U. S. Department of Energy
Oak Ridge Office
Office of Environmental Management
Procedure

SAFETY BASIS DOCUMENT REVIEW

EM–3.5
Revision 2

Prepared: _____ 11/09/2009
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Revision Log

Revision	Description of the Revision	Issue Date
0	Initial Issue.	10/25/2004
1	Update references, clarify steps of the review process, and add new procedural requirements related to new facilities and major modifications.	8/04/2008
2	Update references and eliminate out-of-date material	11/18/2009

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List of Acronyms

AMEM	Assistant Manager for Environmental Management
CFR	Code of Federal Regulations
COA	Condition of Approval
CSDR	Conceptual Safety Design Report
CSVR	Conceptual Safety Validation Report
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
EM	Environmental Management
HAD	Hazards Assessment Document
JCO	Justification for Continued Operation
NST	Nuclear Safety Team
ORO	Oak Ridge Office
PISA	Potential Inadequacy of Safety Analysis
PDSA	Preliminary Documented Safety Analysis
PSDR	Preliminary Safety Design Report
PSVR	Preliminary Safety Validation Report
SCMS	Science Management System
SDS	Safety Design Strategy
SER	Safety Evaluation Report
SME	Subject Matter Expert
SSC	System, Structure, or Component
SVR	Safety Validation Report
TSR	Technical Safety Requirement
USQ	Unreviewed Safety Question
VR	Verification Report

1.0 PURPOSE

This procedure documents the process for assigning responsibility, accountability and providing administrative guidance to Environmental Management (EM) Oak Ridge Office (ORO) for the review and approval of safety basis documents.

2.0 SCOPE

This procedure is applicable to review of safety basis documents for facilities under the management of the Oak Ridge Office of Environmental Management that are submitted by prime contractors for new and existing Hazard Category 1, 2, or 3 nuclear facilities, including major modifications. This review includes facilities that have been downgraded to below Hazard Category 3 by analysis. Included are review requirements for Safety Design Strategy (SDS) documents, Safety Design Reports (SDR), Preliminary Documented Safety Analysis (PDSA), Documented Safety Analysis (DSA), Technical Safety Requirements (TSRs), Hazard Assessment Documents (HADs), Unreviewed Safety Question (USQ) procedures, Justification for Continued Operation (JCO), and Inactive Waste Sites (IWSs).

This procedure also addresses preparation of Department of Energy (DOE) safety basis approval documents that result from review activities. These include SDS approval documents, Safety Validation Reports (SVR), Safety Evaluation Reports (SER) and IWS Verification Reports (VR). Nothing in this procedure changes any requirements contained in any DOE directive, standard, or regulation.

3.0 REFERENCES AND DEFINITIONS

3.1 References

3.1.1 10 CFR Part 830, *Nuclear Safety Management*, January 2001.

3.1.2 ORO Guide, *Safety Basis Document Review Guide*, Revision 2, April 30, 2009.

3.1.3 DOE-STD-1104-2009, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents*, May 2009.

3.1.4 DOE-STD-1189-2008, *Integration of Safety into the Design Process*, March2008.

3.1.5 Memorandum from Jesse Hill Roberson, *Supplemental Environmental Management (EM) Guidance for Implementing 10 CFR 830, Subpart B, Safety Basis Requirements*, May 28, 2002

3.1.6 Memorandum from Paul M. Golan, *Guidelines Related to Unreviewed Safety Question Process*, October 26, 2004.

3.1.7 Memorandum from Inés Triay, *Interim Guidance on Safety Integration Into*

Early Phases of Nuclear Facility Design, July 18, 2006.

3.1.8 Letter from Richard Black to A.J. Eggenberger, *Deliverables 8.5.4 and 8.7 of Implementation plan for Defense Nuclear Facilities Safety Board Recommendation 2004-2, Ventilation System Evaluation Guidance for Safety-Related and Non-Safety- Related Systems*, January 2006.

3.1.9 Science Management System (SCMS); Environment, Safety, and Health Management System; Facility Safety Authorization Subject Area; Procedure 1. "Reviewing and Approving Nuclear Facility Safety Basis Documentation".

3.1.10 Science Management System (SCMS); Environment, Safety, and Health Management System; Facility Safety Authorization Subject Area; Procedure 2. "Reviewing and Approving Safety Documents for Nuclear Facilities downgraded Below Hazard Category 3 Threshold Quantities by Analysis".

3.1.11 Science Management System (SCMS); Environment, Safety, and Health Management System; Facility Safety Authorization Subject Area; Procedure 3. "Reviewing and Approving Contractor's Unreviewed Safety Question (USQ) Process and Processing Potential Inadequacies of the Document Safety Analysis (PISA)".

3.1.12 Science Management System (SCMS); Environment, Safety, and Health Management System; Facility Safety Authorization Subject Area; Procedure 4. "Reviewing and Approving Transportation Safety Documents for Greater than Hazard Category 3 Threshold Quantities".

3.1.13 Science Management System (SCMS); Environment, Safety, and Health Management System; Facility Safety Authorization Subject Area; Procedure 5. "Startup and Restart of Hazard Category 1, 2, and 3 Nuclear Facilities".

3.2 Definitions

3.2.1 Conceptual Safety Design Report (CSDR). A Conceptual Safety Design Report is developed to:

a. document and establish a preliminary inventory of hazardous materials, including radioactive materials and chemicals;
b. document and establish the preliminary hazard categorization of the facility;
c. identify and analyze primary facility hazards and facility Design Basis Accidents;
d. provide an initial determination, based on preliminary hazard analysis, of Safety Class and Safety Significant structures, systems, and components (SSC);
e. include a preliminary assessment of the appropriate Seismic Design Category for the facility itself, as well as the safety SSCs;
f. evaluate the security hazards that can impact the facility safety basis (if applicable); and

g. include a commitment to the nuclear safety design criteria of DOE O 420.1 (or proposed alternative criteria).

3.2.2 Conceptual Safety Validation Report (CSVR). The report prepared by DOE that documents the DOE review of the Conceptual Safety Design Report.

3.2.3 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.

3.2.4 Final Hazards Categorization Document (FHCD). A safety basis document which documents the Final Hazard Category of a facility. A FHCD contains analysis that shows that a facility is less than Hazard Category 3 based on analysis. Since the FHCD performs Final Hazard Categorization, it must be approved by DOE through the issuance of an SER.

3.2.5 Justification for Continued Operation (JCO). 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.

3.2.6 Potential Inadequacy in the Safety Analysis (PISA). 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 analysis supporting the safety basis will be found inadequate or the margin of safety will be found to be reduced.

3.2.7 Preliminary Documented Safety Analysis (PDSA) . Documentation prepared in connection with the design and construction of a new DOE nuclear facility or a major modification to a DOE nuclear facility that provides a reasonable basis for the preliminary conclusion that the nuclear facility can be operated safely through the consideration of factors such as: the nuclear safety design criteria to be satisfied; a safety analysis that derives aspects of design that are necessary to satisfy the nuclear safety design criteria; and an initial listing of the safety management programs that must be developed to address operational safety considerations.

3.2.8 Preliminary Safety Design Report (PSDR). The report developed during Preliminary Design that updates and provides additional site and design details to those provided in the CSDR. The PSDR follows the format and content of the PDSA produced during final design.

3.2.9 Preliminary Safety Validation Report (PSVR). The report prepared by DOE that documents the DOE review of the Preliminary Safety Design Report.

3.2.10 Safety Basis Approval Documents. The documents prepared by DOE in accordance with 10 CFR 830, Subpart B requirements and supporting DOE directives that document the approval basis for Safety Basis Documents. Safety Basis Approval Documents include the SDS approval document,

CSVR, PSVR, SER, and IWS Verification Report.

3.2.11 Safety Basis Documents. The documents prepared in accordance with 10 CFR 830, Subpart B requirements and supporting DOE directives for Hazard Category 1, 2, or 3 nuclear facilities. Safety Basis Documents include the SDS, CSDR, PSDR, PDSA, DSA, TSR, HAD, USQ procedures, JCO, and IWS. Also included are changes to existing facility Safety Basis Documents such as that resulting from a USQ change package.

3.2.12 Safety Design Strategy (SDS). The SDS, as part of the Project Execution Plan, provides a strategy for the early safety design basis development starting in the pre-conceptual design phase. The SDS documents all applicable Safety-in-Design expectations for the early project phases.

3.2.13 Safety Design Report (SDR). The Safety Basis Document terminology that collectively encompasses the Conceptual Safety Design Report and the Preliminary Safety Design Report.

3.2.14 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 of approval.

3.2.15 Safety Validation Report (SVR). The Safety Basis Approval Document terminology that collectively encompasses the Conceptual Safety Validation Report and Preliminary Safety Validation Report.

3.2.16 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.

3.2.17 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.

3.2.18 Verification Report (VR). The report that DOE prepares to establish that Inactive Waste Site documentation demonstrates that the subject EM managed site(s) meets the EM-1 Inactive Waste Site Criteria.

4.0 RESPONSIBILITIES

4.1 Assistant Manager for Environmental Management

4.1.1 Ensures that the contractors develop Safety Basis Documents in accordance with 10 CFR 830, Subpart B and established DOE requirements.

4.1.2 Establishes a management process consistent with regulatory and DOE expectations for the review and approval of Safety Basis Documents.

4.1.3 Ensures that guidance is provided to contractors concerning safety basis issues, when necessary.

4.1.4 Ensures that the Nuclear Safety Team (NST) reviews submitted Safety Basis Documents for technical accuracy and compliance with 10 CFR 830 and establishes DOE requirements within established timeframes and documents the results of the reviews.

4.1.5 Approves Safety Basis Approval Documents and their corresponding Safety Basis Documents, where the Safety Basis approval authority has been delegated

4.2 Facility Operations and Safety Division Director

4.2.1 Approves safety basis reviewer qualifications.

4.2.2 Provides direction and assistance to the Nuclear Safety Team Leader, as necessary, in resolving issues, comments, and differing technical opinions that cannot be satisfactorily resolved by the reviewers.

4.2.3 Interfaces, as necessary, with EM headquarters and Defense Nuclear Facilities Safety Board staff on safety basis issues.

4.2.4 Recommends approval of Safety Basis Approval Documents and related correspondence to the AMEM or his designee.

4.3 Nuclear Safety Team Leader

4.3.1 Assigns the reviews of contractor prepared Safety Basis Documents to Lead Reviewers that meet the qualification requirements specified in Reference 3.1.2.

4.3.2 Resolves comments/issues that cannot be satisfactorily resolved by the Lead Reviewer.

4.3.3 Reviews Safety Basis Approval Documents for technical adequacy.

4.3.4 In cases where it is determined that a Safety Basis Document cannot be approved, informs the Contracting Officer's Representative (COR) with the basis for disapproval clearly documented.

4.3.5 Develops guidance concerning Safety Basis issues.

4.3.6 Documents Safety Basis reviewer qualifications and submits qualifications to AMEM for approval.

4.3.7 Ensures that an assessment of the contractors' USQD Process is performed at least annually.

4.4 Lead Reviewer

4.4.1 Obtains a copy of contractor prepared Safety Basis Documents as assigned by the Nuclear Safety Team Leader.

4.4.2 Enlists the help of a review team, as necessary.

4.4.3 Reviews the contractor submittal against elements identified in the review process (sections 5 and 6).

4.4.4 In cases where it is determined that a Safety Basis Document cannot be approved, informs the Nuclear Safety Team Leader and provides a basis for disapproval.

4.4.5 Prepares Safety Basis Approval Documents to document DOE's basis for approval of contractor prepared Safety Basis Documents.

4.5 Nuclear Safety Team Project Coordinator

4.5.1 Receives, logs, files, and distributes all incoming Safety Basis Documents and all associated correspondence.

4.5.2 Maintains Safety Basis Document status, priorities, Lead Reviewers assignments and DOE approval duration due dates in the NST Project Status log.

4.5.3 Ensures that the Safety Basis Document List is maintained and that the information contained therein is up to date.

4.5.4 Coordinates all NST meetings, prepares correspondence in association with the NST documents and tracks all incoming and outgoing document and correspondence transmittals.

4.5.5 Prepares metrics for the NST Leader's monthly performance review and maintains a spreadsheet with current Oak Ridge Safety Basis Document information

5.0 REQUIREMENTS AND PROCEDURES

5.1 General Requirements for the Safety Basis Review and Approval Process

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NOTE: this section contains requirements applicable to all Safety Basis Documents submitted to EM for review. Requirements unique to the review and approval process for each type of document is provided in later sections.

5.1.1 The NST Leader identifies a qualified Lead Reviewer to review Safety Basis Documents or proposed changes to these documents.

Note: The Lead Reviewer is selected from the list of approved reviewers (Reference paragraphs 4.1.3 and 4.3.1). Alternate qualifications based on knowledge and experience "under the supervision of a qualified individual" may be considered if are approved by the responsible Assistant Manager.

5.1.2 The Nuclear Safety Team Project Coordinator assigns a unique number to each Safety Basis Approval Document and logs that number into the Nuclear Safety Team Project Log.

NOTE: A due date is established based on agreed upon review times with the prime contractor. However, the 90 day review duration established in Reference 3.1.5 by EM-1 cannot be exceeded without AMEM concurrence.

5.1.3 The Lead Reviewer evaluates the technical adequacy of the Safety Basis Document and prepares a Safety Basis Approval Document.

5.1.4 The Lead Reviewer signs the Safety Basis Approval Document and forwards the package to the Nuclear Safety Team Leader for independent review and signature. The Nuclear Safety Team Leader forwards the Safety Basis Approval Document to the Facility Operations and Safety Division Director for concurrence and signature, who, upon completion of this step forwards it to the AMEM for approval.

NOTE: The Nuclear Safety Team Leader may delegate the independent review to a qualified Lead Reviewer who is not directly involved with the safety basis review.

5.1.5 When the Safety Basis Approval Document is approved, the COR formally transmits the document to the contractor. The transmittal letter establishes

any expectations regarding implementation issues.

5.1.6 The Nuclear Safety Team Project Coordinator updates the Safety Basis Document List to incorporate the approved Safety Basis Document. .

5.2 Documented Safety Analysis (DSA), Technical Safety Requirements (TSR), Justifications for Continued Operation (JCO), and associated Change Packages

5.2.1 The Lead Reviewer performs the following:

5.2.1.1 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 multi-disciplined review team are required for the initial issuance of safety documents or for substantial changes to existing documents, commensurate with the level of complexity and hazards of the facility (graded approach).

NOTE: (1) Substantial changes include: additions of new hazards, new methods or analytical approach, or new controls that significantly affect a safety basis document.

(2) Review team members shall include facility representatives and Federal Project Director/ Program Managers even if a multi-disciplined review team is not required.

(3) Reference 3.1.2, Safety Basis Document Review Guide contains guidance on preparing a review plan.

5.2.1.2 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. Guidelines for determining the technical adequacy of the Hazards Analysis and Control Selection are contained in Reference 3.1.2, Safety Basis Document Review Guide. The DOE Federal Project Director/Program Manager and Facility Representative should assist in the review of the document.

5.2.1.3 Promptly communicates comments/issues generated during the review to the prime contractor. The Lead Reviewer identifies areas where agreement cannot be reached through the chain of command for resolution. The DOE Federal Project Director/Program Manager and Facility Representative should be kept informed of issues generated during the review.

5.2.1.4 If EM is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the COR formally notifies the prime contractor that the document cannot

be approved, with the basis for disapproval clearly documented.

NOTE. This step is a "should" because it may be skipped if the prime contractor voluntarily rescinds the submitted Safety Basis Document prior to receiving an official rejection letter.

5.2.1.5 Prepares an SER (or coordinates the review team's input on the SER) for Safety Basis Documents or revisions/updates to approved Safety Basis Documents.

NOTE. (1) A supplement to an existing SER may be sufficient for an annual update, TSR Change, JCO or minor DSA changes.

(2) JCO expectations regarding content and applicability are contained in the Reference 3.1.2, Safety Basis Document Review Guide.

5.2.1.6 The SER must be prepared and issued in accordance with DOE-STD-1104-2009, *Review and Approval of Nonreactor Nuclear Facility Safety Analysis Reports*, to document the basis for EM's approval of the Safety Basis Document. This should be accomplished by following the instructions for SER preparation provided in Reference 3.1.2, Safety Basis Document Review Guide.

5.2.1.7 The Lead Reviewer must ensure that any DOE Conditions for Approval (COA) in the SER constitute an appropriate and minimal essential set of conditions that are clearly stated (with due dates for closure) to facilitate its implementation.

5.3 Inactive Waste Sites (IWS)

5.3.1 For facilities that meet the EM-1 criteria as an Inactive Waste Site, the Lead Reviewer:

5.3.1.1 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. The EM-1 Inactive Waste Site Criteria can be found in Reference 3.1.2, Safety Basis Document Review Guide.

5.3.1.2 Promptly communicates comments/issues generated during the review to the prime contractor. The Lead Reviewer identifies areas where agreement cannot be through the chain of command for resolution. The DOE Federal Project Manager should participate in the review and be kept informed of issues and associated resolutions.

5.3.1.3 If DOE is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the COR formally notifies the prime contractor that the document cannot be approved with the basis for DOE's disapproval clearly documented.

NOTE: This step is a "should" because it may be skipped if the prime contractor voluntarily rescinds the submitted Safety Basis Document prior to receiving an official rejection letter.

5.3.1.4 Prepares a VR in accordance with the instructions found in the Ref. 3.1.2, Safety Basis Document Review Guide.

5.3.1.5 The Lead Reviewer must ensure that any DOE conditions of approval in the VR constitute an appropriate and minimal essential set of conditions that are clearly stated (with due dates for closure) to facilitate its implementation.

5.4 Final Hazard Categorization Documents

5.4.1 The Lead Reviewer performs a review of the assigned final hazard categorization document to ensure its technical adequacy and conformance with the Final Hazard Categorization Document Guidance provided in the Ref. 3.1.2, Safety Basis Document Review Guide. The DOE Federal Project Director/Program Manager and Facility Representative should participate in the review and be kept informed of issues and associated resolutions.

5.4.2 The Lead Reviewer interfaces with the prime contractor on any issues identified during the review. If DOE is unable to approve, the COR formally notifies the prime contractor that the document cannot be approved with the basis for DOE's disapproval clearly documented.

5.4.3 The Lead Reviewer prepares an SER for the Final Hazard Categorization Document to document the DOE basis for approval of Hazard Category 2 or 3 nuclear facilities that have been recategorized as less than Hazard Category 3 (e.g., Radiological) by analysis.

5.4.4 The Lead Reviewer must ensure that any DOE conditions for approval in the SER constitute an appropriate and minimal essential set of conditions that are clearly stated (with due dates for closure) to facilitate its implementation.

5.5 Unreviewed Safety Question Procedures

5.5.1 The Lead Reviewer performs the following:

5.5.1.1 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 is required for the initial issuance of USQ procedures or for substantial changes to existing procedures.

NOTE: Reference 3.1.2, Safety Basis Document Review Guide contains guidance on preparing a USQ procedure review plan.

5.5.1.2 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. Guidelines for determining the technical adequacy of USQ procedures is contained in Reference 3.1.2, Safety Basis Document Review Guide and Reference 3.1.5 (EM guidelines related to the USQ Process).

5.5.1.3 Promptly communicates comments/issues generated during the review to the prime contractor. The Lead Reviewer identifies areas where agreement cannot be reached through the chain of command for resolution.

5.5.1.4 If EM is unable to approve the submitted USQ procedure without substantial clarification and/or numerous conditions for approval, the COR formally notifies the prime contractor that the document cannot be approved, with the basis for disapproval clearly documented.

NOTE. This step is a "should" because it may be skipped if the prime contractor voluntarily rescinds the submitted Safety Basis Document prior to receiving an official rejection letter.

5.5.1.5 Prepares an SER for USQ procedures or revisions/updates to approved procedures.

NOTE. A supplement to an existing SER is sufficient for approving USQ procedure revisions/updates.

5.5.1.6 The SER must be prepared and issued in accordance with DOE-STD-1104-2009, *Review and Approval of Nonreactor Nuclear Facility Safety Analysis*, to document the basis for EM's approval of the USQ procedure. This should be accomplished by following the instructions for SER preparation provided in Reference 3.1.2, Safety Basis Document Review Guide.

5.5.1.7 The Lead Reviewer must ensure that any DOE Conditions of Approval (COA) in the SER constitute an appropriate and minimal

essential set of conditions that are clearly stated (with due dates for closure) to facilitate its implementation.

5.6 Safety Basis Documents for New Facilities and Major Facility Modifications

5.6.1 The Lead Reviewer performs the following:

5.6.1.1 Evaluates the scope of the review effort to determine if additional resources are required and if a review plan is warranted. A review plan and a multi-disciplined review team are required at the initial issuance of the Conceptual Safety Design Report, commensurate with the level of complexity and hazards of the planned facility (graded approach).

NOTE. (1) A review plan is not required to support a review of updates to the Conceptual Safety Design Report that occurs at subsequent design stages (i.e., review of PSDR and PDSA)
(2) Reference 3.1.2, Safety Basis Document Review Guide contains guidance on preparing a review plan.

5.6.1.2 Reviews the document to ensure its technical adequacy and compliance with DOE requirements. Guidelines for determining the technical adequacy of Safety Basis Documents generated for new facilities and major facility modifications are contained in Reference 3.1.3, DOE-STD-1189-2008 and Reference 3.1.5 (EM memorandum related to interim guidance for safety integration)

5.6.1.3 Promptly communicates comments/issues generated during the review to the prime contractor. The Lead Reviewer elevates areas where agreement cannot be reached through the chain of command (i.e., Nuclear Safety Team Leader, and Facility Operations and Safety Division Director) for resolution. The DOE Federal Project Director should be kept informed of issues generated during the review.

5.6.1.4 If EM is unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, the COR formally notifies the prime contractor that the document cannot be approved, with the basis for disapproval clearly documented.

NOTE This step is a "should" because it may be skipped if the prime contractor voluntarily rescinds the submitted Safety Basis Document prior to receiving an official rejection letter.

5.6.1.5 Prepares an SVR for Safety Design Reports at conceptual and preliminary stages of design and an SER for approval of the PDSA as described in Reference 3.1.3, DOE-STD-1189-2008.

5.6.1.6 Prepares an approval document for SDS documents in accordance with guidance of Attachment A

5.6.1.7 The SVR/SER must be prepared and issued in accordance with DOE-STD-1104-96, *Review and Approval of Nonreactor Nuclear Safety Analysis Reports*, to document the basis for EM's approval of the safety basis document. The SER instructions in Reference 3.1.2, Safety Basis Document Review Guide, can be applied to SVRs and SERs generated for new facilities.

5.6.1.8 The Lead Reviewer must ensure that any DOE Conditions of Approval (COA) in the SVR/SER constitute an appropriate and minimal essential set of conditions that are clearly stated (with due dates for closure) to facilitate its implementation.

5.7 Records

The following records must be controlled and maintained by the Nuclear Safety Team Leader:

5.7.1 SVRs, SERs, and SDS approval documents, as well as supporting documentation associated with DOE's review and approval of a Safety Basis Document (e.g., review comments, matrices, transmittal correspondence between the prime contractor and DOE, independent analyses or calculations performed by or for DOE).

5.7.2 Annual summary report(s) of all prime contractor's USQ determinations and any correspondence associated with the DOE determination of the adequacy of the summary report.

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

Attachment A

Guidance for Approval of Safety Design Strategy Documents

Guidance for Approval of
Safety Design Strategy Documents

DOE-STD-1189-2008 requires a Safety Design Strategy (SDS) for newly planned Hazard Category 1, 2, or 3 nuclear facilities. The SDS describes the proposed E&SH tailoring strategy envisioned for the facility. The document is developed in the conceptual design phase and is updated throughout the design process.

The SDS must be approved by the Federal Project Director and Safety Basis Approval Authority, though DOE-STD-1189-2008 does not require a SER to document the approval basis. For the purposes of meeting the standard and this EM procedure, the approval basis may be in the form of a letter that is formally transmitted to the design contractor. The DOE Lead Reviewer shall ensure that a formal correspondence package addresses whether the following elements are met:

(1) The SDS is prepared by the design contractor's Safety Design Integration Team (i.e., reflects input from appropriate project personnel);
(2) SDS format and content are consistent with DOE-STD-1189-2008, Appendix E; and
(3) The SDS is submitted to DOE prior to official contractor submission of a facility's conceptual design documents (an exception is when the implementation date of DOE-STD-1189 is subsequent to conceptual design).

As verification that the SDS is compliant with DOE-STD-1189-2008 (Item #2 above), the checklist provided as an attachment to this guidance must be completed by the DOE Lead Reviewer and attached to the official correspondence package approving the SDS.

If any of the above elements are not satisfactorily addressed, the DOE Lead Reviewer should prepare correspondence that either rejects the SDS or provides explicit actions expected on the part of the design contractor (i.e., actions, completion dates). The SDS should be rejected if it has major deficiencies with respect to DOE-STD-1189-2008 requirements. In cases where the SDS has incomplete information because of the lack of available design information, the Lead Reviewer may consider a condition of approval with expectations tied to future design phases.

In all cases, the DOE Lead Reviewer should seek input from relevant subject matter experts participating on the DOE Integrated Project Team in order to reach a conclusion on the SDS adequacy.

Checklist for SDS Compliance with DOE-STD-1189-2008

Project Name:			Requirement Met?		
			Yes	No	Basis
1	Safety guidance and requirements discussed.				
	1a	Safety-in-Design approach and philosophy discussed (e.g., minimization of materials-at-risk, passive controls over active, etc)			
	1b	Description of criteria or approach for safety functional classification of radiological hazards to public and workers. Meets STD-1189, Appendix A?			
	1c	Identifies safety design criteria to be applied to the project (overarching requirements are sufficient, e.g., commitment to DOE G 420.1-1, -2)			
2	Hazard identification information is complete.				
	2a	Major hazards involved in the project are discussed along with possible consequences			
	2b	Hazard identification based on initial or assumed hazardous inventories			
	2c	Assumed hazardous inventories are consistent with that used in the initial hazard categorization in accordance with DOE-STD-1027-92			
3	Key safety decisions explicitly addressed and consistent with hazard identification information				
	3a	Seismic and other natural phenomena design categorization meets DOE Interim Guidance on Safety Integration into Early Phases of Nuclear Facility Design (reference 3.1.7)and DOE-STD-1189, Appendix A (safety functional classification)			

	3b	Confinement strategy discusses overall approach, including active systems and associated safety functional classification. Strategy is consistent with DOE Interim Guidance on Safety Integration into Early Phases of Nuclear Facility Design (reference 3.1.7) and DNFSB Recommendation 2004-2 Implementation Plan Document "Ventilation System Evaluation Guidance for Safety-Related and Non-Safety- Related Systems" (reference 3.1.8)			
	3c	Fire mitigation strategy includes discussion of fire barriers, segregation, and safety functional classification of suppression systems. Strategy is consistent with DOE Interim Guidance on Safety Integration into Early Phases of Nuclear Facility Design (reference 3.1.7).			
4	Risks to Project Safety Decisions are Summarized.				
	4a	Risks associated with key safety decisions are described (e.g., new technology, need for additional data to substantiate assumptions, hazardous material inventory assumptions).			
5	Safety analysis approach and plan is provided.				
	5a	Deliverables expected to be completed, submitted, and approved are described for all project phases.			
	5b	Integration with other safety discipline efforts is described (e.g., Fire Hazards Analysis)			
	5c	Any tailoring approaches affecting safety basis are described.			
	5d	Use of any safety analysis tools not included in the DOE Safety Software Central Registry is described and justified			
6	Safety Design Integration Team interactions are discussed				
	6a	Role of the Safety Design Integration Team is described, along with any key interactions among Integrated Project Team.			