

CONTROL FORM FOR DOE/ORO DIRECTIVE

PART A (To be completed by the ORO DIRECTIVES MANAGEMENT GROUP, AD-440):

1. DIRECTIVE NUMBER, TITLE, AND DATE:

ORO O 420, CHAPTER XIII, CHANGE 3, SAFETY BASIS DOCUMENTS REVIEW SYSTEM, dated 08/31/2006

2. PURPOSE OF TRANSMITTAL: New Directive Revised Directive Revised Control Form

3. DOES THIS DIRECTIVE CANCEL OR EXTEND ANY OTHER DIRECTIVES? Yes No
If "Yes," list what action (cancel or extend) and list the Directive(s) number(s), title(s), and date(s):

This Directive cancels and replaces ORO O 420, Chapter XIII, Change 2, SAFETY BASIS DOCUMENTS REVIEW SYSTEM, dated 07/19/2004.

The attached Directive is forwarded for review and action. Complete Part B and forward a completed hard copy of this form to ORO DMG, AD-440, by **09/15/2006**.

PART B (To be completed by the DIVISION OF PRIMARY INTEREST [DPI]):

COMPLETE FOR DOE DIRECTIVES ONLY:

4. SUPPLEMENTAL ORO DIRECTIVE REQUIRED?

Is a new or revised supplemental ORO Directive required? Yes No

If "Yes," target date for submission of supplemental ORO Directive is _____.

COMPLETE FOR BOTH DOE AND ORO DIRECTIVES:

5. CONTRACTOR APPLICABILITY.

Does this Directive affect the work performed by ORO Contractors? Yes No

If "Yes," whom? Bechtel Jacobs Company LLC ORAU

UT-Battelle, LLC ISOTEK (Bldg. 3019, ORNL)

Foster Wheeler (FWENC)

Other Contractors (list by name)

6. SUBJECT MATTER EXPERT: Roger Casteel Safety and Health Division, SE-33
Name Organization

Original Signed By

7. APPROVED BY: J. A. Ferrer, Dir., Safety and Health Division 09/01/2006
Signature Organization Date

PART C (To be completed by the ORO DIRECTIVES MANAGEMENT GROUP, AD-440):

APPROVED FOR DISTRIBUTION IN ACCORDANCE WITH OFFICIAL DIRECTIVE DISTRIBUTION LIST:

Original Signed By
Jennifer G. Hamilton

09/01/2006

DMG Team Leader, AD-440

Date

INSTRUCTIONS TO ADDRESSEES: THIS FORM IS TO BE FILED WITH THE DIRECTIVE AND RETAINED.

(Revised 02/10/2006)

U.S. Department of Energy

Oak Ridge Office

ORO O 420
Chapter XIII
Change 3

DATE: 08/31/2006

SUBJECT: SAFETY BASIS DOCUMENTS REVIEW SYSTEM

1. PURPOSE. This Chapter correlates to Title 10 Code of Federal Regulations (CFR) Part 830, NUCLEAR SAFETY MANAGEMENT, Subpart B, "*Safety Basis Requirements*," latest version, by assigning responsibility and accountability and providing the Oak Ridge Office (ORO) with administrative requirements for the review and approval of safety basis documents submitted by contractors for new and existing Hazard Category 1, 2, or 3 nuclear facilities, including major modifications. This includes facilities that have been downgraded to below Hazard Category 3 by analysis. Nothing in this issuance changes the requirements contained in any Department of Energy (DOE) Directive, Standard, or regulation.
2. CANCELLATION. This Chapter cancels and replaces ORO O 420, Chapter XIII, Change 2, SAFETY BASIS DOCUMENTS REVIEW SYSTEM, dated July 19, 2004.
3. APPLICABILITY. The provisions of this Chapter apply to ORO Principal Staff responsible for the review and approval of safety basis documents.
4. RESPONSIBILITIES.
 - a. Manager, ORO.
 - (1) Ensures that ORO has approved Documented Safety Analyses (DSAs), Technical Safety Requirements (TSRs), and Safety Evaluation Reports (SERs) for its Hazard Category 1, 2, and 3 nuclear facilities consistent with 10 CFR 830 and established DOE requirements.
 - (2) Ensures that ORO organizations responsible for Hazard Category 1, 2, and 3 nuclear facilities have management processes (i.e., administrative, technical, procedural, etc.) with the appropriate rigor for the review and approval of safety basis documents. (This process will address the recommendation for approval and transmittal of the safety basis document if approval authority has not been delegated.)
 - (3) Approves SERs and the associated DSAs, TSRs, Unreviewed Safety Question (USQ) change packages, and other safety basis documents where approval authority has been delegated to the ORO Manager. (See ORO O 250, Chapter XI, Change 2, DELEGATIONS AND AGREEMENTS, for information concerning delegations).

- (4) Where approval authority has not been delegated to ORO, transmits the request for approval to the Headquarters (HQ) approval authority.
 - (5) Approves requests for any changes to due dates related to the review and approval of a safety basis document that extend beyond the established timeframe (where the ORO Manager has been delegated approval authority).
 - (6) Assesses ORO Line Organizations' implementation of their safety basis responsibilities to ensure compliant and effective programs in accordance with ORO M 220.1, OAK RIDGE OFFICE ASSESSMENT PROGRAM MANUAL.
- b. Assistant Managers for ORO Line Organizations.
- (1) Ensure that contractors develop safety basis documents in accordance with 10 CFR 830 and established DOE requirements.
 - (2) Establish a management process consistent with regulatory and Departmental expectations for the review and approval of safety basis documents and that also addresses the following requirements:
 - Timeframes for reviewing and approving safety basis documents consistent with the approval authority's expectations;
 - Transmittal of safety basis documents to the approval authority if the review and approval has not been delegated;
 - Documentation of the review and basis for approval in a SER;
 - Peer review of SERs by technically qualified individuals (not required for team reviews);
 - Approval of the SERs and their corresponding safety basis documents, including transmittal of recommendations for approval to the approval authority if approval has not been delegated;
 - Transmittal of comments/issues and approvals to the contractor, through the Contracting Officer's Representative;
 - Prompt identification, proper reporting, and timely correction of safety basis document implementation issues;
 - Maintenance of a list of Hazard Category 1, 2, and 3 nuclear facilities and their corresponding safety basis documents; and
 - Evaluation of contractor's annual summary report for USQ determinations performed since its last submittal.
 - (3) Maintain a sufficient number of qualified staff to review safety basis documents and prepare SERs.
 - (4) Provide guidance to contractors concerning safety basis issues, when necessary.

- (5) Review submitted safety basis documents for technical accuracy and compliance with 10 CFR 830 and established DOE requirements within the established timeframes and document the results of the reviews.

NOTE: ORO G 420.13, Revision 1, SAFETY BASIS DOCUMENTS REVIEW GUIDE, provides useful guidance that can be used to perform reviews, conduct assessments, and prepare SERs.

- (6) Resolve issues, comments, and differing technical opinions that cannot be satisfactorily resolved by the reviewers.
- (7) Approve SERs and their corresponding safety basis documents where the approval authority has been delegated to an Assistant Manager. (See ORO O 250, Chapter XI, Change 2).
- (8) Assess contractor safety basis processes and activities in accordance with ORO M 100, Revision 1, ORO MANAGEMENT SYSTEM DESCRIPTION.

c. Assistant Manager for Environment, Safety, and Health.

- (1) Serves as the Division of Primary Interest for proposed DOE Rules, Directives, Policies, Standards, Manuals, and Guidance pertaining to safety basis requirements.
- (2) Establishes and maintains this Directive and related guidance, Manuals, requirements, and Policies that form the infrastructure for the overall safety basis document generation, assessment, review, and approval process.
- (3) Establishes a process for the review and approval or recommendation for approval of safety basis documents consistent with requirements outlined in Paragraph 4b(2) above.
- (4) Maintains a sufficient number of qualified staff to review safety basis documents, conduct assessments, and prepare SERs.
- (5) Supports ORO Line Organizations, when requested, in reviewing DSAs, TSRs, and other safety basis documents, preparing and peer reviewing SERs, assessing contractor safety basis processes and activities, performing other safety basis activities, and providing other services and advice.
- (6) In collaboration with ORO Line Management and the Training and Development Group, provides expert technical advice in the development of core safety basis technical qualification requirements documents and training.

5. REQUIREMENTS AND PROCEDURES.

a. Requirements for the Safety Basis Review and Approval Process.

NOTE: This section contains requirements applicable to all safety basis documents submitted to ORO for review. Guidance for the review and approval of each type of safety basis document is available in ORO G 420.13, Revision 1.

- (1) Safety basis documents to be submitted for DOE approval must be formally transmitted from the contractor to the responsible program Assistant Manager.
- (2) The safety basis document is logged into a tracking system and its due date established. The due date will be based on the Assistant Manager's established timeframe and the date the document was received. Any changes to due dates beyond the established timeframe must be approved in advance by the assigning Assistant Manager.
- (3) The responsible Assistant Manager's organization identifies a reviewer(s) (SER preparer). The reviewer(s) must be qualified under the DOE Technical Qualification Program. Alternate qualifications based on knowledge and experience or "*under the supervision of a qualified individual*" may be considered if they are approved by the responsible Assistant Manager. The identification of a technically qualified individual to review the SER is not required for team reviews, since multiple reviewers are already engaged in the process.
- (4) The reviewer(s) performs the following:
 - (a) Evaluates the scope of the review effort to determine if additional resources are required and if a review plan is warranted. Use of a review plan and a multidisciplined review team are highly recommended for the initial issuance of safety basis documents, commensurate with the level of complexity and hazards of the facility (graded approach).
 - (b) Reviews the safety basis document and evaluates its technical accuracy and compliance with 10 CFR 830 and DOE requirements. Documents any comments/issues identified. The guidance provided in ORO G 420.13, Revision 1, can be utilized in this review.
 - (c) Promptly communicates comments/issues generated during the review to the contractor through formal communications. Elevates areas where agreement cannot be reached through the chain of command for resolution. Notifies ORO Line Personnel responsible for the facility (e.g., Facility's Program/Project Manager[s]/Program Coordinator[s] and Facility Representative[s]) of the comments/issues.

- (d) If DOE is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the reviewer(s) notifies ORO Line Personnel responsible for the facility of the required action and formally transmits the document back to the contractor, with the basis for DOE's disapproval clearly documented.

NOTE: This step is a "should" because it may be skipped if the contractor voluntarily submits a modified document based on DOE's comments prior to receiving an official rejection letter.

- (e) If the safety basis document can be approved, the reviewer(s) prepares an SER (or coordinates the review team's input on the SER) to document the review and basis for approval of safety basis documents in accordance with DOE-STD-1104-96, Change Notice 3, REVIEW AND APPROVAL OF NUCLEAR FACILITY SAFETY BASIS DOCUMENTS (DOCUMENTED SAFETY ANALYSES AND TECHNICAL SAFETY REQUIREMENTS).

NOTE: A supplement to an existing SER may be sufficient for an annual update or revision to the safety basis document, disposition of a USQ, or other minor changes.

- (f) The reviewer(s) must ensure that DOE's conditions for approval in the SER constitute an appropriate and minimal essential set of conditions that is clearly stated to facilitate its implementation.
- (5) A technically qualified individual reviews the SER to verify that it is comprehensive and technically adequate. This peer verification is intended to provide a double check of the conclusions that were derived and to identify inadvertent omissions. Comments/issues generated by the peer review must be resolved with the lead preparer or elevated through the chain of command.
 - (6) The responsible ORO Line Organization obtains approval of the SER and the safety basis document from the Approval Authority. (See ORO O 250, Chapter XI, Change 2, for information concerning delegations.
 - (7) After the safety basis document is approved, an approval letter is formally transmitted to the contractor with a copy of the SER. The transmittal letter establishes DOE's expectations regarding any implementation issues.
 - (8) The responsible ORO Line Organization ensures the contractor has properly implemented the safety basis document requirements. Safety basis changes or improvements that are within the scope of DOE O 425.1C, STARTUP AND RESTART OF NUCLEAR FACILITIES, may require a readiness assessment or operational readiness review in order to verify safety basis implementation.
 - (9) The responsible ORO Line Organization verifies that the safety basis list and authorization agreement have been updated, as appropriate.

b. Records.

The following records must be controlled and maintained by the responsible ORO Line Organization. These documents are quality assurance records and shall be retained in accordance with the DOE Records Inventory Disposition Schedule:

- Submitted safety basis documents (e.g., DSAs, TSRs, USQ Change Package), SERs and supporting documentation associated with DOE's review and approval of a safety basis document (e.g., review comments, resolution matrices, transmittal correspondence between the contractor and DOE, independent analyses or calculations performed by or for DOE);
- Annual summary report of all contractors USQ determinations and any correspondence associated with the DOE determination of the adequacy of the summary report; and
- USQ correspondence between the contractor and DOE and any related documentation (e.g., notifications, schedule for resolution, compensatory actions).

6. REFERENCES.

- a. DOE G 421.1-2, IMPLEMENTATION GUIDE FOR USE IN DEVELOPING DOCUMENTED SAFETY ANALYSES TO MEET SUBPART B OF 10 CFR 830, dated October 24, 2001.
- b. DOE G 423.1-1, IMPLEMENTATION GUIDE FOR USE IN DEVELOPING TECHNICAL SAFETY REQUIREMENTS, dated October 24, 2001.
- c. DOE G 424.1-1A, IMPLEMENTATION GUIDE FOR USE IN ADDRESSING UNREVIEWED SAFETY QUESTION REQUIREMENTS, dated July 24, 2006.
- d. DOE O 425.1C, STARTUP AND RESTART OF NUCLEAR FACILITIES, dated March 13, 2003.
- e. DOE-STD-1027-92, Change Notice 1, HAZARD CATEGORIZATION AND ACCIDENT ANALYSIS TECHNIQUES FOR COMPLIANCE WITH DOE ORDER 5480.23, *NUCLEAR SAFETY ANALYSIS REPORTS*, dated September 1997.
- f. DOE-STD-1104-96, Change Notice 3, REVIEW AND APPROVAL OF NUCLEAR FACILITY SAFETY BASIS DOCUMENTS (DOCUMENTED SAFETY ANALYSES AND TECHNICAL SAFETY REQUIREMENTS), dated December 2005.
- g. ORO M 100, Revision 1, ORO MANAGEMENT SYSTEM DESCRIPTION, dated September 9, 2005, and subsequent revisions.
- h. ORO M 220.1, OAK RIDGE OFFICE ASSESSMENT PROGRAM MANUAL, dated June 20, 2006, and subsequent revisions.
- i. ORO O 250, Chapter XI, Change 2, DELEGATIONS, AND AGREEMENTS, dated August 22, 2006, and subsequent revisions.

- j. ORO G 420.13, Revision 1, SAFETY BASIS DOCUMENT REVIEW GUIDE, dated August 31, 2006, and subsequent revisions.

7. DEFINITIONS.

- a. **DOCUMENTED SAFETY ANALYSIS (DSA).** A documented analysis of the extent to which a nuclear facility can be operated safely with respect to the workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.
- b. **GRADED APPROACH.** The process for ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with (1) the relative importance to safety and safeguards and security, (2) the magnitude of any hazard(s) involved, (3) the life cycle stage of the facility, (4) the programmatic mission of the facility, (5) the particular characteristics of the facility, (6) the relative importance of the radiological and nonradiological hazards, and (7) any other relevant factor.
- c. **HAZARD CLASSIFICATION.** Evaluation of the consequences of unmitigated releases to classify nuclear facilities or operations into the following hazard categories:

- Hazard Category 1: The hazard analysis shows the potential for significant off-site consequences.
- Hazard Category 2: The hazard analysis shows the potential for significant on-site consequences.
- Hazard Category 3: The hazard analysis shows the potential for only significant localized consequences.

NOTE: DOE-STD-1027-92, Change Notice 1, provides guidance and radiological threshold values for determining a facility's Hazard Category.

- d. **REVIEWER (SAFETY EVALUATION REPORT [SER] PREPARER).** The qualified individual selected by the assigning ORO Line Organization to review a safety basis document and, if applicable, direct the review team.
- e. **SAFETY EVALUATION REPORT (SER).** The report that DOE prepares to document (1) the sufficiency of the safety basis document(s) for a Hazard Category 1, 2, or 3 nuclear facility, (2) the extent to which a contractor has satisfied the requirements of 10 CFR 830, Subpart B, and (3) the basis for DOE's approval of the facility's safety basis document(s), including any conditions for approval.
- f. **TECHNICAL SAFETY REQUIREMENTS (TSRs).** The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include (as appropriate for the work and the hazards identified in the DSA for the facility) the safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

- g. **UNREVIEWED SAFETY QUESTION (USQ).** A situation where (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the DSA could be increased, (2) the possibility of an accident or malfunction of a different type than any previously evaluated in the DSA could be created, (3) a margin of safety could be reduced, or (4) the DSA may not be bounding or may be otherwise inadequate.
- 8. CONTRACTOR REQUIREMENTS DOCUMENT. None.
- 9. ATTACHMENTS. None.