



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

**PROTOCOL – EA-30-01
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Office of Enterprise Assessments
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**Office of Environment, Safety and Health Assessments
Protocol for the Development and Maintenance of
Criteria and Review Approach Documents**

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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 and review approach documents (CRADs) used by the Office of Environment, Safety and Health Assessments (EA-30). The EA-30 CRADs are selected, modified (if required), and referenced in assessment plans for the EA-30 Tier 2 Offices (i.e., Office of Nuclear Safety and Environmental Assessments (EA-31), the Office of Worker Safety and Health Assessments (EA-32), the Office of Emergency Management Assessments (EA-33), and the Office of Nuclear Engineering and Safety Basis Assessments (EA-34)). As stated in Section 4.2 of DOE G 226.1-2A, *Federal Line Management Oversight of Department of Energy Nuclear Facilities*, “CRADs are used to establish the depth and detail of an assessment and to provide clarity and consistent guidance to the assessment team, as well as to the organization being assessed.”

2.0 APPLICABILITY

This protocol is applicable to EA-30.

3.0 REQUIREMENTS

1. The Office of Enterprise Assessments (EA) Office of Environment, Safety and Health Assessments’ assessment activities are to be performed in accordance with DOE Order 227.1A (Change 1), *Independent Oversight Program*, and applicable EA-wide and EA-30-specific protocols and CRADs.
2. EA CRADs are documents used by EA-30 Tier 2 organizations to assess contractor 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. Standardization of EA CRADs supports consistency in the assessment process.
3. Due to the uniqueness and diversity of DOE nuclear facilities, EA assessment plans that reference CRADs may be tailored to meet assessment objectives. 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 assessment.
4. EA-30 CRADs must contain the following sections: (A CRAD template is located on EAShare on the EA-30 page under Templates.) [Note: There is no expectation to update existing CRADs to new templates if requirements have not changed or significant improvement cannot be identified]
 - Purpose section (i.e., a generic purpose statement)
 - Applicability section (i.e., a statement regarding who is approved to use the CRAD. For site or facility-specific CRADs, this section also includes the site or facility for which the CRAD is applicable. When a CRAD is revised, the revision should include a statement in the applicability section that the previous version of the CRAD is superseded.
 - Feedback section (i.e., a generic statement regarding the methods to provide feedback)
 - Body section containing the criteria and review approach elements including the identification of relevant DOE directives and other regulatory requirements used to establish criteria to define and/or measure performance objectives.

5. As stated in DOE Guide 226.1-2A, section 4.2.1, the body section of EA-30 CRADs consists of the following elements:

- **Performance Objectives** – 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.

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

Creating the Performance Objectives. As stated in DOE Guide 226.1-2A, section 4.2.1, *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. As stated in DOE Guide 226.1-2A, section 4.2.1, *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 Order 420.1C)

Creating the Criteria. As stated in DOE Guide 226.1-2A, section 4.2.1, *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”).*

Creating the Lines of Inquiry. The lines of inquiry (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. The questions listed should be viewed as core performance expectations that the assessor will use to assess the organization’s compliance with requirements. The listed questions need to be created based on

specific requirements from the criteria such as DOE Orders, Code of Federal Regulations (CFRs) or consensus standards and materials incorporated by reference such as those listed in 10 CFR 851.27. The scope and complexity of the lines of inquiry can be tailored for various levels of management and workers.

DOE guides, standards, and good practices that are associated with requirements may be useful in developing LOIs; however, they cannot be used to establish facts to support a deficiency or finding. Each LOI should be designed to ensure the answers 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 do 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?

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 walkdowns, 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. When practical, 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. 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.*

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

(Note: Existing CRADs can be found at the following EA website link:
<https://www.energy.gov/ea/criteria-and-review-approach-documents>)

- a. Notify the Director of EA-30 (for EA-30 CRADs) or the cognizant Tier 2 Director of the intent to develop a new CRAD or update an existing CRAD. Obtain approval 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. For updates of existing CRADs, obtain the current CRAD from the EA-30 Administrative Team.
- c. Create or modify the CRAD using the EA-30 CRAD template located on EAShare on the EA-30 page under Templates.
- d. As determined by the cognizant Director, perform a document peer review by appropriate EA-30 staff and a subject matter expert (SME) for the subject area. (A comment form template, which can be used to document comments and their corresponding resolutions, is located on EAShare on the EA-30 page under Templates.)
- e. Provide the draft CRAD to the cognizant Director(s) for review.
- f. Request the EA-30 Administrative Team to format and complete a review of the document.

- g. Obtain approval of the CRAD. EA-30 CRADs are approved by the Director of EA-30. Other CRADs are approved by the cognizant Tier 2 Director and then provided to the Director of EA-30 for information.
 - h. After approval, the EA-30 Administrative Team adds the updated or new CRAD to the EA website and, when directed by the cognizant Director, removes the previous version of the updated CRAD. The previous version of an updated CRAD that is referenced in an existing approved assessment plan should remain on the EA website for at least 60 days following the distribution and posting of the report for that assessment. Obsolete CRADs will be archived in EAShare.
 - i. In circumstances where a CRAD needs to be updated but a previous version will be used for an indeterminate amount of time (such as to include a new or revised directive or standard), then the updated CRAD may be given a unique number and a unique title for clarity.
7. CRADs will be reviewed regularly to ensure that they are necessary to retain and are consistent with applicable requirements documents.
- a. CRADs are updated prior to use when applicable requirement documents change.
 - b. At a minimum, each CRAD will be reviewed within two years of its effective or latest review date to determine whether it should be retained, updated, or archived.
 - c. CRADs to be retained will be revised as necessary to incorporate information from new or revised source documents and to incorporate any feedback received as part of the continuous improvement process. Biennial reviews that do not result in a revision to the CRAD will be documented by adding the date of the latest biennial review on the cover sheet of the CRAD.
 - d. Previous versions of updated CRADs will be archived and will not be used for any assessments unless they are referenced in an existing approved assessment plan.
 - e. A CRAD will not be obsolete or unavailable for use merely because it has exceeded its biennial review period.

4.0 RESPONSIBILITIES

Director, Office of Environment, Safety and Health Assessments

- Approves revisions to this protocol
- Reviews and approves requests for development of a new EA-30 CRAD or update of an existing EA-30 CRAD
- Reviews and approves new and updated EA-30 CRADs.

EA-30 Tier 2 Directors

- Reviews and approves requests for development of a new CRAD or update of an existing CRAD within cognizant subject areas
- Reviews and approves new and updated CRADs within cognizant subject areas
- Assigns appropriate technical staff SME to create, update, and maintain CRADs
- Ensures that the SMEs who are responsible for creating or updating CRADs possess qualifications, competencies, and experience commensurate with their assignments.
- Ensures that CRADs within cognizant subject areas are updated in accordance with new or revised requirements and are in support of continuous improvement; at a minimum biennially (every two years).

Subject Matter Experts

- As directed, review CRADs periodically and when referenced requirements change to ensure that the information contained in the CRAD is current
- Provide recommendations for revisions to CRADs based on the issuance of new or revised source documents and in support of continuous improvement
- As directed, complete biennial reviews on assigned CRADs.

EA-30 Administrative Team

- Maintains CRAD templates
- Formats and prepares CRADs prior to placement on the EA website
- Supports the Directors in ensuring that CRADs are maintained current and reviewed at a minimum biennially (every two years)
- Documents completed biennial reviews of CRADs on the cover sheet of the CRADs
- Adds updated and new CRADs to the EA website
- Removes out-of-date CRADs from the EA website and archives them on EAShare
- Maintains a list of staff assignments for maintenance and updates of CRADs.

5.0 REFERENCES

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