear safety culture of the field element *Federal project management* line organization and its supporting contractor(s). The declaration should also discuss the actions taken by the field manager in response to feedback (EM-wide and site specific) from the FY 2010 EM Federal Employee Safety Culture Survey and an assessment of the effectiveness of the actions to address the specific areas for improvement.

**Criterion 5: Safety Performance Objectives, Measures, and Commitments (POMCs)**

- a. Evaluate and describe the progress towards meeting FY 2011 POMCs and its influence on establishing FY 2012 POMCs, including discussion of field element and contractor performance against FY 2011 POMCs. See section 4.0 for guidance on development and approval of field office and contractor POMCs.
- b. Provide the field manager approved POMCs for both the field office and contractor(s) for FY 2012. These FY 2012 POMCs must include:
  - 1) POMCs to improve or enhance work planning and control performance. Work planning and control consists of many processes and elements such as planning, hazards analysis, and coordination with other work activities, effective supervision, attentive and trained workers, pre and post-job briefings, accurate documentation, and oversight of these elements.
  - 2) Occupational injury and illness rate goals (Total Recordable Case and Days Away from Work, Restricted Work or Transfer Case Rates) to continue improvement and support EM-wide rate goals.

- 3) Leading and lagging indicators specific to nuclear, radiologic or other high hazard facilities at the site to ensure safety of workers, the environment, and the public.
- 4) Indicators to address nuclear safety culture aspects discussed under criterion 4.

#### **4.0 Guidance on Development of FY 2012 POMCs**

Each year, EM HQ, field offices, and contractors develop POMCs for tracking and reporting. The purpose of POMCs is to:

- 1) Establish specific objectives/goals and commitments for key improvement initiatives and safety performance metrics.
- 2) Provide performance benchmarks.
- 3) Provide quantitative feedback and comparative analysis.
- 4) Establish leading indicators to provide insights into areas that may challenge nuclear safety.

DOE P 450.4A, *Integrated Safety Management Policy*, and DOE O 450.2, *Integrated Safety Management*, and DEAR Clause 48 C.F.R 970.5223-1 establish expectations for DOE Environment Safety and Health (ES&H) goals and performance objectives, measures, and commitments to be developed annually. Site-specific ES&H and QA performance measures are established annually to drive performance improvement or maintain excellent performance. As noted in Goal 5 of the Journey to Excellence, EM's ultimate ES&H goal is zero accident, work-related injuries and illnesses, regulatory enforcement actions, and reportable environmental releases. QA performance goals are established and maintained in the EM Corporate QA Program. These goals are to be pursued through a systematic and concerted process of continuous performance improvements using performance measurement. The ES&H and QA goals are expected to drive performance excellence, thereby reducing or precluding other work-related injuries and illnesses and adverse impacts to the public and environment. The annual ES&H safety goals and metrics, established in accordance with DOE O 450.2, must be fully integrated with the ISMS POMCs. Quality goals and metrics established by both HQ and field elements must also be fully integrated with the QA POMCs as established in the EM Corporate QA Program.

The following process for developing EM field and contractor POMCs is recommended:

- 1) Field offices provide EM HQ guidance, supplemented by field element guidance and direction to its contractors and solicit from its contractors for developing their site-specific safety performance measures.
- 2) Field offices develop their site-specific safety performance measures as noted under item b of criterion 5, as augmented by EM HQ safety performance goals and direction.

- 3) Field offices provide direction to its contractors on their contract-specific ISMS and QA POMCs.
- 4) Contractors submit their contract-specific ISMS and QA POMCs to the DOE field office for approval.
- 5) DOE field offices develop their site-specific ISMS and QA POMCs and submit them to EM HQ via the ISMS/QA declaration submittal process.

## 5.0 Annual Effectiveness Review and Declaration Report

Include a declarative statement such as “ISMS and QAP have or have not been implemented and effective at ensuring safety and quality performance or effective but needing improvement.” Include an executive summary of the effectiveness review results along with any objective evidence that supports the field manager’s declaration for the field element and each contractor. The declaration report must address all five criteria including sub criteria. If a criterion is not applicable, it should be stated in the declaration with a brief explanation stating the reasons for any criterion not being applicable.

The report should provide the following attachments:

- 1) Current Update of Field Office ISMS Description  
(Note: Annual update of the ISMS Description is not required if no substantial changes are deemed necessary. In such cases, a statement to this effect should be included in the ISMS Declaration report.)
- 2) EM Corporate QA Performance Metrics Summary Reports per EM guidance memoranda at the following website:  
<http://www.em.doe.gov/Pages/qualityassurance.aspx>
- 3) Tables of FY 2011 Field element and contractor POMC results and DOE field element and DOE approved contractor FY 2012 POMCs.

## 6.0 Contact

**Braj K. Singh, EM Office of Safety Management (EM-21), (301) 903-3037,  
Braj.Singh@hq.doe.gov.**

## 7.0 References

DEAR Clause 970.5223-1, *Integration of environment, safety, and health into work planning and execution*

DOE O 210.2A, *DOE Corporate Operating Experience Program*

DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*

DOE P 226.1B, *Department of Energy Oversight Policy*

DOE M 231.1-2, *Occurrence Reporting and Processing of Operations Information*

DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*

DOE G 414.1-1B, *Management and Independent Assessments Guide*

DOE O 414.1D, *Quality Assurance*

DOE O 442.1A, *Department of Energy Employee Concerns Program*

DOE M 442.1, *Differing Professional Opinions Manual for Technical Issues Involving Environment, Safety, and Health*

DOE O 450.2, *Integrated Safety Management*

DOE P 450.4A, *Integrated Safety Management Policy*

DOE G 450.4-1B (Volumes 1 & 2), *Integrated Safety Management System Guide*

DOE G 450.4-1C, *Integrated Safety Management System Guide (Draft)*

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

DOE-STD-1189-2008, *Integration of Safety into the Design Process*

EM Corporate Quality Assurance Program, EM-QA-001, dated November 2008

EM Protocol/Field Self-Assessment of Site-Specific QAP/QIP, dated February 2010

URS *Global Management & Operations Services Work Planning and Control Program Standard*, July 2011

Energy Facilities Contractor Group Nuclear Safety Culture Resources at  
[http://www.efcog.org/wg/ism\\_pmi/index.htm](http://www.efcog.org/wg/ism_pmi/index.htm) and  
[http://www.efcog.org/wg/ism\\_pmi/EFCOG\\_DOE\\_safety\\_culture.htm](http://www.efcog.org/wg/ism_pmi/EFCOG_DOE_safety_culture.htm) and  
[http://www.efcog.org/wg/ism\\_sctt/docs/safety\\_culture\\_assessment\\_012309\\_final.pdf](http://www.efcog.org/wg/ism_sctt/docs/safety_culture_assessment_012309_final.pdf)

Institute of Nuclear Power Operations, *Principles of a Strong Nuclear Safety Culture*, 2004

Nuclear Regulatory Commission, *Final Safety Culture Policy Statement*, Federal Register Vol.76, No. 114, June 14 2011

Nuclear Regulatory Commission, *Inspection Manual Chapter 0310*, February 23, 2010