OFFICE OF ENVIRONMENT, SAFETY AND HEALTH ASSESSMENTS PROTOCOL FOR THE DEVELOPMENT AND MAINTENANCE OF CRITERIA REVIEW AND APPROACH DOCUMENTS

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Office of Enterprise Assessments
U.S. Department of Energy

Office of Environment, Safety and Heath Assessments
Protocol for the Development and Maintenance of
Criteria Review and Approach Documents

March 2015

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1.0 PURPOSE

The purpose of this protocol is to establish the requirements and responsibilities for the development and maintenance of criteria review and approach documents (CRADs) used by the Office of Environment, Safety and Health Assessments (EA-30). The EA-30 CRADs are carefully selected, modified (if required), and referenced in review plans for the Office of Nuclear Safety and Environmental Assessments (EA-31), Office of Worker Safety and Health Assessments (EA-32), and the Office of Emergency Management Assessments (EA-33). These plans are used to provide an outline of the activities planned to assess the effectiveness of safety and emergency management processes and practices used by line management and contractor organizations, as well as to evaluate their performance in protecting our workers, the public, and the environment from the hazards associated with U.S. Department of Energy (DOE) activities and sites.

2.0 APPLICABILITY

This protocol is applicable to EA-31, EA-32, and EA-33.

3.0 REQUIREMENTS

1. The Office of Enterprise Assessments (EA) Office of Environment, Safety and Health Assessments' review activities are to be performed in accordance with DOE Order 227.1, *Independent Oversight Program*, and applicable EA-wide and EA-30 specific protocols and CRADs.

2. The EA CRADs are documents used by EA-31, EA-32, and EA-33 to assess contactor and Federal performance in accordance with applicable laws, statutes, rules, executive orders, national standards, DOE directives, DOE-approved plans and program documents, site specific procedures, and contractual requirements. All EA CRADs are standardized and are posted on the EA website to provide a tool for use by DOE and contractor line organizations as they prepare for EA appraisals. Standardization of the EA CRADs also supports consistency in the appraisal process. Due to the unique configuration of the multiple facilities that EA reviews, CRADs are sometimes tailored for targeted reviews. These modifications can include an increase or decrease in the number and focus of review criteria items, review approach items or lines of inquiry, and will typically be discussed in the specific plan that is developed for each review. All CRAD modifications must be approved by the responsible subordinate EA-30 Office Director or his/her designee.

3. EA-30 CRADs must contain the following sections:

    - Purpose section (i.e., a generic purpose statement, as shown in Appendix A). This section also includes reference to Department directives that establish responsibilities or requirements associated with the subject area as appropriate.

    - Applicability section (i.e., a statement regarding who is approved to use the CRAD, as shown in Appendix A).

    - Feedback section (i.e., a generic statement regarding the methods to provide feedback, as shown in Appendix A).

- Body section containing the criteria review and approach elements, as shown in Appendix A.

4. In accordance with DOE Guide 226.1-2, *Federal Line Management Oversight of Department of Energy Nuclear Facilities*, the body section of EA-30 CRADs consists of the following elements:

   - **Performance Objective** – Identification of the expectation(s) or requirement(s) to be verified, which reflect the complete scope of the assessment.

   - **Criteria** – The specifics by which the performance objectives are measured, including regulatory and/or site-specific requirements.

   - **Review Approach** – A statement of the documents, interviews, and observations (e.g., work or shift evolutions) that are used to obtain objective evidence in order to determine whether a criterion is met or not.

   EA-30 CRADS will typically include assessment of the applicable line oversight function.

   Appendix A provides an example of a suitably formatted CRAD, using the following guidance contained in DOE G 226.1-2:

   Creating the Performance Objective. The objective in each CRAD includes all, or portions, of one or more requirements or performance attributes being assessed. When writing the performance objective for a review of implementation of a nuclear facility safety management program (SMP) or functional area, the goal or objective of the SMP or functional area is typically clearly stated in the scope and purpose section of the relevant directive. To write the objectives, use the following as a guide:
   - Begin with requirements;
   - Use performance goals;
   - Use performance expectations; and
   - Treat functional areas broadly, allowing criteria to address specifics.

   Example:

   OBJECTIVE: Line management has established and implemented a fire protection program to ensure adequate protection of operations and activities. (10 CFR 830, DOE O 420.1C)

   Criteria. The criteria in the CRAD are developed to reflect the objective and address all requirements/performance attributes, regardless of the approach used in developing the criteria. The criteria should follow, and be clearly related to, the requirements, which may include regulatory and/or site-specific procedural requirements. It is important to remember that the sum of the criteria should provide an adequate basis for determining whether the objective has been met. Each specific criterion is a statement of the specific actions or attributes the team members use to make a judgment that Federal and/or contractor programs and management systems, including assurance and oversight systems, are performing effectively and complying with DOE requirements. The criteria should be specific statements that are:
   - Measurable (e.g., the "program will have 10 working elements"); and
   - Assessable (e.g., "there is documented evidence of meeting the working elements").

   Criteria statements may also be derived from guides, standards, and good practices that are associated with requirements.

Review Approach. The Review Approach section of the CRAD describes the documents to be reviewed, the personnel to be interviewed, and the field activities, including tours and walk-downs, to be observed to allow the team to reach a conclusion as to whether the criteria have been met. Any documents expected to be reviewed (e.g., procedures, drawings, logs, reports, correspondence, other evaluations) should be cited in the CRAD. It is important to research and determine how documents that control work (e.g., procedures) are promulgated. There are two ways to determine whether documents are being followed or understood: interviews and observations of work or shift evolutions. The titles of the personnel to be interviewed, along with the shift evolutions to be observed, should be recorded in the CRAD. The CRAD should also list any other references (e.g., DOE orders, mandatory standards, or site-specific requirements) against which the criteria are to be assessed.

For the interview portion of the CRAD, reviewers should develop lines of inquiry (LOIs). LOIs are sets of questions that are directly related to the criteria and are used to determine whether an objective or criterion is met or not. Questions are tailored for various levels of management and workers. Each LOI should be designed to ensure the answers from each interview are complete, unambiguous, and sufficiently comprehensive. Questions that can be answered with a "yes" or "no" may be used but should be followed with an open-ended question that would provide insight and details supporting the one-word answer. For example:

- Does the contractor perform periodic assessments of the fire protection program?
- If yes, what mechanisms does line management use to ensure that assessments are performed and that the contractor's fire protection program is effective?
- If no, why doesn't the contractor perform periodic assessments?

The review approach links back to each of the criteria. If the review approach is conducted correctly, the documented review becomes a major part of the final write-up.

5. EA-30 staff will use the following steps in the development of a CRAD:

   a. Notify the Director of EA-30 and the appropriate Director of EA-31, EA-32, or EA-33 of the intent to develop a new CRAD or update an existing CRAD. Obtain permission before proceeding; management will verify that the new or updated CRAD is needed and that the employee updating the CRAD has the necessary qualifications and experience to perform the task.

   b. Obtain the CRAD template or the current CRAD from the EA-30 Management Analyst.

   c. Create or modify the CRAD using the EA-30 CRAD template format, as shown in Appendix A.

   d. Perform a document peer review by EA-30 staff and a subject matter expert (SME) for the subject area.

   e. Request the EA-30 Management Analyst to format and complete a review of the document.

   f. Submit the document through the appropriate Director of EA-31, EA-32, or EA-33 to the Director of EA-30 for approval.

   g. After approval, the EA-30 Management Analyst adds the updated or new CRAD to the EA website and removes the out-of-date CRAD as necessary.

6. CRADs will be updated to ensure that they are current when new or revised source documents are issued and in support of continuous improvement. As a minimum each CRAD will be evaluated biannually (every 2 years) to ensure that changes have been made to incorporate new or revised source documents.

   Existing CRADs can be found at the following EA website link:
   http://energy.gov/iea/listings/criteria-review-and-approach-documents

4.0 RESPONSIBILITIES

Director, Office of Environment, Safety and Health Assessments

- Approves revisions to this protocol.

Directors, EA-31, EA-32, or EA-33

- Approves CRADs.
- Reviews requests for development of a new CRAD or update of an existing CRAD within appropriate subject area.
- Reviews new and updated CRADs within appropriate subject area.
- Assigns appropriate technical staff SME to create, update, and maintain CRADs.
- Ensures that the SMEs creating or updating CRADs possess qualifications, competencies, and experience commensurate with their assignments and are free of any potential conflict of interest.
- Ensures CRADs are updated in accordance with new or revised requirements and are in support of continuous improvement; at a minimum biannually (every 2 years).

Subject Matter Experts

- Reviews CRADs periodically and when referenced requirements change to ensure that the information contained in the CRAD is current.
- Provides recommendations for revisions to CRADs based on the issuance of new or revised source documents and in support of continuous improvement.

EA-30 Management Analyst

- Maintains CRAD templates.
- Formats CRADs prior to placement on the EA website.
- Supports the Director in assuring that CRADs are maintained current and reviewed at a minimum biannually (every 2 years).

- Adds updated and new CRADs to the EA website.
- Removes out-of-date CRADs from the EA website.
- Maintains a list of staff assignments for maintenance and updates of CRADS.

5.0 REFERENCES

- DOE Order 227.1, *Independent Oversight Program*
- DOE Guide 226.1-2, *Federal Line Management Oversight of Department of Energy Nuclear Facilities*

APPENDIX A

Office of Environment, Safety and Health Assessments CRAD Template

		Number: EA CRAD (enter EA-31, 32, or 33) Revision: (enter Rev. #) Effective Date:
(Name of CRAD) Criteria Review and Approach Document		
Authorization and Approval	Director, Office of (enter EA-31, 32, or 33) Date:	Lead, (enter name) Title Date:

1.0 PURPOSE

Within the Office of Enterprise Assessments (EA), the Office of Environment, Safety and Health Assessments (EA-30) mission is to assess the effectiveness of those safety and emergency management systems and practices used by line and contractor organizations in implementing Integrated Safety Management; and to provide clear, concise, and independent evaluations of performance in protecting our workers, the public, and the environment from the hazards associated with Department of Energy (DOE) activities and sites.

In addition to the general independent oversight requirements and responsibilities specified in DOE Order 227.1, *Independent Oversight Program*, this criteria review and approach document (CRAD), in part, fulfills the responsibility assigned to EA in (reference source document) to (paraphrase responsibility or requirement).

A key to success is the rigor and comprehensiveness of our process; and, as with any process, we continually strive to improve and provide additional value and insight to field operations. Integral to this is our commitment to enhance our program. We continue to make CRADs available for use by DOE line and contractor assessment personnel in developing effective DOE oversight, contractor self-assessment, and corrective action processes; the current revision is available at: http://energy.gov/iea/listings/criteria-review-and-approach-documents.

2.0 APPLICABILITY

The following CRAD is approved for use by the Office of (enter EA-31, 32, or 33).

3.0 FEEDBACK

Comments and suggestions for improvements on this CRAD can be directed to the Director, Office of Environment, Safety and Health Assessments, at (301) 903-5392.

4.0 CRITERIA REVIEW AND APPROACH

An example of a suitably formatted CRAD for Radiation Protection (RP) is as follows:

OBJECTIVE

RP.1: Site Contractor line management has established radiation protection safety management programs (SMPs), including organizational structure and administration, to ensure effective implementation and control of all radiological protection activities. (10 CFR 835.101)

CRITERIA

1. The Site Contractor Radiation Protection Program has been effectively implemented in support of the full scope of facility operations, including bioassays, the As Low As Reasonably Achievable (ALARA) principle, radiological work permits (RWPs), survey requirements, and decontamination (10 CFR 835, Radiation Protection Program for 10 CFR 835, Occupational Radiation Protection).

    - Is there a documented Radiation Protection Program (RPP) that adequately addresses the flow down of regulatory requirements including how each element of 10 CFR 835 is implemented? (Note the development of LOI questions that directly relate to the criteria.)

    - Are updates to the RPP submitted to DOE: whenever a change or addition to the RPP is made (if the change decreases the effectiveness of the RPP); prior to the initiation of a task not within the scope of the RPP; within 180 days of any modification to 10 CFR 835?

2. Assessments of program elements are performed, including: boundary control stations and access controls; routine surveys and monitoring (both airborne and surface); survey records and maps; and, bioassay baseline and continuing monitoring processes and records. The results of the assessments are evaluated and issues are resolved. The assessments confirm the adequacy of the radiation protection program in support of facility activities (Site Contractor Radiation Control (RadCon) Manual, RadCon Internal Audit Program).

3. An adequate number of radiation protection program personnel, including radiological control technicians, radiation control engineers, and support technicians, are assigned and available to support facility activities (10 CFR 835, Site Contractor RadCon Manual).
    - Are the organizational responsibilities for radiological protection well defined and understood with staffing and resources sufficient to accomplish assigned tasks?

- Are radiological protection requirements actively administered by site/facility management and supervision and adhered to by personnel, and do managers and supervisors observe radiological protection activities to ensure adherence to established policies and procedures and to identify and correct problems?

4. Instrumentation in support of facility activities is appropriate, adequate inventory is provided, calibrations are current, and source checks are performed as required (10 CFR 835, Site Contractor RadCon Manual).

5. Packaging and Transportation (P&T) program requirements necessary to support the facility have been incorporated into the Site Contractor program. Program requirements include P&T of both radioactive waste and other radioactive material (DOE O 460.1B, DOE O 460.2A, Standards/Requirements Identification (S/RID)).

6. Facility radioactive waste management procedures and processes are compliant with the Site Contractor Radioactive Waste Management Program. Adequate personnel, facilities, and equipment are available to support facility radioactive waste management processes and activities. The Site Contractor has assessed the adequacy and compliance of the facility's radioactive waste management processes. Issues have been resolved, and the program has been assessed as adequate to support facility operations (DOE O 435.1C, S/RID).

APPROACH

Record Review:

- Site Contractor assessment records associated with the radiation protection program, material P&T programs, and radioactive waste management programs as they apply to facility operations and activities.
- Site Contractor Manual, Radiation Protection Program Plan
- RWPs
- Work packages related to facility activities for which radiological controls are appropriate
- Documented Safety Analysis
- Technical Safety Requirements
- Contamination Control Plan
- ALARA review documentation
- Bioassay plans and results
- Routine assessments and oversight of RadCon program implementation in support of facility operations
- Facility radiation protection program equipment calibration data
- P&T plans and procedures for movement of radioactive material
- Site Contractor P&T program documentation in support of facility operations
- Site Contractor Radioactive Waste Management Program documentation in support of facility operations

Interviews:

- RadCon Lead
- Facility Manager
- P&T Manager responsible for the facility
- Work Control Lead for the facility
- Work planners who support the facility

- Cognizant System Engineer(s) who support the facility
- Selected facility operational and support personnel

Observations:
- Facility operational demonstrations
- Facility and building walkdowns and reviews
- Operational demonstration of P&T activities
- RadCon equipment calibration procedures
- Boundary Control Stations
- Routine and special radiation and contamination surveys