DIRECTIVES CONTROL FORM - ORO FINAL DIRECTIVE

PART A (To be completed by the Division of Primary Interest (DPI)

1. **NUMBER AND TITLE OF DIRECTIVE**: **ORO O 420, Chapter XIII, Change 1, SAFETY BASIS DOCUMENTS REVIEW SYSTEM**

2. **PURPOSE OF TRANSMITTAL**: ____ New Directive X Revised Directive

3. **THIS DOCUMENT MAY AFFECT THE WORK PERFORMED BY THE FOLLOWING CONTRACTORS:** (Check appropriate boxes)

   X No (all contractors)

   ____ Yes If yes, whom? __ Bechtel Jacobs Co. __ BWXT Y-12 __ ORAU __ UT-Battelle __ SURA

   ____ Other contractors (list by type)

   Many ORO contractors have approved S/RIDs or WSS sets that may affect applicability of contractor requirements from this directive. Applicability of contractor requirements must take into account the approved standards set for each particular contract.

4. **SIGNIFICANT PROVISIONS**: Are there any significant changes or impact?

   X No ___ Yes If yes, describe: This is a revised chapter in the 420 series. Minor editorial changes include revisions to paragraphs 2, 5a(7), and 6j; adds paragraph 6l and renumbers 6l to 6m.

5. **CONTACT POINT**: Jorge Ferrer (Name) | Nuclear Safety Division, SE-33 (Organization) | 576-6638 (Telephone)

PART B (To be completed by the Directives Management Group (DMG)):

6. **FILING INSTRUCTIONS**:

Remove	Dated	Insert	Dated
ORO Control Form	06/07/2002	ORO Control Form	07/24/2002
ORO O 420, Chapter XIII, Pages XIII-1 thru XIII-10	06/07/2002	ORO O 420, Chapter XIII, Chg. 1, Pages XIII-1 thru XIII-10	07/24/2002

ORO Directives are available on the ORO Directives Management Home Page at http://www.ornl.gov/doe_oro_dmg/oro_dir.htm. The ORO Directives will no longer be mailed in printed copy unless you do not have Internet capabilities.

7. **APPROVED FOR DISTRIBUTION IN ACCORDANCE WITH THE OFFICIAL DIRECTIVES DISTRIBUTION LIST**:

Original Signed By
Wayne H. Albaugh — 07/24/2002
Signature: DMG Team Leader, AD-440 — Date

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

U.S. Department of Energy

Oak Ridge Operations

ORO O 420
Chapter XIII
Change 1

DATE: 07/24/2002

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, dated January 10, 2001, by assigning responsibility and accountability and providing administrative guidance to Oak Ridge Operations Office (ORO) for the review and approval of safety basis documents prepared by contractors for new and existing Hazard Category 1, 2, or 3 nuclear facilities, including major modifications. Nothing in this issuance changes any requirements contained in any Department of Energy (DOE) directive, standard, or regulation.

2. CANCELLATION. This chapter cancels and replaces ORO O 420, Chapter XIII, SAFETY BASIS DOCUMENTS REVIEW SYSTEM, dated June 7, 2002.

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. ORO Manager or Deputy for Operations.

      (1) Ensures that the DOE basis for approving the safety basis document is adequately reflected in the Safety Evaluation Report (SER).

      (2) Reviews minority opinions and/or resolves open technical differences.

      (3) Approves Documented Safety Analyses (DSAs), Technical Safety Requirements, Unreviewed Safety Questions (USQs), and issues the associated SERs for nuclear facilities if so delegated by the Cognizant Secretarial Officer where redelegation to subordinate levels of ORO is not authorized. In accordance with the delegation of approval authority for ORO's non-nuclear facilities, the same review and approval process could be applied to safety bases for moderate and high hazard facilities, as appropriate.

         NOTE: This responsibility must remain with ORO Manager and may not be redelegated.

(4) Approves requests for any changes to due dates related to a safety basis document review and approval process that extend beyond 90 days (where the ORO Manager or an Assistant Manager has been delegated approval authority).

(5) Determines the need for an additional independent review of SERs that are prepared and approved by ORO Assistant Managers (i.e., those facilities where approval authority is delegated to an Assistant Manager and the Assistant Manager for Environment, Safety, Health, and Emergency Management [AMESH] is not already providing an independent review).

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 and guidelines.

(2) Provide guidance to contractors concerning safety basis issues, when necessary.

NOTE: The Nuclear Safety Division should be consulted on guidance provided to the contractor related to issues not previously addressed in DOE requirements or guidance documents where the ORO Manager is the approval authority.

(3) Review submitted safety basis documents for technical accuracy and compliance with DOE requirements and guidelines.

(4) Resolve issues and comments generated by DOE reviews.

(5) Develop the SERs where approval authority has been delegated to the ORO Manager or to an Assistant Manager.

(6) Ensure that SERs are properly reviewed and approved.

NOTE: A technically qualified individual must approve the SER. Generally, this is expected to be a qualified Senior Technical Safety Manager within the responsible line organization. A single individual can perform the technical review and approve the SER.

(7) Approve safety basis documents where the approval authority has been delegated to an Assistant Manager. Forward safety basis documents to the Deputy for Operations for a determination on whether an independent review by the AMESH is necessary.

(8) Obtain approval of the safety basis document from the ORO Manager (if approval authority lies with the ORO Manager) or transmit the request for approval through the ORO Manager to the Headquarters (HQ) approval authority (if approval authority has not been delegated). For Office of Nuclear Energy facilities where approval authority has not been delegated,

transmit the safety basis document directly to the Cognizant Secretarial Officer.

(9) Verify contractor implementation of the safety basis documents.

(10) Ensure that implementation issues are promptly identified, properly reported, and adequately corrected in a timely manner.

(11) Ensure that the safety basis list is updated.

(12) Maintain a list of managers and staff who are qualified to review and approve safety basis documents.

(13) Perform an evaluation of the contractor's annual summary report of all the USQ determinations that were performed since the prior submission to assess the continued adequacy of the contractor's implementation of its USQ process. Document and transmit to the contractor through the Contracting Officer's Representative (COR) any trends, anomalies, or deficiencies identified during the review.

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

(1) Manages the ORO review and comment process on DOE Rules, Orders, Policies, Standards, Guidance, and external requests for assistance.

(2) Establishes and maintains this directive and related policies for the overall safety basis document generation, review, and approval process.

(3) Performs technical assessments of contractor procedures for the development of safety basis documents to ensure conformance with DOE requirements and guidelines.

(4) Provides technical support to the line organizations, including preparation of SERs, when requested by the responsible organization.

(5) Performs an independent review of SERs prior to the ORO Manager's approval or submission to HQ for approval or for those SERs where the Deputy for Operations believes further independent review is necessary.

(6) Provides expert technical advice to the Training and Development Group for the development of technical qualification requirements documents and training.

(7) Maintains a list of AMESH managers and staff who are qualified to review and approve safety basis documents.

5. REQUIREMENTS AND PROCEDURES.

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

(1) All safety basis documents to be officially reviewed by DOE for approval purposes must be formally transmitted from the contractor to the responsible organization's Assistant Manager through the COR.

(2) The COR must log the safety basis document into the tracking system, with a due date for approval of 90 days from the date of receipt (for safety basis documents where appropriate ORO organizations' have approval authority), and notify the Assistant Manager. Any changes to due dates must be approved in advance by the Deputy for Operations.

(3) The responsible Assistant Manager's organization identifies a lead reviewer (SER preparer) and a technical reviewer (peer verification). The lead reviewer and technical reviewer 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 technical reviewer is not required for team reviews, since multiple reviewers are already engaged in the process.

(4) The lead reviewer 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 document to ensure its technical adequacy and compliance with DOE requirements.

(c) Promptly communicates comments/issues generated during the review to the contractor through the COR. The lead reviewer elevates areas where agreement cannot be reached through the chain of command for resolution.

(d) If DOE is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the lead reviewer formally transmits the document back to the contractor through the COR 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) Prepares an SER (or coordinates the review team's input on the SER) for safety basis documents for new, existing, and/or major modifications for Hazard Category 1, 2, or 3 nuclear facilities and for revisions/updates to compliant safety basis documents.

NOTE: A supplement to an existing SER may be sufficient for an annual update.

(f) The SER must be prepared and issued in accordance with DOE-STD-1104-96, REVIEW AND APPROVAL OF NONREACTOR NUCLEAR FACILITY SAFETY ANALYSIS REPORTS, or per the SER preparation guidelines in procedure AMESH-SB-1, *Review of Safety Basis Documents*, to document the basis for DOE's approval of the safety basis document.

(g) The lead reviewer 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) The technical reviewer must review the safety basis submittal and the SER to verify that the SER 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 technical reviewer must be resolved with the lead preparer or elevated through the chain of command. This step can be accomplished through the AMESH's independent review function.

(6) A technically qualified individual must approve the SER. Generally, this is expected to be a qualified Senior Technical Safety Manager within the responsible line organization. A single individual can perform the technical review and approve the SER.

(7) The responsible line organization must confirm the safety basis approval authority as specified in ORO O 420, Chapter XIV, (see paragraph 6b of this chapter) and prepare an approval package that includes the following:

- A memorandum that summarizes the safety basis submittal, conditions for approval, exemptions/exceptions, any nonstandard compliance issues, and a recommendation for approval.
- The SER.
- The contractor safety basis submittal.
- A concurrence correspondence form.

(8) The responsible Assistant Manager concurs with the SER approval and forwards the package to the AMESH for concurrence.

NOTE: For safety basis documents where the line Assistant Manager is the approval authority, this step should involve contacting the Deputy for Operations for a decision on the need for an independent check by the

AMESH organization.

(9) The AMESH organization must perform an independent check of SERs for safety basis documents where the ORO Manager is the approval authority, as well as for other SERs as specifically directed by the Deputy for Operations. The purpose of this check is to provide the ORO Manager with assurance that the SER provides an adequate technical and regulatory basis to approve the safety basis submittal and any associated exemptions, exceptions, and/or nonstandard compliance issues. The depth of the review is commensurate with the risk and complexity of the safety basis. The independent reviewer must address any issues in writing to the SER lead preparer, and if the issues are not resolved promptly, the independent reviewer elevates them through the chain of command using the ORO dispute resolution process. The independent reviewer must document the basis for reaching his/her conclusions on the adequacy of the SER.

(10) When the AMESH-identified issues with the SER have been resolved, the AMESH routes the approval package through the chain of command to the approval authority.

(11) If the safety basis document is approved, the COR transmits a formal approval letter to the contractor with a copy of the SER. The transmittal letter establishes DOE's expectations regarding any implementation issues or the need for an implementation plan, as well as any reviews required by DOE O 425.1B.

(12) The responsible line organization performs a verification review of the contractor's implementation of the safety basis to ensure that the requirements have been properly implemented and that personnel are aware of the changes, as appropriate. Safety basis changes or improvements that are within the scope of DOE O 425.1B may require a readiness assessment or operational readiness review in order to verify safety basis implementation.

(13) The line organization verifies that the safety basis list and authorization agreement have been updated, as appropriate.

b. Potential Inadequacy of the Safety Analysis (PISA)/USQ Review Process.

(1) If a PISA involving facilities or operations under ORO line organization's cognizance is declared, the responsible ORO line organization must perform the following:

(a) Assesses the contractor's self-imposed operating restrictions or lack thereof. If the facility or operation cannot be maintained in its current configuration without significantly increasing the risk to the workers, the public, or the environment, the COR directs the contractor to curtail or suspend operations and/or the movement of fissionable material or to implement emergency actions or protective measures, as necessary, to place the facility or operation in a safe condition.

(b) Monitors the contractor's activities related to the PISA and the associated USQ determination for timeliness and technical adequacy. The COR identifies issues in writing to the contractor for resolution.

(c) Determines the need and schedule for the contractor to submit a Justification for Continued Operations (JCO) to request authorization to continue essential operations prior to DOE's completion of its review of the contractor's evaluation of the safety of the situation, based on the need for continued essential operations, judgment of the potential risk, and the projected schedule for completing the evaluation of the safety of the situation.

(2) If the contractor determines that the PISA is a positive USQ, the responsible line organization manages the DOE review of the contractor's evaluation of the safety of the situation (including the supporting safety analyses and calculations) and approval of any associated safety basis document changes using the process outlined above in paragraph 4a. This includes the review and approval of a JCO, if one is determined necessary, prior to formal submission of a permanent change to the safety basis.

(3) If the contractor determines that the PISA is not a USQ, the responsible line organization promptly evaluates the contractor's basis for removing any restrictions associated with the PISA situation.

(4) The responsible line organization must determine the startup or restart requirements in accordance with DOE O 425.1B for activities involving a positive USQ.

NOTE: A JCO may be used to authorize restart of a facility's limited essential operations from a shutdown following a USQ declaration provided appropriate compensatory measures are in place.

(5) The line organization must review the contractor's annual USQ summary report to identify any trends, anomalies, or deficiencies.

c. Records.

The following records must be controlled and maintained by the responsible line organization:

- 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

- USQ correspondence between the contractor and DOE and any related documentation (e.g., notifications, schedule for resolution, compensatory actions, JCOs)

d. Implementing Procedures.

The following approved procedures must be implemented, as applicable to the respective ORO organization:

- OSOP-240, *Review and Approval of Nuclear Facility Authorization Basis Documents*, latest revision.
- EM-7.3, *EM Safety Basis Document Review, Approval and Tracking*, latest revision.
- AMESH-SB-1, *Review of Safety Basis Documents*, latest revision.
- AU-2.2, *Review and Approval of Safety Basis Documents Procedure*, latest revision.

6. REFERENCES.

a. 10 CFR 830, NUCLEAR SAFETY MANAGEMENT, January 10, 2001.

b. DOE O 425.1B, STARTUP AND RESTART OF NUCLEAR FACILITIES, December 21, 2000.

c. DOE G 421.1-2, IMPLEMENTATION GUIDE FOR USE IN DEVELOPING DOCUMENTED SAFETY ANALYSIS TO MEET SUBPART B OF 10 CFR 830, October 2001.

d. DOE G 423.1-1, IMPLEMENTATION GUIDE FOR USE IN DEVELOPING TECHNICAL SAFETY REQUIREMENTS, October 2001.

e. DOE G 424.1-1, IMPLEMENTATION GUIDE FOR USE IN ADDRESSING UNREVIEWED SAFETY QUESTION REQUIREMENTS, October 2001.

f. DOE-STD-1027-92, HAZARD CATEGORIZATION AND ACCIDENT ANALYSIS TECHNIQUES FOR COMPLIANCE WITH DOE ORDER 5480.23, NUCLEAR SAFETY ANALYSIS REPORTS, December 1992.

g. DOE-STD-1104-96, REVIEW AND APPROVAL OF NONREACTOR NUCLEAR FACILITY SAFETY ANALYSIS REPORTS, February 1996.

h. ORO O 410, Chapter V, PROCESS FOR TECHNICAL DISPUTE RESOLUTION, June 2002.

i. ORO M 411.1-1D, MANUAL OF SAFETY MANAGEMENT FUNCTIONS, RESPONSIBILITIES, AND AUTHORITIES, LEVEL II, FOR OAK RIDGE OPERATIONS, October 31, 2000, and any subsequent revisions.

j. ORO O 420, Chapter V, DELEGATION OF APPROVAL AUTHORITY FOR DOE 5480.21, 5480.22, 5480.23, AND 5481.1B, September 30, 1996, and any subsequent revisions.

k. ORO O 420, Chapter XI, AUTHORIZATION AGREEMENTS, April 4, 2000, and any subsequent revisions.

l. ORO O 420, Chapter XIV, DELEGATION OF APPROVAL AUTHORITY FOR SAFETY BASIS DOCUMENTS, dated July 24, 2002.

m. AMESH-SB-1, REVIEW OF SAFETY BASIS DOCUMENTATION, latest revision.

7. DEFINITIONS.

a. Documented Safety Analysis. 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 provides guidance and radiological threshold values for determining a facility's Hazard Category.

d. Justification for Continued Operation: A document requesting DOE's approval of operation on a temporary basis after identifying a PISA, USQ, or other condition where the current safety basis requirements cannot be fully met or do not address the identified concern.

e. Lead Reviewer (SER Preparer). The qualified individual selected by the Responsible Organization to review a safety basis document and, if applicable, direct the review team.

f. Potential Inadequacy in the Safety Analysis. A PISA is an issue or problem for which the extent of impact on the safety analysis is not known. However, there exists sufficient possibility that after further evaluation, the safety analysis supporting the safety basis will be found inadequate or the margin of safety will be found to be reduced.

g. Responsible Organization. The ORO Line Assistant Manager who is responsible for providing direction to the contractor submitting the safety basis document for approval.

h. Safety Evaluation Report. The report that DOE prepares to document (1) the sufficiency of the DSA 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 safety basis, including any conditions for approval.

i. Technical Reviewer. A reviewer assigned to perform a peer review of the comprehensiveness and technical adequacy of the safety basis document and associated SER. This may be accomplished through the AMESH's independent review function.

j. Technical Safety Requirements. 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.

k. Unreviewed Safety Question. 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