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February 1996

CHANGE NOTICE NO. 2

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DOE STANDARD

REVIEW AND APPROVAL OF NUCLEAR FACILITY SAFETY BASIS DOCUMENTS (DOCUMENTED SAFETY ANALYSES AND TECHNICAL SAFETY REQUIREMENTS)



U.S. Department of Energy
Washington, DC 20585

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Change Notice No. 2

DOE-STD-1104-96

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Change Notice 1***Review and Approval of Nuclear Facility Safety Basis Documents
(Documented Safety Analyses and Technical Safety Requirements)***

Page / Section	Change
Entire Document	Safety Analysis Report (SAR) was changed to Documented Safety Analysis (DSA).
Entire Document	Terminology in the Standard was changed to be consistent with 10 CFR 830.
Entire Document	Description of DOE review and approval effort was expanded to include Technical Safety Requirements (TSRs).
Entire Document	References to DOE 5480.23 were changed to 10 CFR 830.
Entire Document	References to Cognizant Secretarial Officer (CSO) were changed to DOE Management Official.
Entire Document	References to DOE Order 5480.21, "Unreviewed Safety Questions", were changed to 10 CFR 830.203, "Unreviewed safety question process".
p. ii	The address for obtaining copies of this Standard was changed.
p. v / Table of Contents	New chapter on Approval Bases for Technical Safety Requirements was added.
p. v / Table of Contents	New section on Technical Safety Requirements was added to Section 4, "Safety Evaluation Reports".
p. vii / Foreword	New address was provided for beneficial comments.
p. ix / Guiding Principles	Guidance was added regarding the use of other than safe harbor methodologies.
p. 1 / Applicability and Scope	Guidance for facilities under the Office of Nuclear Energy, Science and Technology, was deleted.
p. 3 / Sect. 1.1 Responsibilities and Authorities	Requirements from 10 CFR 830 for review of safety basis replaced DOE 5480.23 requirements.
p. 10 / Sect. 2.2 Hazard and Accident Analyses	Requirements from 10 CFR 830 were added.
p. 11 / Sect. 2.4 Hazard Controls	Requirements from 10 CFR 830 were added.
p. 12 / Sect. 2.5 Safety Management Program Characteristics	Requirements from 10 CFR 830 were added.
p. 12 / Sect. 2.5 Programmatic Control	Guidance on the use of descriptions of institutional programs in Integrated Safety Management System documents and site-wide manuals was added.
p. 13 / Sect. 3 Approval Bases for Technical Safety Requirements	New section on approval bases for TSRs was added.
p. 18 / Sect. 4.10 Technical Safety Requirements	New section on documenting review and approval of TSRs in the Safety Evaluation Report (SER) was added.

Change Notice 2
Review and Approval of Nuclear Facility Safety Basis Documents
(Documented Safety Analyses and Technical Safety Requirements)

<u>Page / Section</u>	<u>Change</u>
<u>Throughout</u>	<u>Added detail on expectation for conditions of approval for safety bases in response to request from the Defense Nuclear Facilities Safety Board</u>
<u>1.4 Issue Origination and Resolution</u>	<u>Added discussion on conditions of approval</u>
<u>2.6 Conditions of Approval</u>	<u>Added a new section on conditions of approval for DSAs.</u>
<u>4.5 Base Information</u>	<u>Added discussion on expectations of documentation in SER on conditions of approval.</u>

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FOREWORD

1. This Department of Energy Standard (DOE-STD)-1104 Change Notice No. 1, "Review and Approval of Nuclear Facility Safety Basis Documents (Documented Safety Analyses and Technical Safety Requirements)," is approved for use or reference by DOE, including the National Nuclear Security Administration (NNSA), or its contractors.
2. Title 10 of the Code of Federal Regulations (CFR) Part 830 Final Rule, "Nuclear Safety Management", issued 10 January 2001, establishes requirements for nuclear facility Documented Safety Analyses (DSAs) and Technical Safety Requirements (TSRs) or TSR-equivalent documents for environmental restoration activities.

This Standard was prepared to be consistent with the 10 CFR 830 Rule and its Implementation Guides and should be used in conjunction with the Rule and its Implementation Guides.

3. Beneficial comments (e.g., recommendations, additions, and deletions) and any pertinent data that may be of use in improving this document should be sent by letter to

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GUIDING PRINCIPLES

The following guiding principles pertain to the application and provisions of this Standard.

- The documents (i.e., DOE orders, manuals, guides, and standards) listed in Table 2 of Appendix A to 10 CFR 830 Subpart B provide approved methodologies for meeting the DSA requirements of 10 CFR 830. Developed consistent with and as a companion to these documents, this standard does not reiterate the provisions of these documents.
- If a contractor uses a method other than a safe harbor method, it must obtain DOE approval of the method before developing the DSA. Likewise, if a contractor uses a safe harbor method to develop the DSA, but does not follow the method completely, the contractor should request DOE approval of the method with the specific deviations noted. The use of alternative methods or specific deviations from the safe harbor methods must have, (1) for NNSA facilities the approval of the Deputy Administrator or for non-NNSA facilities the approval or concurrence [if the responsibility is delegated to the field element manager (FEM)] of the Cognizant Secretarial Office (CSO) as specified in paragraph 9.3.1 of DOE Manual 411.1-1B, "Safety Management Functions, Responsibilities, and Authorities Manual (FRAM)", and (2) the approval of the FEM and the review and concurrence (or comment if an NNSA facility is involved) of the DOE Headquarters Office of Environment, Safety, and Health (DOE HQ / EH) as specified in paragraph 9.4.1.6 of the FRAM.
- The DOE Management Official (i.e., the Assistant Secretary, the Assistant Administrator, or the Office Director) who is primarily responsible for a DOE nuclear facility may assign responsibility to their designees for review and approval of the DSA and TSRs and delegate authority commensurate with this responsibility. Paragraph 9.4.1.6 of the FRAM states that a Cognizant Secretarial Officer can delegate this authority to the FEM for the facility. Through such actions, the DOE Management Official establishes a new approval authority but does not relinquish the ultimate responsibility and authority in ensuring adequate performance of that approval authority. In carrying out assigned responsibilities, the approval authority, if not the DOE Management Official, is at all times accountable to the DOE Management Official.
- Independent review of the DSA and TSRs facilitates achieving defensible approval. Since both the preparation and the review and approval of these documents may fall under the purview of the approval authority, independent review is achieved by designating a review team leader with the responsibility and authority to conduct independent assessments. The review team leader is independent of any responsibility for preparation of the documents under review.
- The approval authority is the single point of contact between DOE and the facility contractor for all areas of review and approval of DSA and TSRs. In this capacity, the approval authority serves as the focal point through which DOE interfaces with the facility contractor and from which directions to the facility contractor originate. This is accomplished through the review team leader and in conjunction with official contractor interfaces.
- DOE is responsible for both the operation and the regulation (e.g., review and approval of DSAs and TSRs) of the facilities for which these

documents are required. This dual role places fundamental limits on the ability of DOE to completely segregate the processes of preparation and review of these documents. For example, the FEM has responsibility for both the operation of the facility and the review and approval of the DSA and TSRs. However, in order to be as objective as possible in the review process, most of the reviewers of the DSA and TSRs should not be responsible for the operation of the facility, including the preparation of the DSA and TSRs. It is not expected that these reviews will be conducted completely separate from the preparation. This standard encourages interface between the two processes to develop familiarity with the facility's safety basis, to respond to requests from the preparer for early identification and resolution of potential issues, and to discern the scope of subsequent review and the extent of approval documentation required.

- DOE strives for an effective, streamlined review and approval process for DSAs and TSRs while still achieving an acceptable level of safety assurance. This Standard advocates proper planning for a review and encourages an integrated review process where all parties with vested interest in a facility safety basis coordinate throughout the review and approval.
- DOE manages review issues requiring resolution for approval in that reviewers establish and document the safety significance of issues prior to submittal for possible resolution. Guidance is provided to focus facility contractor's resolution of issues on those issues determined to be necessary for adequately establishing and documenting the facility safety basis.
- This Standard provides guidelines for reviewing the DSA through assessment of the major subject areas of a safety analysis as defined by the following DSA approval bases:
 - Base information;
 - Hazard and accident analyses;
 - Safety structures, systems, and components (SSCs);
 - Derivation of technical safety requirements; and
 - Safety management program characteristics
- This Standard also provides guidelines for reviewing the TSRs. There is only one approval basis for a TSR document and that is the TSR provisions themselves. Determining the adequacy of the TSRs generally entails a disciplined analysis and tracing of commitments to hazard controls in a DSA through appropriate provisions that implement these controls in a TSR document.
- The Safety Evaluation Report (SER) is primarily a management document that provides the approval authority the basis for the extent and detail of the review of the DSA and TSRs and the basis for and any conditions of approval. This Standard endorses the concept that the contents of a SER are concise summary statements and that little benefit is gained from the wholesale recapturing of elements already contained in a DOE-owned DSA or TSRs or from reproducing original analysis that, if deemed critical, is performed as part of the review process.

- SERs document the bases for approving revisions of DSAs/TSRs, including annual updates. Those revisions determined to not involve an unreviewed safety question (USQ) in accordance with 10 CFR 830.203, "Unreviewed safety question process", are considered administrative and/or editorial in nature and may be reviewed and approved by DOE subsequent to implementation of the changes by the facility contractor.

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INTRODUCTION

Safety and health assurance may be increased by standardizing the process of reviewing and approving DSAs and TSRs. Although complete standardization of the process (e.g., standardized review plan) requires substantial commitments and is complicated by the diversity of facility operations throughout the DOE complex, certain benefits are gained by standardizing fundamental elements of the review and approval process. To that end, the Standard establishes DOE guidelines for the review and approval of these documents, including preparation of SERs, for nuclear facilities.

APPLICABILITY AND SCOPE

Guidance provided in this Standard is applicable to the review and approval of DSAs and TSRs and revisions thereto, including required annual updates (i.e., 10 CFR 830 annual updates), for existing nuclear facilities. Therefore, this Standard is appropriate for Hazard Category 1, 2, or 3 facilities (classified in accordance with DOE-STD-1027 Change Notice No. 1, "Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports") that document their safety basis in accordance with 10 CFR 830. For new facilities in which conceptual design or construction activities are in progress, the review and approval process for the Preliminary Documented Safety Analysis (PDSA) is much more focused on the adequacy of the proposed design for safety and on confirming that construction is within approved design in accordance with 10 CFR 830.206, "Preliminary documented safety analysis". Provisions of this Standard may be applied to the process of reviewing and approving PDSAs documenting conceptual and/or preliminary designs to the extent judged to be beneficial.

The body of this Standard focuses on management of the review and approval process, provides guidelines for establishing the basis of approval, and recommends a format and content of SERs. Specific review guidelines that are technical in nature are more appropriately addressed individually by subject matter and require more detailed guidance and discussion. Therefore, the body provides general guidelines as opposed to a comprehensive list of technical safety criteria [e.g., standardized review plan (SRP)]. Thus, this Standard does not constitute a SRP in the same context as the SRP employed by the Nuclear Regulatory Commission.

This Standard is applicable to government-owned, government-operated (GOGO) facilities in which DOE performs the function of the facility contractor.

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1. MANAGEMENT AND COORDINATION

1.1 Responsibilities and Authorities

Appendix A of 10 CFR 830 states "The DOE Management Official for a DOE nuclear facility (that is, the Assistant Secretary, the Assistant Administrator, or the Office Director who is primarily responsible for the management of the facility) has primary responsibility within DOE for ensuring that the safety basis for the facility is adequate and complies with the safety basis requirements of Part 830." It further states "The DOE Management Official is responsible for ensuring the timely and proper (1) review of all safety basis documents submitted to DOE and (2) preparation of a safety evaluation report concerning the safety basis for a facility." Paragraph 9.4.1.6 of the FRAM states that a CSO can delegate this authority to the FEM for the facility. By assigning responsibilities for the review and approval of the DSA to another individual, the DOE Management Official for the facility establishes that individual as the new approval authority. Assigning responsibilities carries concurrent delegation of authority recognized by the line management and those responsible for monitoring and auditing implementation of the Rule.

The approval authority is responsible for providing a defensible review and approval of the DSA. Achieving defensible review and approval is facilitated by an independent review process. Since both the preparation of the DSA and its review and approval typically fall within the purview of the approval authority, the approval authority assigns a review team leader the responsibility of performing the independent review. In making this assignment, the approval authority ensures that the review team leader maintains sufficient independence of the line organization responsible for the DSA preparation (i.e., no responsibility for preparation of the DSA under review) and possesses the technical competence relevant to the DSA of concern. The details of independently reviewing the DSA, up to and including recommending approval to the approval authority, are managed by the review team leader.

The approval authority has responsibility as the single point of contact between DOE and the facility contractor for all matters regarding review of the DSA. This responsibility is typically assigned to the review team leader, but the approval authority remains the final authority on any points requiring arbitration. The single point of contact is the focal point through which DOE and the facility contractor interface and from which directions to the facility contractor originate. Requests for any material on the DSA, determination of the significance of identified issues on such material, and direction to the facility contractor for resolution of issues are approved by the single point of contact. As appropriate, transmittal of official communications and directions involving significant work effort by the facility contractor are coordinated with the facility Contracting Officer. Line management personnel and representatives of organizations responsible for monitoring and auditing 10 CFR 830 implementation coordinate their activities through the single point of contact as well.

The approval authority has the specific responsibility of ensuring the review and approval process represents all DOE entities with vested interest in the facility under review and considers commitments made to agencies outside DOE. Agencies external to DOE, however, have no standing under the Orders/Rules structure for approval. Identifying safety issues and their resolution may involve negotiations between concerned organizations. Discounting a safety issue raised by any vested interest without giving the issue proper consideration could reduce safety assurance.

On behalf of the approval authority, the review team leader coordinates the day-to-day aspects of managing the review and approval process for the DSA. General responsibilities in this capacity include:

- Representing the focal point for interface between DOE and the facility contractor for review matters;
- Developing a review plan, including review milestones developed in consultation with the facility contractor;
- Establishing and managing the review team;
- Supervising the overall review process, including planning and scheduling changes;
- Coordinating, scheduling, and arbitrating issue resolution; and
- Preparing a SER.

The approval authority does not relinquish responsibility for ensuring adequate performance of the review team leader in fulfilling assigned responsibilities. Final approval of the DSA and SER issuance remain an unassignable responsibility function of the approval authority and are based on consideration of the review team leader's recommendations.

1.2 Planning

A review plan defines the extent and details of the review process, deemed necessary for each DSA. Well before submittal of the DSA for approval, plans should be developed in coordination with the facility contractor where support of the contractor will be required (e.g., briefings on the DSA, facility walkthroughs, and issue resolution). The review plan can be very brief for the least hazardous or the least complex facility DSAs and is generally not necessary for the review of revisions and annual updates of DSAs. The plan should be approved by the approval authority with a copy forwarded to the facility contractor for their information. Basic components of a review plan include:

- Scope and objectives of the review and their bases, including technical-, mission-, and/or project-related influences impacting the extent and detail of the review;
- Methodology of the review, including basic task identification, objectives, and criteria by which the review is to be conducted;
- Resources required for the review;
- Process and requirements for providing orientation for the reviewers (e.g. briefings, training on review plan and review criteria, facility walkthroughs, etc.);
- Means of coordinating the review (e.g., periodic monitoring of individual tasks, documentation of review efforts, formats for issue submittal and responses, tracking of issues and their resolutions, record keeping, etc.);
- Required SER reviews and signoffs;
- Schedule for the review, including key milestones for the review process (e.g., dates of facility walkthroughs, briefings, and/or meetings, calendar time allotted for issue submittal and issue resolution, SER reviews, and final SER approval).

The review plan is developed from a general understanding of the overall facility safety basis gleaned from existing safety basis documentation (e.g., Basis for Interim Operations), familiarity with the facility, and DOE experiences with similar facilities. Typical considerations include facility hazard category, complexity of operations, dominant accident concerns apparent, known operational and / or design vulnerabilities, existing mission or program influences (e.g., mission-related considerations and objectives) and time constraints for the review and approval. Careful consideration should be given to developing the review plan and any subsequent updating of the plan due to major changes in the DSA development schedule, provisions, or approach to its review. Many elements considered in planning the review will be summarized as part of

the SER to document the basis and the extent and detail of the review. The primary focus of DOE oversight of the review process is the basis for the extent and detail of the review, with secondary focus being the adequate implementation of the review. Documentation establishing the basis and conduct of the review is maintained for subsequent demonstration that the review process was complete and adequate.

An important part of planning is selecting the individuals composing the review team. Members of the review team are typically selected based on technical qualifications, experience, familiarity with the subject matter, independence from preparation of the DSA, understanding of DOE's safety assurance strategy (e.g., nuclear safety requirements), and availability. The review team requires a core team with expertise in process hazards analysis and accident analysis. The core of the review effort is assessing the hazard and accident analysis in the DSA because these analyses are the primary sources of original material with which the remainder of the DSA is aligned. Other personnel with diverse experience in safety and health and facility operations are not necessarily members of the core team but collectively provide support as needed for a thorough assessment of the facility safety basis. The extent of support necessary is generally reflected by the hazard and complexity level of the activities being examined. Personnel resources may be augmented with available personnel from DOE Headquarters or unaffiliated Field/Operations Offices. To support single review efforts, the review team should include representatives from any party responsible for the review of the DSA and may also include representatives of parties responsible for oversight of the review and approval to monitor the review process.

1.3 Interactions

DOE has certain fundamental limits on its ability to completely separate the DSA preparation and review processes because it is responsible for both the operation and regulation of the facilities for which DSAs are prepared, reviewed, and approved. Therefore, reviews are not expected to be conducted completely segregated from preparation of the DSA. Some degree of interaction between the preparation and review processes is useful in streamlining the review and approval. This interaction provides the means by which DOE keeps abreast of issues that arise during development of the DSA and by which DOE responds to requests from the DSA preparer to assist in resolving fundamental conceptual issues. It is through such interaction that DOE is afforded the opportunity to commence research on potential issues in preparation for the official review.

It is important to maintain a balance in the interaction of the review and preparation processes. Requests for material outside the provisions of the review plan are made solely by the review team leader. Reviewers do not directly request draft material from the preparers. Informal direction of preparation by reviewers is unacceptable. Tendencies exist for facility contractors to view any comments or direction offered by reviewers as a firm prerequisite for approval. The actual preparation of and changes to a DSA are the responsibilities of the preparers, not the review team or its members. Therefore, comments or advice affecting preparation should result from unequivocal solicitation by the preparer. Even so, the review team leader, as authorized by the approval authority, is the only authority for originating any official intervention driving the content and details of a DSA. Any intervention is officially communicated by DOE to the facility contractor after ensuring that it is crucial to the development of the facility safety basis and originates from a sound technical foundation (i.e., undergone technically qualified independent review). Even then, intervention generally takes the form of guidance or recommendation and is well documented for subsequent reference by the reviewers during the review.

1.4 Issue Origination and Resolution

Traditionally, in reviewing DSAs, both line management personnel and representatives of other organizations, were known to generate a large number of comments, many of which were not commensurate with a consistent concept of the DSA and its purpose. The preparer of the DSA has often borne the sole burden of resolving all such comments while reviewers have not been held accountable for justifying comments. This often resulted in forced integration of contradictory comments or comments contrary to a particular approach or structure for the DSA. To prevent such occurrences, the approval authority, through the review team leader, maintains authority to determine what issues are significant and are transmitted to the preparer for formal (i.e., a documented, traceable, written record) resolution. For this reason, increased "burden of proof" lies with reviewers to justify the safety significance of an issue through substantiation of its impact on the safety basis if left unresolved. Each significant issue submitted should be accompanied by justification for its significance. The review team leader, and subsequently the approval authority, rely upon these justifications in determining the relevance of all issues.

A significant issue identifies a problem or concern that affects the utility or validity of the safety basis documentation. Such issues are generally those involving: (1) hazardous material or energy release with significant consequences to the public, worker, or environment that will otherwise be left without coverage in the DSA; (2) technical errors that invalidate major conclusions relevant to the safety basis; or (3) failure to cover topical material required by DOE regulations, directives, and guidance on DSAs. DSAs prepared in accordance with 10 CFR 830 use the graded approach in documenting the facility safety basis. The absence of information in a DSA is not a potential issue unless that absence adversely impacts the adequacy of the facility safety basis documentation. For example, DOE-STD-3009 Change Notice No. 2 states that standard industrial hazards are not generically covered in the DSA. But an issue requiring that a standard industrial hazard be included in a DSA would be justified if a clear case can be made there is a potential contributor to a significant release of hazardous material involving that hazard. If thorough justification of the significance of an issue is not provided and supported, then the review team leader may refrain from transmitting to the DSA preparer the issue as significant and requiring resolution. Such judgments may be appealed to the approving authority.

While only significant issues require formal resolution, the review team leader will typically transmit all issues to the preparer that will improve overall preparation of the DSA. The preparer may resolve these issues to the extent they enhance the final product without formal response. In the process outlined by this Standard, the objective is not to document a large number of issues but to contribute to improving the DSA to meet the mission established by 10 CFR 830 and the intent of amplifying guidance, (i.e., to provide assurance that the DSA appropriately establishes the safety basis of the facility).

For issues transmitted to the preparer as significant, the preparer formally prepares resolutions and submits them to the review team leader. The review team leader transmits proposed resolutions to reviewers originating the issues, who may in turn respond if a resolution is considered unsatisfactory. All responses are transmitted through the review team leader, who schedules and arbitrates the process of resolution. The review team leader may consider proposed resolutions satisfactory in the absence of timely responses or adequate justification of unacceptability by the issue originator. As a matter of course, the review team leader ensures that the preparer is formally notified of acceptable and unacceptable resolutions proposed for significant issues.

Reviewers or the preparer of the DSA may appeal the disposition of an issue by the review team leader to the approval authority. The approval authority determines the final disposition of issues as it is the ultimate responsibility of the approval authority to achieve a defensible position for the final product (i.e., determine when resolution is adequate). Neither a reviewer nor the preparer has veto power over ultimate resolution or disposition of an issue and neither need be satisfied with the final resolution. The review team leader ensures that final disposition of significant issues is documented (i.e., traceable, written record), including minority opinions and dissenting views.

As stated in 10 CFR 830.202, contractors must incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE. The regulation also states that the safety evaluation report (SER) must document the basis for approval of the safety basis for the facility including any conditions of approval. Documenting directed changes and conditions of approval in the SER provides a way to address inadequacies in the safety basis that are not significant enough to warrant rejection of the safety basis but which need to be addressed. Chapter 2 provides guidance on what constitutes an appropriate condition of approval for documented safety analyses (DSAs). Chapter 4 presents guidance on information to be documented in the SER for each condition of approval.

To ensure adequate tracking and closure of conditions of approval DOE site office staff should:

- Verify that contractors have a documented process for
 - tracking conditions of approval to closure.
 - verifying satisfactory closure of the condition of approval.
 - notifying DOE when a condition of approval has been satisfied, and
 - managing any conditions of approval until they are closed;
- Ensure that when a condition of approval is satisfied the basis for closure is documented in the next update of the DSA and the closure of the condition of approval is noted in the DOE approval of that update of the DSA; and
- Periodically assess the closure and status of conditions of approval, as well as the contractor tracking process.

Technical Safety Requirements (TSRs) identify the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility/activity/process. Consistent with 10 CFR 830.202 the SER may direct changes or impose additional hazard controls to be applied to the TSR before operation, but it is not appropriate to specify temporary conditions to be applied to TSRs. These directed changes must be incorporated into the TSRs prior to operation under the approved safety basis.

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2. APPROVAL BASES FOR DOCUMENTED SAFETY ANALYSES

DOE evaluates the DSA by considering the extent to which the DSA (1) adequately addresses the criteria set forth in 10 CFR 830.202 and 10 CFR 830.204 and (2) satisfies the provisions of the methodology used to prepare the DSA. DSA review and approval focuses on the adequacy of the following approval bases:

- Base information;
- Hazard and accident analyses;
- Safety structures, systems, and components;
- Derivation of technical safety requirements ; and
- Safety management program characteristics.

Once technical justification exists to support conclusions that the DSA adequately describes how the facility is satisfactory with respect to the approval bases, the DSA may generally be considered adequate. These approval bases also form the foundation for documenting DSA approval in a SER.

2.1 Base Information

Base information is the first of the approval bases that should be reviewed and encompasses elements of DSA preparation, completeness, and general content. Base information is not reviewed for accuracy in and of itself but for sufficiency to allow assessment of the other approval bases that rely on this information. The review for sufficiency can range from a simple screening effort to more detailed discussions, depending on the complexity of the DSA.

Insufficient or incomplete base information in a DSA may prevent further review of the DSA. Reviewers should require resolution of major discrepancies in base information (e.g., incomplete site characteristics) before evaluation of the more specific aspects (e.g., hazard and accident analyses) of the safety basis proceeds. It is for this reason that the SER need only provide a brief statement as to the adequacy of base information.

For example, for DSAs adhering to DOE-STD-3009 Change Notice No. 2 format, the review of base information primarily determines the sufficiency of the information provided in the Executive Summary, Site Characteristics (Chapter 1), Facility Description (Chapter 2), and to some extent material generic to all DSA chapters (e.g., statutes, rules, Orders, and principal health and safety criteria). Determining the adequacy of base information generally entails being able to conclude that the DSA contains sufficient documentation and basis to arrive at the following conclusions:

- The facility contractor development and approval processes (e.g., personnel involvement in developing the DSA, management cognizance and acceptance, internal reviews, etc.) demonstrate sufficient commitment to establish the facility safety basis.
- The facility mission(s) and scope of operations (i.e., the scope of work to be performed) for which safety basis approval is being sought are clearly stated and reflected in the type and scope of operations analyzed in the DSA. For example, a DSA documenting the safety basis of a spent fuel storage facility whose mission includes size reduction of spent fuel elements would be unacceptable if the DSA omitted safety analysis of size reduction operations.

- A description of the facility's life-cycle stage, mission(s), scope of operations, and the design of safety structures, systems, and components is presented, including explanation of the impact on the facility safety basis.
- Clear basis for and provisions of exemptions, consent agreements, and open issues are presented.
- Description of the site, facility, and operational processes provide a knowledgeable reviewer sufficient background material to understand the major elements of the safety analysis.
- Correlation is established between actual facility arrangements and operations with those stated in the DSA. This may be accomplished successfully through reference to facility walkthroughs during DSA preparation. Walkthroughs may also be warranted during DSA review to provide some level of assurance that the actual physical arrangement of a facility corresponds to that documented in the DSA. For example, a walkthrough may be considered for a facility and/or operation that was modified in the time frame between when DSA development was started and completed. This is not intended to imply the review team must perform detailed verifications of facility configuration. The objective is to allow the review team to conclude that the basic descriptions provided are fundamentally up-to-date and correct.

2.2 Hazard and Accident Analyses

Another of the DSA approval bases is hazard and accident analyses and forms the foundation upon which the remaining approval bases (i.e., safety SSCs, derivation of TSRs, and safety management program characteristics) rely. Determining the adequacy of hazard and accident analyses generally entails being able to conclude that the DSA contains sufficient documentation and basis to arrive at the following conclusions:

- The hazard analysis includes hazard identification that specifies or estimates the hazards relevant for DSA consideration (i.e., both natural and man-made hazards associated with the work and the facility) in terms of type, quantity, and form, and also includes properly performed facility hazard categorization.
- The final hazard category for the facility is determined consistent with DOE-STD-1027 Change Notice No. 1 or successor document. Any differences between the final hazard category and the initial hazard category are explained.
- The hazard analysis includes hazard evaluation that covers the activities for which approval is sought, is consistent in approach with safe harbor methodologies, identifies preventive and mitigative features for the spectrum of events examined, and identifies dominant accident scenarios through ranking.
- The hazard analysis evaluates normal, abnormal, and accident conditions, including consideration of natural and man-made external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and

other hazardous materials, and consideration of the need for analysis of accidents which may be beyond the design basis of the facility.

- The hazard analysis results are clearly characterized in terms of public safety, defense in depth, worker safety, and environmental protection. The logic behind assessing the results in terms of safety-significant SSCs and designation of TSRs is understandable and internally consistent.
- Subsequent accident analysis clearly substantiates the findings and delineations of hazard analysis for the subset of events examined and confirms their potential consequences. Events potentially exceeding evaluation guidelines need to clearly identify associated safety-class SSCs and basis of TSR deviations.

The goal of the review is to ensure that the safety basis is comprehensive relative to hazards presented and is based on a consistent, substantiated logic.

2.3 Safety Structures, Systems, and Components

The next DSA approval basis is safety structures, systems, and components. Identification of safety SSCs (i.e., safety-class SSCs and safety-significant SSCs) is a product of the hazard and accident analyses. Determining the adequacy of safety SSCs generally entails being able to conclude that the DSA contains sufficient documentation and basis to arrive at the following conclusions:

- The safety SSCs identified and described are consistent with the logic presented in the hazard and accident analyses.
- Safety functions for safety SSCs are defined with clarity and are consistent with the bases derived in the hazard and accident analyses.
- Functional requirements and system evaluations are derived from the safety functions and provide evidence that the safety functions can be performed.
- Control of safety SSCs relevant to TSR development is clearly defined.

2.4 Derivation of Technical Safety Requirements

Derivation of technical safety requirements is the next of the DSA approval bases. Hazard controls are derived to eliminate, limit, or mitigate hazards and are generally safety SSCs or commitments to safety management programs, which are ultimately included in TSRs. Identification of TSRs results from the most significant preventative and mitigative features identified in the hazard and accident analyses and from the designation of safety SSCs. Determining the adequacy of the derivation of TSRs generally entails being able to conclude that the DSA contains sufficient documentation and basis to arrive at the following conclusions:

- TSRs are identified to ensure adequate protection of workers, the public, and the environment.
- The bases for deriving TSRs, that are identified and described in the hazard and accident analyses and safety SSC chapters, are consistent with the logic and assumptions presented in the analyses.

- The bases for deriving safety limits, limiting control settings, limiting conditions for operation, surveillance requirements, and administrative controls are provided as appropriate.
- The process for maintaining the TSRs current at all times and for controlling their use is defined.

2.5 Safety Management Program Characteristics

Safety management program characteristics is the last of the DSA approval bases and encompasses the elements of institutional programs and facility management that are necessary to ensure safe operations based on assumptions made in the hazard and accident analyses. While these elements must be addressed in the DSA, generic descriptions of these institutional programs should not be duplicated in the DSA if they can be referenced in Integrated Safety Management System (ISMS) documents or site-wide manuals. These institutional programs include (where applicable) quality assurance, procedures, maintenance, personnel training, conduct of operations, emergency preparedness, fire protection, waste management, radiation protection, and criticality safety. Identification of safety management program characteristics is a product of hazard and accident analyses, designation of safety SSCs, and derivation of TSRs. Determining the adequacy of safety management program characteristics generally entails being able to conclude that the DSA contains sufficient documentation and basis to arrive at the following conclusions:

- The major programs needed to provide programmatic safety management are identified.
- Basic provisions of identified programs are noted, and references to facility or site program documentation are provided.

The acceptance of safety management program characteristics does not constitute acceptance of the adequacy of program compliance with DOE directives. That can only be accomplished by detailed compliance review of each of the programs, which is beyond the scope of a DSA.

2.6 Conditions of Approval

Conditions of approval should be used to document actions that need to be completed to address certain inadequacies in the DSA. Purely editorial issues (e.g., punctuation, misspelling) that do not change the meaning or technical content of the statement should not be handled through conditions of approval. Conditions of approval should not be used to approve DSAs with fundamental flaws. Large numbers of conditions of approval for a single DSA may indicate that the DSA is fundamentally flawed and should prompt a review of which issues should be corrected prior to approval of the DSA. DOE should not approve conditions of approval for extended periods of time. A defined closure date or milestone should be identified in the condition of approval. If a condition is intended to be applied for an extended period of time the DSA should reflect that condition as part of the analysis.

The following criteria constitute a basis for rejection of the DSA and should not be addressed through conditions of approval.

1. There is insufficient information to document the conclusion that there is reasonable assurance of adequate protection of the worker, the public, and the environment.

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2. The DSA does not meet the regulatory requirements of 10 CFR Part 830 and does not have an approved exemption in accordance with 10 CFR Part 820, Subpart E.
3. Significant issues were identified during the acceptance review that would prevent conducting a successful technical review.
4. The base information contained in the DSA is insufficient to describe the activities, processes, or systems to enable the hazard analyst to identify a complete set of hazards for the covered facility/activity/program.
5. The Hazard Analysis (HA) is incomplete (e.g., there are missing hazards; the response is incomplete, unavailable, or misapplied).
6. The Accident Analysis (AA) is incomplete (e.g., a scenario does not bound the hazard from the HA, there are incorrect calculations supporting the AA conclusions).

Conditions of approval cannot be used to allow the facility/activity/program to be outside of the approved safety basis or to be inconsistent with law or other requirements.

An example of a situation where a condition of approval would be appropriate for a DSA is the use of a fire watch where a fire barrier is needed per the safety analysis but it has not yet been installed.

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3.0 APPROVAL BASIS FOR TECHNICAL SAFETY REQUIREMENTS

3.1 Management and Coordination

DOE reviews of TSRs are generally conducted in coordination with DSA reviews, and by many of the same team members. This provides an economy of effort, because team members, by virtue of their familiarity with the DSA, have an understanding of the commitments made in the DSA that need to be reflected in the TSR. The discussions in Section 1 of this Standard relative to management and coordination of DSA reviews are equally applicable to the TSR review process. The management plan should address both DSA and TSR reviews. Because the TSRs must implement commitments made in the DSA, approvals and implementation of both the DSA and TSRs must be coordinated.

3.2 Approval Bases

The approval bases for the TSR document are the TSR provisions. These TSR provisions may be design features, safety limits, operating limits (limiting control settings and limiting conditions of operation), surveillance requirements, or administrative controls (primarily commitments to implement safety management programs according to the facility-specific characteristics described in the DSA). The approval bases for a TSR document include a disciplined analysis and tracing of commitments to hazard controls through appropriate provisions that implement these controls in a TSR document. In some cases the specific treatment of safety controls in the TSR is committed to in the DSA; in other cases, it is a judgment call as to the appropriate TSR treatment. Determining the adequacy of the TSR provisions generally entails being able to conclude that

- Hazard controls that are discussed in the DSA are faithfully translated into TSR provisions.
- The TSR provisions are appropriate and consistent with the DSA.

The sources of information in a DSA regarding these provisions are the hazards analysis, including description of hazard controls; the description of safety structures, systems, and components (SSCs), the classification of these SSCs as Safety Class, Safety Significant, or other important defense-in-depth SSCs, the description of the functional requirements for the safety SSCs, and the derivation of TSRs section; and the descriptions of the safety management programs.

3.2.1 Hazards Analysis

A hazards analysis will include a disciplined analysis of all hazards within the scope of the DSA, including a listing of applicable preventative and mitigative hazard controls. These controls may include safety SSCs, design features, and provisions of various safety management programs. These controls should be regarded as DSA commitments. They should be traced through DSA documentation to specific TSR provisions.

3.2.2 Safety SSC

Safety SSCs must be described in sufficient detail in a DSA so that their functional requirements are defined and the bases for TSR requirements are derived. These safety SSCs will be either active or passive. If passive, they should also be considered for designation as "Design Features" in the TSR. These are features of facility design that may not be changed without DOE review and approval. A crosscheck between DSA-identified important design features and the Design Features section of the TSR should

be conducted to assure consistency. If active, safety-class SSCs will usually have a safety limit and a limiting control setting associated with it, as well as a surveillance requirement. An active Safety Significant SSC may have a limiting condition of operation and surveillance requirement and/or specific provisions of a maintenance management program associated with it. In any case, safety SSCs must be addressed specifically in TSR provisions. Technical bases for limiting control settings and surveillance requirements in the Bases appendix of the TSR should be reviewed for adequacy. All these provisions are directed at assurance that the safety function of the SSC will be protected.

3.2.3 Other Important Defense-In-Depth SSCs

DOE Standards define only Safety Class and Safety Significant SSCs, criteria for their designation, and design requirements (in the case of new design). Provisions exist for line management to designate additional important defense-in-depth items, independent of safety analysis. If such items are designated, it should be confirmed that any management direction relative to assurance of safety function is implemented through the TSR.

3.2.4 Safety Management Programs

Hazards analyses may invoke particular aspects of safety management programs, such as emergency preparedness, criticality safety, procedures and training, etc. Any particular provisions of these programs unique to the facility should have been described in the DSA. The administrative controls section of the TSR should include commitments to implement those programs identified in the DSA as important to the facility's safety basis.

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4. SAFETY EVALUATION REPORTS

The review process results in the generation of a SER integral to the facility's authorization basis. The SER for a given facility or operation documents: (1) that an appropriate review of the DSA and TSRs was conducted and (2) bases for approving these documents and any conditions of approval. Approval signifies that DOE has accepted these documents as appropriately documenting the safety basis of a facility and as serving as the basis for operational controls (e.g., technical safety requirements, programmatic control, etc.) necessary to maintain an acceptable operating envelope.

The SER is developed specifically to document acceptance of the DSA and TSRs. Therefore, significant issues concerning these documents are typically resolved and incorporated in the DSA and TSRs before the final SER is prepared. An analysis that was not performed during preparation of the DSA and TSRs but is determined to be required to complete the review is also documented independently of the SER. Only statements pertinent to accepting the facility basis are included in the SER. In accomplishing this, informed judgment and discretion are used to focus the SER on facts that clearly reflect the actual conditions of the facility safety basis. The SER does not need to repeat in wholesale fashion material contained in the DSA and TSRs.

The SER is intended to provide an overall summary of the methodology, assumptions, bases, conclusions, and commitments in the DSA and TSRs rather than a total reanalysis (i.e., independent verification and validation) of those activities addressed in the these documents. During the review process selected limited independent verification and validation can be performed, for example in cases where (1) there may be significant questions about the validity of the original analysis, (2) where the risks are significant, and/or (3) the analysis is critical to the overall conclusions in the DSA and TSRs; however, significant discrepancies should be resolved as part of the development effort for the DSA and TSRs and, if deemed appropriate, only briefly documented in the SER. The SER clearly states any conditions of approval that impose additional commitments to which facility management must adhere beyond those already documented in the DSA and TSRs. In general, conditions that could be incorporated into the body of these documents are so incorporated during the review process as prompted by issue resolution (as opposed to being addressed in the SER and potentially invalidating portions of the DSA and TSRs). However, if necessary, the approval authority can expedite approval by defining specific conditions of approval in the SER without requiring revision of the DSA and TSRs.

Approval statements addressing specific areas of the safety basis are augmented with brief summaries of the most significant facility-specific points in those areas to provide a basic context to understand what is being approved. In stating the adequacy of the approval bases, it may also prove advantageous and/or warranted for the SER to discuss areas of concern or issues with significant ramifications for facility operations. Generally, these issues will have been resolved and any inquiries into them will have been completed during the review process. Any discussion of issues in the SER should be on a summary level and directed towards clarifying some specific aspect of approval or demonstrating understanding of some aspect of the facility safety basis.

If the SER imposes a condition of approval (e.g., additional compensatory measures, alterations of stated commitments, etc.) on the facility safety basis documented in the DSA and TSRs, then the SER necessarily modifies that facility safety basis. In such cases, conditions cited in the SER become part of the facility safety basis. Therefore, a facility safety basis is composed of an approved DSA and TSRs modified as necessary by the SER to reflect DOE-imposed conditions of authorization. The SER or memorandum stating the conditions is subsequently appended to the DSA and TSRs.

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Specification of conditions in the SER not currently in place in these documents should identify an expected schedule for completion.

Revisions of DSAs and TSRs, including DSA annual updates, undergo review and approval. Review and approval of revisions are a matter of endorsing the incorporation of changes in the safety basis since the last approval rather than performing a new assessment of the previously approved safety basis documents. Modifications to the facility operations not encompassed by the safety basis as documented in a DSA and TSRs invoke the USQ process. Therefore, revisions are generally administrative and/or editorial in nature in that they incorporate final disposition of USQs, and conditions of approval stated in the existing SER, and/or minor changes that clarify the safety basis documentation. For this reason, administrative and editorial revisions determined to not involve a USQ, can be performed by the facility contractor at any time without prior DOE approval. The facility contractor provides a copy of the revision, with a discussion of the changes, to the approval authority within thirty (30) days of implementing the changes for subsequent DOE review and approval. Review and approval of revisions of DSAs and TSRs do not typically warrant a significant new effort (e.g., detailed review plan, formal review team) and may be as simple as merely indicating the latest revision numbers for simple administrative and/or editorial changes.

SERs document the bases for approving revisions, including annual updates. A SER for a revision typically does not provide the complete basis of approval for that DSA and TSRs and only provides the basis of approving changes in the provisions resulting from the revision. Therefore, SERs for revisions are appended to the SER documenting the last comprehensive determination of the basis of approval of the DSA and TSRs. Collectively, a SER and its appendices provide the complete basis of approval for any given DSA and TSRs. A SER without appendices is generated upon the next comprehensive determination and documentation of the basis of approval for that DSA and TSRs, or at the discretion of the approval authority.

The remainder of this chapter provides the recommended format and content for a SER. The SER addresses only those issues that are germane to documenting the basis of acceptance of the DSA and TSRs; therefore the SER is subject to the graded approach. Summaries of material already contained in a DSA and TSRs should be brief but sufficient to provide a knowledgeable reader a basic understanding of the basis of approving these documents.

4.1 Title Page

The title page provides the unique identifier information for both the DSA and TSRs and the SER. Minimum information consists of: (1) SER title, revision number, and date issued; (2) title, revision number, and date issued for the DSA and TSRs; (3) facility name and identification number, if any; (4) site; and (5) DOE contractor's name and appropriate contract number.

4.2 Signature Page

The signature page provides the identification and signature of the approval authority, and the date of the approval of the DSA and TSRs. Other signatures may be provided at the discretion of the approval authority.

4.3 Executive Summary

This section presents summary information regarding the basis of approval of the DSA and TSRs. The introduction contains the following information, briefly summarized: (1) clear identification of the facility for which approval is being granted and its hazard

category; (2) statement of the facility mission and scope of operations encompassed by the facility mission; (3) summary of the major facility hazards and dominant accident scenarios; (4) discussion of pertinent exemptions and/or consent agreements impacting the approval; (5) discussions of major mission- and project-related influences impacting the decision to authorize operation; and (6) any conditions of approval and/or open issues raised with regard to the approval bases, including schedules for completion (if applicable). The executive summary concludes with a statement on the acceptability of the DSA and TSRs indicating that these documents have undergone an appropriate review and that the facility safety basis as documented is acceptable with stated conditions of approval, if any.

4.4 Review Process

This section provides a brief description of the review process the DSA and TSRs have undergone and its basis. Because there is no generic level of review effort required, this section is more the historical top-level documentation of the review process and the rationale for level of effort and detail. Typical information summarized includes: (1) basic premises of review, particularly those representing some consensus with the preparer of the DSA/TSRs; (2) summation of the review effort; (3) key participants in the review process; and (4) scope of special efforts, if any (e.g., selected independent calculations, walkthroughs, etc.). Discussion should be brief but still sufficient to provide an understanding of the thoroughness of the review process and its basis. This section does not provide a documented record of the details of the review (e.g., issue resolution files).

4.5 Base Information

This section documents the bases of approving the adequacy of base information, including any conditions of approval imposed. A statement of adequacy is generally focused and brief. This may entail nothing more than a paragraph stating that the DSA contains sufficient background and fundamental information to support the review of the more technical aspects of the DSA (i.e., review of the remaining approval bases). The majority of any inadequacies in the base information will require revision to the DSA prior to SER preparation or may be sufficiently minor that they can be resolved in a future DSA revision.

In addition to bases of acceptance, this SER section provides a brief synopsis of major site, facility, and operational process features. This information is intended for the sole purpose of providing a minimal, facility-specific context for SER bases of approval, such that an elementary understanding of the operational envelope can be gleaned from the SER. The SER does not, however, attempt to repeat detailed safety basis information contained in the DSA.

Conditions of approval should be written in such a manner that the conditions required to be met and actions required to be implemented are clearly articulated. Durations, implementation periods, and/or completion dates should also be specified so that it is clear when compliance with the condition of approval is expected to occur. The reason for including any conditions of approval should be clearly stated in the SER, as well as the basis for the conclusion that continued operation under the condition of approval is acceptable and consistent with adequate protection of workers, the public.

4.6 Hazard and Accident Analyses

This section documents the bases for approving the hazard and accident analyses, including any conditions of approval imposed. Such documentation focuses on the

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completeness of the analysis and the consistency of the logic used throughout the analysis process.

In addition to bases of acceptance, this SER section provides: (1) a brief synopsis of hazards identified; (2) fundamental aspects of defense in depth, worker safety, and environmental protection; (3) dominant accident potentials; and (4) accident consequences relative to the DOE-STD-3009 Change Notice No. 2 Evaluation Guideline. The purpose of summarizing this information is not to recapture detailed information already present in the DSA. The summary provides the reader an elementary understanding of the major facility hazards. In summarizing this information the SER does not repeat the details of the DSA assumptions or calculations. The SER may, however, discuss essential aspects of important issues resolved during the review process.

4.7 Safety Structures, Systems, and Components

This section documents the bases for approving the designation of safety SSCs and their associated safety functions, functional requirements, system evaluations, and potential TSR coverage, including any conditions of approval imposed. Focus is on the consistency of the logic developed in hazard and accident analyses being carried through to the identification of safety SSCs and the definitions and descriptions provided for these SSCs.

In addition to bases of acceptance, this SER section provides a brief synopsis of safety SSCs and their safety functions as determined in the hazard and accident analyses. The purpose of summarizing this information is not to recapture detailed information already presented in the DSA. The summary provides a reader an elementary understanding of the safety SSCs and the bases of their designation in hazard and accident analyses. The SER may, however, discuss essential aspects of important issues resolved during the review process.

4.8 Derivation of Technical Safety Requirements

This section documents the bases for approving the derivation of TSRs, including any conditions of approval imposed. Such documentation focuses on the consistency of the logic developed in the hazard and accident analyses and safety SSC chapters being carried through to the derivation of TSRs. The TSRs required by 10 CFR 830.205 are not specified in a DSA, which is only required to provide the basis of their derivation.

In addition to bases of acceptance, the SER section provides a brief synopsis of the derivation of TSRs as a function of the hazard and accident analyses. This information is intended for the sole purpose of providing minimal, facility-specific context for SER bases of approval, such that an elementary understanding of the operational envelope can be gleaned from the SER. The SER does not, however, attempt to repeat detailed information contained in the DSA.

4.9 Safety Management Program Characteristics

This section documents the bases of approving safety management program characteristics, including any conditions of approval imposed. These bases do not relate to compliance with regulatory requirements, but to identification of the basic capability and awareness of fundamental provisions needed for maintaining the adequacy of the facility safety basis. This approval simply documents that the basic elements of the institutional safety management programs depended on for ensuring facility safety basis are adequate and that these elements can and will be implemented. A list of these programs briefly noting their general significance to defense in depth, worker safety,

and/or dominant accident scenarios is provided, but no summary of the information from each programmatic chapter is needed.

4.10 Technical Safety Requirements

This section documents the basis of approving the TSRs. It should be verified that all the commitments for safety controls that are made in the DSA are carried through to TSR provisions. Judgment needs to be exercised in the specifics of the form of TSR treatment (e.g., LCOs or administrative controls). The technical bases for these judgments should be documented as part of the review, and summarized in this section of the SER.

4.11 Records

This section provides references to the essential records, documentation, and information generated throughout the review process. This may include reference to records of: (1) the review plan and schedule; (2) minutes of review meetings, including meeting with the facility contractor; (3) dates and the results of facility walkthroughs; (4) submittal of issues and their disposition; (5) documentation generated in resolution of issues; and (6) documentation regarding commitments made by the facility contractor for approval of the DSA and TSRs. References should be complete and accurate enough to locate necessary information during future revision and review activities, if needed.

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CONCLUDING MATERIAL**Review Activities****Preparing Activity**

DOE EH-53

DOE Field OrganizationsDOE Headquarters

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Laboratories and M&O Contractors

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ALMO	KCAO	PIAO
ALO	KEH	PNL
ANL	LAAO	PPPL
ARAO	LANL	PRAO
ASKC	LBL	REEC
BAH	LLNL	RFO
BAO	LMIT	RFP
BDM	MAO	RLO
BNL	METC	RSN
BPA	MKF	SAIC
BTAO	LMES	SLAC
CAI	M&H	SNLA
CHO	MMSC	SNLL
EMI	MND	SRO
EML	NVO	SURA
ETEC	OHO	TRW
FAO	OAK	UCMC
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