

INTRODUCTION

The “Standard Review Plan for the Review of a License Application for the Tank Waste Remediation System Privatization (TWRS-P) Project]” provides U.S. Nuclear Regulatory Commission (NRC) guidance for the review and evaluation of health, safety, and environmental protection in applications for licenses for remediation of radioactive tank waste at Hanford. The guidance is also applicable to the review and evaluation of proposed amendments and license renewal applications. Specific filing requirements for license applications, and for issuance of such licenses, are in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as revised¹. Although 10 CFR Part 70, as revised, does not specifically include a TWRS-P facility in § 70.60, “Applicability,” the regulation specifies applicable facilities include, “any other activity that the Commission determines could significantly affect public health and safety.”

The principal purpose of the Standard Review Plan (SRP) is to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. The SRP also should be used as the basis for the review of requests by licensees for changes in their licenses. Thus, the SRP, at any point in time, can provide a basis for the review of proposed new or renewal applications, and amendments to existing licenses, as well as modifications to the SRP resulting from new NRC requirements and licensee initiatives.

Another important purpose of the SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. Because the SRP describes the scope, level of detail, and acceptance criteria for reviewers, it can serve as regulatory guidance for applicants who need to determine what information should be presented in a license application.

The responsibility of the staff in the review of a license application, renewal application, or license amendment for a TWRS-P facility is to determine that there is reasonable assurance that the facility can and will be operated in a manner that will not be inimical to the common defense and security, and will provide reasonable protection of the health and safety of workers and the public, and the environment. To carry out this responsibility, the staff evaluates information provided by an applicant and through independent assessments determines that the applicant has demonstrated a reasonable safety program that is in accordance with regulatory requirements. To facilitate carrying out this responsibility, the SRP clearly states and identifies those standards, criteria, and bases that the staff should use in reaching licensing decisions.

The staff believes that a TWRS-P facility is an activity that could significantly affect public health and safety, and therefore plans to invoke the requirements found in Subpart H of 10 CFR Part 70 for this type of facility. As such, 10 CFR Part 70, as revised, require that an applicant submit a complete description of the safety program for the possession and use of SNM to show how compliance with the applicable requirements will be accomplished. The Safety Program

¹ Nuclear Regulatory Commission (U.S.), Washington, D.C. “Domestic Licensing of Special Nuclear Material (10 CFR Part 70).” *Federal Register*: Vol. 64, No. 146. pp. 41338--41357. July 30, 1999.

Description must be sufficiently detailed to permit the staff to obtain reasonable assurance that the facility is designed and will be operated without undue risk to the health and safety of workers or the public. Prior to submission of the program description, an applicant should have analyzed the facility in sufficient detail to conclude that it is designed and can be operated safely. The Safety Program Description is the principal document with which the applicant provides the information needed by staff to understand the basis for conclusion. When reviewed and approved by the staff, and incorporated in the NRC license by reference, the Safety Program Description, in its entirety and in its parts, is the safety basis on which the license is issued, and may not be changed except through the process defined in 10 CFR 70.72.

The requirements in 10 CFR Part 70 specify, in general terms, the information to be supplied in a Safety Program Description. The specific information to be submitted by an applicant and evaluated by staff is identified in this SRP. Prospective applicants should study the topic areas treated in this document (generally, chapter headings) and the subsections within each topic area, specifically the subsections headed "Areas of Review" and "Acceptance Criteria." A license application should contain a Safety Program Description that addresses all the topics in the Table of Contents of this SRP, in the same order as presented in this document.

In this SRP, information is provided to assist the licensing staff and the applicant in understanding the underlying objective of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents NRC staff has prepared for licensing facilities under 10 CFR Part 70, and the details of the staff review process set out in individual SRP sections. Analyses by the staff are intended to provide regulatory confirmation of reasonable assurance of safe design and operation. A staff determination of reasonable assurance leads to a decision to issue or renew a license or to approve an amendment. In the case of a staff determination of inadequate description or commitments, the staff should inform the applicant of what is needed and the basis upon which the determination was made.

The "Acceptance Criteria" delineated in this SRP are intended to communicate the underlying objectives but not to represent the only means of satisfying that objective. An applicant should tailor its safety program to the features of its particular facility. If approaches different from the SRP are chosen, the applicant should identify the portions of its application that differ from the design approaches and acceptance criteria of the SRP and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The staff retains the responsibility to make an independent determination of the adequacy of what is proposed.

The major topics addressed within the Safety Program Description of a facility license application are addressed in separate SRP sections; each of those sections, or chapters, includes subsections described below.

The applicant's integrated safety analysis (ISA) is the central focus for the selection of design and operational safety measures and the management control systems that assure the availability and reliability of those measures. It is the ISA that provides a comprehensive evaluation and presentation, useful to both the applicant and the NRC, of the distribution of risk among the many activities ongoing at the TWRS-P facility. The NRC expects to be able to use the ISA summary to focus its resources on the dominant risks of facility design and operation

and the safety controls and assurances necessary to ensure that those controls remain available and reliable. Accordingly, staff reviewers should conduct a coordinated review of the ISA summary and focus on the portions of the summary that are applicable to each of the technical areas treated in the chapters of the SRP. The acceptance criteria in each of the SRP chapters are the criteria that apply to the dominant risks of operation. The applicant has the opportunity to justify lesser criteria for those design and operational features that can be shown to represent lesser risk than the accident or failure sequences that pose the dominant risks.

While recognizing the fundamental importance of the ISA to understanding the risk at a facility, certain SRP chapters are less dependent on ISA outcomes than others. The chapters concerning radiation safety, environmental protection, emergency management, and decommissioning, for example, contain acceptance criteria that are set primarily by existing regulations and will not be affected by issuing the revision to 10 CFR Part 70. Finally, for new facilities (that have not already been designed, built, licensed and operated), certain baseline design criteria have been specified in 10 CFR Part 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." These criteria identify safety considerations that an applicant must address in its facility design. The ISA for the complete facility design may indicate when reduced levels of assurance may be acceptable. A more detailed description of the application of these criteria is given in the discussion of Section 4, "Acceptance Criteria" below.

Section 1. PURPOSE OF REVIEW

This section is a brief statement of the purpose for and objectives of reviewing the subject areas. It emphasizes the staff's evaluation of the ways the applicant can achieve identified performance objectives and ensures through the review that the applicant has used a multi-disciplinary, systems-oriented approach to establishing designs, controls, and procedures within individual technical areas.

Section 2. RESPONSIBILITY FOR REVIEW

This section identifies the organization and individuals by function, within NRC, responsible for evaluating the subject or functional area covered by the SRP. If reviewers with expertise in other areas are to participate in the evaluation, they are identified by function. In general, the Licensing Project Manager has responsibility for the total review product, a safety evaluation report for an application. However, an identified technical specialist should have primary responsibility for a particular review topic, usually an SRP chapter. One or more specialists may have supporting responsibility. In most situations the review is performed by a team of specialist reviewers including the lead reviewer for the ISA and the project manager. Although they individually perform their review tasks, the reviews are extensively coordinated and integrated to ensure consistency in approach and to ensure risk-informed reviews. The project manager oversees and directs the coordination of the reviewers. The reviewers' immediate line management has the responsibility to ensure that an adequate review is performed by qualified reviewers.

Section 3. AREAS OF REVIEW

This section describes the topics, functions, systems, structures, equipment, and components, analyses, data, or other information that should be reviewed as part of that particular subject

area of the license application. Because the section identifies information to be reviewed in evaluating the adequacy of the application, it identifies the acceptable content of an applicant's submittal in the areas discussed. The areas of review identified in this section obviate the need for a separate Standard Format and Content Guide.

The topics identified in this section also set the content of the next two sections of the SRP. Both Section 4, "Acceptance Criteria," and Section 5, "Review Procedures," should address, in the same order, the topics set forth in this section as areas to be reviewed. This section also identifies the information needed or the review expected from other NRC individuals to permit the individual charged with primary review responsibility to complete the review.

Section 4. ACCEPTANCE CRITERIA

This section contains a statement of the applicable NRC criteria based on regulatory requirements, and the bases for determining the acceptability of the applicant's commitments relative to the design, programs, or functions within the scope of the particular SRP section. Technical bases consist of specific criteria such as NRC regulations, regulatory guides, NUREG reports, industry codes and standards, and branch technical positions. To the extent practicable, the acceptance criteria identify, as objectively or quantitatively as is feasible, specific criteria and other technical bases that are to be satisfied. The acceptance criteria (including branch technical positions or other information) present positions and approaches that are acceptable to the staff. They are not considered the only acceptable positions or approaches. Others may be proposed by an applicant.

It is NRC's intent that the SRP present acceptance criteria for each technical function area (e.g., nuclear criticality safety, fire safety, radiation safety), and for the management measures (e.g., quality assurance, maintenance, audits and assessments), that allow an applicant to provide a level of protection commensurate with the accident risk inherent in the process activities proposed. For example, at process stations (or for an entire process or sub-process) for which the inherent risk to workers, the public, or the environment is demonstrably small, the applicant needs to provide only those design and operating controls which assure that small risk. The key element in the regulatory transaction involving presentation by an applicant, and review and approval by the NRC, is an adequate demonstration of acceptable control of risk by the applicant, which then supports a competent and informed review by NRC staff. The starting point for the applicant's demonstration of acceptable control of risk is the ISA.

The applicant's ISA summary (described in and reviewed under Chapter 3 of this SRP) is the primary supporting rationale for the safety level of design and operational features. There are, however, design and operational features and management controls that may be required independent of the ISA results presented by an applicant. This is to meet the requirements of 10 CFR Part 70.64, for new facilities or new processes at existing facilities, or, for all facilities, other NRC requirements such as 10 CFR Parts 20 and 51. The level of detail presented in the ISA summary and in other parts of the application represents the safety basis committed to by the applicant, and it is that basis which is subject to the provisions of 10 CFR Part 70, as revised, regarding changes that a licensee may make to the facility without prior NRC approval.

NRC should find an application acceptable if an applicant commits to the design features and management measures defined by the acceptance criteria within this SRP. The criteria in this SRP represent the design features or management measures that support an NRC finding of

reasonable assurance of adequate protection, independent of any ISA findings or conclusions that could lead to NRC approval of reduced levels of assurance for certain design features or management measures where the associated risk does not warrant the same high level of assurance.

An applicant for license renewal or an amendment for an existing facility responding to the requirements of 10 CFR Part 70, may propose structures, systems, and components (SSC) or management measures that meet less stringent acceptance criteria than described in the SRP based on supporting analyses from the applicant's ISA. The ISA may be used to justify a reduced level of assurance for particular items relied on for safety, that are associated with lesser risk accident sequences, as defined by the applicant's analysis of likelihood and consequences pursuant to 10 CFR Part 70, as revised. The SRP criteria shown in this SRP apply to those SSC and management measures that are involved in the higher risk accident sequences as defined in Part 70, as revised.

For proposed new facilities or amendments for new processes proposed at existing facilities, the acceptance criteria described in the SRP apply for design purposes and should be addressed in the applicant's licensing submittal for all SSC and management measures and that section's requirement to comply with the baseline design criteria (BDCs) of Part 70, as revised. The BDCs are consistent with risk-informed regulation, in that, for new processes or new facilities, NRC recognizes that good engineering practice dictates certain minimum requirements be applied as design and safety considerations, generally independent of the risk-based information ultimately obtained through the ISA. However, the applicant may use the ISA summary to justify reduced criteria for some SSC and management measures consistent with ISA summary for a facility final design. Proposed reductions in the level of assurance should be considered by the NRC staff, and, if accepted, should also constitute compliance with the BDCs.

Section 5. REVIEW PROCEDURES

This section describes how the review should be performed. It describes procedures that the reviewer should follow to achieve an acceptable scope and depth of review and to obtain reasonable assurance that the applicant has provided appropriate commitments to ensure that it will operate the facility safely. This includes identifying licensee commitments to verify and could include directing the reviewer to coordinate with others having review responsibilities for other portions of the application than that assigned to the reviewer. This section should provide whatever procedural guidance is necessary to evaluate the applicant's level of achievement of the acceptance criteria.

Section 6. EVALUATION FINDINGS

This section presents the type of positive conclusion that is sought for the particular review area to support a decision to grant a license or amendment. The review must be adequate to permit the reviewer to support this conclusion. For each section, a conclusion of this type should be included in the staff's Safety Evaluation Report (SER) in which the staff publishes the results of its review. The SER should also contain a description of the review, including aspects of the review that received special emphasis; matters that were modified by the applicant during the review; matters that require additional information or will be resolved in the future; aspects where the plant's design or the applicant's proposals deviate from the criteria in the SRP; and

the bases for any deviations from the SRP or proposed exemptions from the regulations. Staff reviews may be documented in the form of draft SERs that identify open issues requiring resolution before the staff can make a positive finding in favor of the license issuance or amendment.

Section 7. REFERENCES

This section lists references that should be consulted in the review process. However, they may not always be relevant to the review, depending on the action and approaches proposed by the applicant.