INTRODUCTION

NUREG-1520, "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility" (hereafter referred to as the SRP) provides U.S. Nuclear Regulatory Commission (NRC) guidance for reviewing and evaluating the health, safety, and environmental protection aspects of applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. This guidance is specific to fuel cycle facilities regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," that is, facilities that are authorized for or are seeking a license to possess and use more than a critical mass of SNM. This guidance also applies to the review and evaluation of proposed amendments and license renewal applications for nuclear fuel cycle facilities. This guidance does not apply to conversion facilities,[1] gaseous diffusion plants,[2] reprocessing facilities, and plutonium processing facilities.[3]

The principal purpose of this SRP is to ensure the quality and uniformity of reviews conducted by the staff of the NRC's Office of Nuclear Material Safety and Safeguards (NMSS). This SRP also provides a well-defined foundation from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. Another important purpose of this SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. In addition, because this SRP describes the scope, level of detail, and acceptance criteria for reviews, it serves as regulatory guidance for applicants who need to determine what information to present in a license application and related documents.

This SRP addresses the long-standing health, safety, and environmental protection requirements of 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR Part 70, as well as the accident safety requirements reflected in 10 CFR Part 70 Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." The NRC review criteria applicable to the safeguards sections of license applications are published in NUREG1280, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment: 10 CFR Part 74, Subpart E," issued April 1995 (for high-enriched uranium facilities), and NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control Plans for high enriched uranium facilities and low enriched uranium facilities, respectively(FNMC) Plan Required for Low-Enriched Uranium Facilities," issued December 1995.

Subpart H of 10 CFR Part 70 identifies risk-informed performance requirements and requires applicants and existing licensees to conduct an integrated safety analysis (ISA) and submit an ISA Summary, as well as other information. Chapters 3 (ISA and ISA Summary) and 11

[1] The NRC regulates conversion facilities under the provisions of 10 CFR Part 40, "Domestic Licensing of Source Material."

[2] The NRC regulates gaseous diffusion plants under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." This regulation specifically applies to those portions of the Portsmouth and Paducah Gaseous Diffusion Plants located in Piketon, OH, and Paducah, KY, respectively, that are leased by the United States Enrichment Corporation.

[3] Guidance for the review of a license application for a Mixed Oxide (MOX) Fuel Fabrication Facility is provided in NUREG-1718, "Standard Review Plan for the Review of a License Application for a MOX Fuel Fabrication Facility," issued August 2000.

(Management Measures) of this SRP are the primary chapters that address the staff's review in relation to the performance and other related requirements of Subpart H. For new facilities that have not already been designed, built, licensed and operated, Subpart H also requires adherence to baseline design criteria, as specified in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities."

This SRP is a guidance document that is intended for use during the review of license applications, license renewal applications, and amendment applications. This SRP does not preclude licensees or applicants from suggesting alternative approaches to those specified in the SRP to demonstrate compliance with applicable regulations.

In reviewing a license application, renewal application, or license amendment for a fuel cycle facility, the staff must determine whether 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 adequately protect the health and safety of workers, the public, and the environment. To carry out this responsibility, the staff evaluates the information that the applicant provides and, through independent assessments, determines whether the applicant has proposed an adequate safety program that is compliant with regulatory requirements. To assist the staff in carrying out this responsibility, this SRP clearly states and identifies those standards, criteria, and bases that the staff will use in reaching licensing decisions.

An application for a 10 CFR Part 70 license must include specific information on the proposed equipment and facility in accordance with 10 CFR 70.22(a)(7), which states that each application shall contain the following:

> A description of equipment and facilities which will be used by the applicant to protect health and minimize danger to life or property (such as handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems, etc.).

In reviewing 10 CFR Part 70 license applications, the staff uses a reasonable assurance paradigm and focuses on the programmatic provisions of the applicant's proposed activities. Consequently, the licensing decision is ultimately based on information with a sufficient level of detail that permits reviewers to understand process system functions, and functionally, how items relied on for safety (IROFS) can perform as intended and be reliable. This staff review method is intended to ensure that the staff decision is based on a reasonable assurance that the submitted ISA Summary is complete and that the licensee will comply with the ISA and maintain it consistent with the regulations. The level of detail required for a licensing decision generally does not require a final facility design; however, identification of all IROFS and possible accident sequences is necessary to make a licensing decision. Even though detailed information about each IROFS is not required, sufficient information has to be provided to understand the process, theory of operation and functions of each IROFS and reasonable assurance that the ISA Summary is complete. For uranium enrichment facilities, to ensure that the applicant's programs have been sufficiently implemented and commitments have been properly applied in the final facility design and in the constructed facility, 10 CFR 70.32(k) states that the following:

> "No person may commence operation of a uranium enrichment facility until the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license."

This requirement applied through inspections, and not by licensing reviews, will ensure that the programmatic commitments made by licensee are properly applied in the as built facility. This inspection is intended to inspect the final design of the facility and the procedures that have been prepared to implement the licensee's commitments that are reflected in the license. The purpose of the review is to verify through inspection that the facility has been constructed in accordance with its license. Furthermore, for significant modifications to existing fuel cycle facilities, such as the licensing and construction of new processes, the staff may impose a license condition that specifies that an operational readiness review (ORR) inspection be conducted before operation to verify that the new part of the facility has been constructed in accordance with the requirements of the license. To facilitate the planning and accomplishment of a risk-informed ORR, the staff relies upon the licensee to provide a complete set of information. This complete set of information has been referred to in some projects as IROFS boundary packages.[4] For simplicity they will be referred to hereinafter in this document as IROFS boundary packages. Regardless of what they are called in a license application, the key point is that they provide information to the reviewers and inspectors about supporting systems that directly affect the effectiveness of the IROFS and the reliability and availability of the IROFS as required by 10 CFR 70.62(d). Inspectors use this information during the ORR inspection to determine if the licensee meets the requirements in 10 CFR 70.23(a)(3)–(4) and in 10 CFR 70.61(e).

In developing the performance requirements in 10 CFR Part 70, the NRC anticipated that, in the future, changes will be made to the facility design and processes and, therefore, described a process for addressing these changes is described in 10 CFR 70.72, "Facility Changes and Change Processes.". For a uranium enrichment facility, the licensee may make changes to its design, after receiving its license, during the construction phase and after operations begin.

[4] IROFS boundary packages are documents that contain the physical descriptions and parameters of structures, systems, and components that are used to meet the performance requirements of 10 CFR 70.61, "Performance Requirements." IROFS boundary definition packages are also prepared for administrative procedures or worker actions that are defined as IROFS. The boundary packages identify the specific functions to be performed by an IROFS and identify any items that may affect the function of the IROFS. The boundary packages also identify the facility areas in which the IROFS is used, design and functional attributes, management measures, any open items, and supporting documentation (e.g., piping and instrumentation diagrams, schematics).

Design and functional attributes should include safety functions such as separation from other IROFS, redundancy and diversity, fail-safe design, set points, environmental qualification, seismic qualification, and fire protection. System interfaces such as instrumentation, electrical, cooling, and lubrication requirements should also be included under design and functional attributes.

Management measures should address all of the management measures required to be applied to IROFS under 10 CFR 70.4, "Definitions," and include summary descriptions; references to maintenance, training, and procedures documents; or both, as appropriate for the IROFS. The references should be adequate to identify the actual working-level training or procedures document.

Open items that affect the reliability, the effectiveness, or both of the IROFS should be closed by the time of the ORR. The open items section should identify open items associated with the IROFS during the review and describe how the open items were resolved.

These changes, therefore, need to be submitted and reviewed in accordance with 10 CFR 70.72.

An applicant submits a complete description of the safety program for the possession and use of SNM to show how it will ensure compliance with the applicable requirements. It must describe the safety program in sufficient detail to permit the staff to determine with reasonable assurance that the facility is designed and will be operated without undue risk to the health and safety of workers or the public. Before submitting a program description, an applicant should have analyzed the facility in sufficient detail to conclude that it is designed and can be operated safely.

The requirements in 10 CFR 70.22, "Contents of Applications"; 10 CFR 70.23, "Requirements for the Approval of Applications"; and Subpart H to 10 CFR Part 70 specify, in general terms, the information to be supplied in a safety program description. As such, this SRP identifies the specific information that an applicant should submit for staff evaluation. Prospective applicants should study the topic areas treated in this SRP and the sections within each chapter (particularly those regarding areas of review and acceptance criteria). To facilitate the staff's review, a license application should contain a safety program description that addresses the contents of this SRP in the same order as presented in this document. Applicants may reference material submitted in one location in a license application at another location to avoid unnecessary duplication.

In addition, 10 CFR 70.61 requires each applicant to evaluate, in an ISA performed in accordance with 10 CFR 70.62, "Safety Program and Integrated Safety Analysis," compliance with the performance requirements in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d). The regulations in 10 CFR 70.65 describe the requirements for the contents of the ISA Summary that must be submitted with the application. According to 10 CFR 70.65(b)(3), the ISA must contain the following:

> A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to §70.62(c)(1)(i)- (iii) and a general description of the types of accident sequences.

The regulations in 10 CFR 70.65(b)(6) require that the ISA contain the following:

> A list briefly describing each item relied on for safety which is identified pursuant to §70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of §70.61.

Based on the information in the ISA Summary provided in accordance with 10 CFR 70.65, the NRC makes licensing decisions as required under 10 CFR 70.21, "Filing," 10 CFR 70.22, 10 CFR 70.23, and 10 CFR 70.60, "Applicability," through 10 CFR 70.66, "Additional Requirements for Approval of License Application." These decisions include compliance with the performance requirements, the baseline design criteria, defense in depth, and the adequacy of management measures.

This SRP provides information and guidance to assist the licensing staff and the applicant in understanding the underlying objectives of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents that the NRC staff has prepared for licensing fuel cycle facilities, and information about aspects of the staff review process set out in individual SRP sections. Staff analyses 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. If the staff determines that an application contains inadequate descriptions or commitments, the staff will inform the applicant of what is needed and the basis on which the determination was made.

The acceptance criteria delineated in this SRP are intended to communicate the underlying objectives, but they do not represent the only means of satisfying those objectives. An applicant should tailor its safety program to the particular features of its facility. If an applicant chooses approaches other than those presented in this SRP, the applicant should identify the portions of its license application that differ from the design approaches and acceptance criteria of the SRP, and should document 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 concerning the adequacy of the applicant's proposed approaches.

Each SRP chapter is structured to include the (1) purpose of the review, (2) responsibility for the review, (3) areas of review, (4) acceptance criteria, (5) procedure procedures, (6)) evaluation findings, and (7)) references.

Purpose of Review

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

Responsibility for Review

This section identifies the NRC organization and individuals (by function) who are responsible for evaluating the specific subject or functional area. If reviewers with expertise in other areas are to participate in the evaluation, they also are identified by function. In general, the licensing project manager has responsibility for the total review product, which is referred to as a safety evaluation report (SER). However, an identified technical specialist will have primary responsibility for a particular review topic (usually an SRP chapter), and one or more specialists may have supporting responsibility. This team of specialist reviewers performs the overall application review. Although they individually perform their review tasks, the reviews are extensively coordinated and integrated to ensure consistency in approach and to promote risk-informed reviews. The licensing project manager oversees and directs the coordination of the reviewers. The reviewers' immediate line management has the responsibility to ensure that qualified reviewers perform an adequate review.

Areas of Review

This section describes the topics, functions, systems, components, analyses, applicant commitments, data, or other information that should be reviewed as part of the given subject

area of the license application. Because this 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, covering the acceptance criteria and review procedures. Applications should address, in the same order, the topics set forth as areas of review. This section also identifies the information needed or the review expected from other NRC staff to permit the individual charged with primary review responsibility to complete the review.

Acceptance Criteria

This section defines a set of applicable NRC acceptance criteria on the basis of regulatory requirements, and these collectively establish the basis for assessing 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, and industry codes and standards. As such, the acceptance criteria present positions and approaches that are acceptable to the staff. As noted above, the NRC does not consider them to be the only acceptable positions or approaches, and the applicant may propose others.

The requirements for approval of an application appear in 10 CFR 70.23(a). These requirements state that the NRC will approve an application upon finding that the applicant is qualified, the proposed equipment and facilities are adequate to protect health and minimize danger to life or property, and the proposed procedures are adequate. As a technical matter, NMSS will determine how final the design must be to make this finding. The NRC staff will interpret applicant commitments to follow an industry standard as a commitment to adhere to all "shall" statements in the standard. The staff will not consider suggestions and recommendations in the standards (so-called "should" statements) as binding commitments by the applicant, unless the applicant specifically states an intent to treat the "should" statements as binding commitments (i.e., treat them as if they are "shall" statements). The applicant may make such commitments as part of its description of the safety program basis. If the staff finds that a definitive commitment to a "should" statement is necessary to provide adequate protection, the reviewer will raise this as an issue in any request for additional information on specific licensing actions. However, applicants should note that some industry or consensus standards specifically direct users to provide justifications for not abiding by recommendations contained in the standards. For example, American National Standards Institute/American Nuclear Society Standard 8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," states that "when recommendations are not implemented, justification shall be provided," thus effectively mixing "should" and "shall" statements. In such instances, applicants should be prepared to justify any decisions not to abide by recommendations contained in the standards.

This SRP presents acceptance criteria for each technical function area (e.g., nuclear criticality safety, fire safety, radiation safety) and the management measures (e.g., configuration management, maintenance, audits, and assessments) that an applicant uses to provide a level of protection commensurate with the accident risk inherent in the proposed process activities. 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 that ensure that risk remains small. The key

guidance on acceptable methods for evaluating the chemical and radiological consequences of potential accidents. NUREG-1601, "Chemical Process Safety at Fuel Cycle Facilities," issued August 1997, provides guidance on chemical safety practices acceptable for compliance with the regulations.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are derived from and support compliance with the relevant requirements of 10 CFR Part 70. The ISA will form the basis for the safety program by identifying potential accidents, designating IROFS and management measures, and evaluating the likelihood and consequences of each accident sequence for compliance with the performance requirements of 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the applicant to perform and maintain an ISA. The remainder of the criteria address the ISA results, as documented in the ISA Summary, and whether those documented results demonstrate that the applicant's IROFS and management measures can reasonably be expected to ensure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61. The acceptance criteria are thus intended to support the ultimate finding of the license review that, based on the information submitted and reviewed, there is reasonable assurance that the proposed facility, IROFS, safety programs, and management measures conforming to the commitments in the application comply with the regulations and provide adequate protection of public health and safety.

A high level of detail describing the process designs and IROFS might not be submitted with the license application or ISA Summary. In other words, the applicant might not provide information about all the components in a system, because not every component would be a safety-related component. In particular, for proposed new facilities, the level of detail may be limited since the hardware has not actually been fabricated. However, the applicant must describe the IROFS in enough detail to permit an understanding of the intended safety function and to permit an assessment that it is capable of the reliability expected of it in the evaluation of likelihoods of accident sequences. The NRC staff may obtain additional details for processes selected for the vertical slice review by visiting the applicant's site. While there may be an *actual* difference in the level of detail known about processes and IROFS, as documented at the applicant's site, for existing and proposed new facilities, the minimum level of detail that is sufficient in descriptions of processes and IROFS, as documented in the ISA Summary, does not differ between existing and proposed new facilities.

The purpose of the review, and its acceptance criteria, for most facilities, is primarily to permit a finding that the applicant's safety program, including the ISA program as described, provides reasonable assurance that compliance will be achieved. However, to generate the ISA Summary, which is a required submission, the applicant must first perform an ISA. This in turn requires that the applicant identify process designs, accident sequences, and IROFS. These latter items are not programmatic, but are elements of design and analysis of design. Attainment of reasonable assurance that the ISA program is and will be effective does not usually require that all safety elements and IROFS be reviewed in full detail, nor is it required that the applicant's description of IROFS and process designs be at the level of detail that will eventually exist at the time of operations (see the discussion of vertical slice review in Section 3.5). The requisite level of detail to achieve reasonable assurance may vary among processes, depending on factors such as use of established technology, commitment to standards, applicant expertise, industry experience, safety margins, and inherent difficulty in achieving the safety function. However, the underlying requirements for the descriptions are exactly the same for each process and IROFS; namely, "…a description of each process…in

sufficient detail to understand the theory of operation…" (10 CFR 70.65(3)); and "a description of IROFS…in sufficient detail to understand their functions in relation to the performance requirements…" (10 CFR 70.65(8)). Thus, the requirements for new technology are no different than those for old technology, but more explanatory detail may be necessary to meet the requirements related to "sufficient detail to understand."

3.4.3.1 Safety Program and Integrated Safety Analysis Commitments

This section discusses the acceptance criteria for license commitments pertaining to the facility's safety program including the performance of an ISA. A number of specific safety program requirements related to the ISA appear in 10 CFR Part 70. Section 3.4.3.2 presents the acceptance criteria for the content of the ISA Summary. These include the primary requirements that an ISA be conducted and that, based on the ISA Summary submitted, there is reasonable assurance that the applicant's facility and safety program complies with the ISA requirements of 10 CFR Part 70, Subpart H, including the performance requirements of 10 CFR 70.61. For each component of the safety program, several elements may be necessary, including organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices, among others.

Procedures and industry standards for hardware safety controls vary according to the type of equipment and by the degree of reliability and performance required in specific applications. For this reason, blanket commitments to apply all standards in all cases may not appear in the license application. However, some standards for engineering practices and hardware and software design or analysis are generic. Hence, an applicant may specify a general commitment to such a generic standard or may make conditional commitments to standards, subject to specified applicability criteria. The purpose of such commitments is to support likelihood or other performance evaluations for compliance with the regulations. NRC guidance has endorsed some standards, possibly with exceptions. Such commitments to standards are acceptable if they are consistent with their use in demonstrating compliance and with specific NRC guidance.

Among those engineering practices and standards that are generically applicable to IROFS and safety controls are those that apply to personnel activities relevant to administrative controls, management measures, or human-machine interfaces. This area is called human factors engineering. Human factors engineering should generally be part of the safety program. Human factors practices should be incorporated into the applicant's safety program sufficiently to ensure that IROFS and management measures perform their functions in meeting the requirements of 10 CFR Part 70. Appendix E to this chapter describes areas of review and acceptance criteria for human factors engineering in the context of 10 CFR Part 70 for fuel cycle facilities.

The applicant's commitments for each of the three elements of the safety program defined in 10 CFR 70.62(a) should be acceptable if the applicant does the following:

(1) Process Safety Information

a. The applicant commits to compiling and maintaining an up-to-date database of process safety information. Written process safety information will be used in updating the ISA and in identifying and understanding the hazards associated