

Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

Draft Report for Comment



NUREG-1520, Rev. 1

Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

Draft Report for Comment

Manuscript Completed: August 2009
Date Published: August 2009

Office of Nuclear Material Safety and Safeguards

ABSTRACT

This “Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility” (NUREG-1520) provides guidance to the staff reviewers in the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate nuclear fuel cycle facilities. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. As such, this SRP ensures the quality, uniformity, and predictability of the staff reviews. This SRP also makes information about licensing acceptance criteria widely available to interested members of the public and the regulated industry and is intended to improve industry and public stakeholder understanding of the staff review process. Each SRP section addresses the responsibilities of the staff reviewers, the matters that they review, the Commission's regulations pertinent to specific technical matters, the acceptance criteria used by the staff, the process and procedures used to accomplish the review, and the conclusions that are appropriate to summarize the review.

This SRP also addresses the long-standing health, safety, and environmental protection requirements of Title 10, Parts 20 and 70, of the *Code of Federal Regulations* (10 CFR Parts 20 and 70) as well as the amended accident safety requirements reflected in the new Subpart H of 10 CFR Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are primarily set by regulations that remained unaffected by the recent revision to 10 CFR Part 70.

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 11 (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.

This SRP is not a substitute for NRC regulations and compliance is not required. The approaches and methods in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

This SRP focuses on safety and environmental impact reviews. Review criteria applicable to the safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1065.¹

¹ Standard format and content guides for Fundamental Nuclear Material Control Plans
August 2009

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, draft, in your comments, and send them by September 25, 2009 to the following address:

Chief, Rulemaking and Directives Branch
U.S. Nuclear Regulatory Commission
Mail Stop TWB-05-B01
Washington, DC 20555-0001

Electronic comments may be submitted to the NRC through the Federal e-Rulemaking Portal at <http://www.regulations.gov>;

For any questions about the material in this report, please contact:

Cinthyia I. Román
Chemical Engineer
Mail Stop: EBB2C40M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Office: EBB2-A22
Phone: 301-415-1186
E-mail: Cinthyia.Roman@nrc.gov

CONTENTS

Page

ABSTRACT	iii
EXECUTIVE SUMMARY	ix
ACRONYMS AND ABBREVIATIONS.....	xi
GLOSSARY	xv
INTRODUCTION	1
1 GENERAL INFORMATION.....	1-1
1.1 FACILITY AND PROCESS OVERVIEW	1-1
1.1.1 Purpose of Review	1-1
1.1.2 Responsibility for Review	1-1
1.1.3 Areas of Review	1-1
1.1.4 Acceptance Criteria	1-2
1.1.5 Review Procedures	1-3
1.1.6 Evaluation Findings.....	1-4
1.1.7 References.....	1-4
1.2 INSTITUTIONAL INFORMATION	1-5
1.2.1 Purpose of Review	1-5
1.2.2 Responsibility for Review	1-5
1.2.3 Areas of Review	1-5
1.2.4 Acceptance Criteria.....	1-6
1.2.5 Review Procedures	1-7
1.2.6 Evaluation Findings.....	1-8
1.2.7 References.....	1-8
1.3 SITE DESCRIPTION	1-9
1.3.1 Purpose of Review	1-9
1.3.2 Responsibility for Review	1-9
1.3.3 Areas of Review	1-9
1.3.4 Acceptance Criteria.....	1-11
1.3.5 Review Procedures	1-11
1.3.6 Evaluation Findings.....	1-12
1.3.7 References.....	1-12
2 ORGANIZATION AND ADMINISTRATION	2-1
2.1 PURPOSE OF REVIEW.....	2-1
2.2 RESPONSIBILITY FOR REVIEW	2-1
2.3 AREAS OF REVIEW	2-1
2.4 ACCEPTANCE CRITERIA	2-2
2.4.1 Regulatory Requirements	2-2
2.4.2 Regulatory Guidance	2-2
2.4.3 Regulatory Acceptance Criteria	2-2
2.5 REVIEW PROCEDURES.....	2-3
2.5.1 Acceptance Review	2-3
2.5.2 Safety Evaluation.....	2-4
2.6 EVALUATION FINDINGS.....	2-4
2.7 REFERENCES.....	2-5

3	INTEGRATED SAFETY ANALYSIS (ISA) AND ISA SUMMARY	3-1
3.1	PURPOSE OF REVIEW	3-1
3.2	RESPONSIBILITY FOR REVIEW	3-2
3.3	AREAS OF REVIEW	3-3
3.3.1	Safety Program and ISA Commitments	3-4
3.3.2	ISA Summary and ISA Documentation	3-4
3.4	ACCEPTANCE CRITERIA	3-7
3.4.1	Regulatory Requirements	3-7
3.4.2	Regulatory Guidance	3-8
3.4.3	Regulatory Acceptance Criteria	3-9
3.5	REVIEW PROCEDURES	3-29
3.5.1	Acceptance Review	3-30
3.5.2	Safety Evaluation	3-30
3.6	EVALUATION FINDINGS.....	3-34
3.7	REFERENCES	3-35
	APPENDIX A: EXAMPLE PROCEDURE FOR ACCIDENT SEQUENCE EVALUATION.....	3-A-1
	ANNEX TO APPENDIX A: USE OF APPENDIX A RISK INDEX METHODOLOGY...3-AA-1	
	APPENDIX B: QUALITATIVE CRITERIA FOR EVALUATION OF LIKELIHOOD	3-B-1
	APPENDIX C: INITIATING EVENT FREQUENCY	3-C-1
	APPENDIX D: NATURAL PHENOMENA HAZARDS	3-D-1
	ANNEX TO APPENDIX D: EXAMPLE OF NATURAL PHENOMENA HAZARDS	
	REVIEW FOR COMPLIANCE WITH 10 CFR 70.61	3-AD-1
4	RADIATION PROTECTION.....	4-1
4.1	PURPOSE OF REVIEW	4-1
4.2	RESPONSIBILITY FOR REVIEW	4-1
4.3	AREAS OF REVIEW	4-1
4.4	ACCEPTANCE CRITERIA	4-3
4.4.1	Commitment to Radiation Protection Program Implementation	4-3
4.4.2	Commitment to an ALARA Program	4-3
4.4.3	Organization and Personnel Qualifications	4-5
4.4.4	Commitment to Written Procedures	4-6
4.4.5	Radiation Safety Training.....	4-6
4.4.6	Ventilation and Respiratory Protection Programs	4-8
4.4.7	Radiation Surveys and Monitoring Programs.....	4-9
4.4.8	Control of Radiological Risk Resulting from Accidents	4-13
4.4.9	Additional Program Commitments	4-15
4.5	REVIEW PROCEDURES	4-16
4.5.1	Acceptance Review.....	4-16
4.5.2	Safety Evaluation	4-16
4.6	EVALUATION FINDINGS.....	4-16
4.7	REFERENCES	4-17
	APPENDIX A TO CHAPTER 4: CONSIDERATION FOR RADIOLOGICAL RISK IN	
	ACCIDENT SEQUENCES	4-A-1
5	NUCLEAR CRITICALITY SAFETY.....	5-1
5.1	PURPOSE OF REVIEW	5-1
5.2	RESPONSIBILITY FOR REVIEW	5-1
5.3	AREAS OF REVIEW	5-1
5.3.1	License Application	5-1
5.3.2	Nuclear Criticality Safety Program	5-2

5.3.3	Safety Program	5-3
5.4	ACCEPTANCE CRITERIA	5-4
5.4.1	Regulatory Requirements	5-4
5.4.2	Regulatory Guidance	5-5
5.4.3	Regulatory Acceptance Criteria	5-5
5.5	REVIEW PROCEDURES	5-21
5.5.1	Acceptance Review.....	5-21
5.5.2	Safety Evaluation	5-21
5.6	EVALUATION FINDINGS.....	5-23
5.7	REFERENCES	5-23
6	CHEMICAL PROCESS SAFETY	6-1
6.1	PURPOSE OF REVIEW	6-1
6.2	RESPONSIBILITY FOR REVIEW	6-1
6.3	AREAS OF REVIEW	6-2
6.4	ACCEPTANCE CRITERIA	6-3
6.4.1	Regulatory Requirements	6-3
6.4.2	Regulatory Guidance	6-4
6.4.3	Regulatory Acceptance Criteria	6-4
6.5	REVIEW PROCEDURES	6-7
6.5.1	Acceptance Review	6-7
6.5.2	Safety Evaluation.....	6-8
6.6	EVALUATION FINDINGS.....	6-9
6.7	REFERENCES	6-10
7	FIRE SAFETY	7-1
7.1	PURPOSE OF REVIEW	7-1
7.2	RESPONSIBILITY FOR REVIEW	7-1
7.3	AREAS OF REVIEW	7-1
7.4	ACCEPTANCE CRITERIA	7-2
7.4.1	Regulatory Requirements	7-2
7.4.2	Regulatory Guidance	7-3
7.4.3	Regulatory Acceptance Criteria	7-3
7.5	REVIEW PROCEDURES	7-9
7.5.1	Acceptance Review.....	7-9
7.5.2	Safety Evaluation	7-9
7.6	EVALUATION FINDINGS.....	7-10
7.7	REFERENCES	7-11
8	EMERGENCY MANAGEMENT	8-1
8.1	PURPOSE OF REVIEW	8-1
8.2	RESPONSIBILITY FOR REVIEW	8-1
8.3	AREAS OF REVIEW	8-1
8.3.1	Emergency Plan	8-2
8.3.2	Evaluation That No Emergency Plan is Required.....	8-2
8.4	ACCEPTANCE CRITERIA	8-3
8.4.1	Regulatory Requirements	8-3
8.4.2	Regulatory Guidance	8-3
8.4.3	Regulatory Acceptance Criteria	8-4
8.4.3.1	Emergency Plan.....	8-4
8.4.3.2	Evaluation That No Emergency Plan Is Required.....	8-12
8.5	AMENDMENTS OR CHANGES TO THE EMERGENCY PLAN	8-14

8.6	REVIEW PROCEDURES	8-14
8.7	EVALUATION FINDINGS.....	8-15
8.8	REFERENCES.....	8-16
9	ENVIRONMENTAL PROTECTION	9-1
9.1	PURPOSE OF REVIEW	9-1
9.2	RESPONSIBILITY FOR REVIEW	9-1
9.3	AREAS OF REVIEW	9-1
9.4	ACCEPTANCE CRITERIA	9-4
9.4.1	Regulatory Requirements	9-4
9.4.2	Regulatory Guidance	9-5
9.4.3	Regulatory Acceptance Criteria	9-6
9.5	REVIEW PROCEDURES	9-14
9.6	EVALUATION FINDINGS.....	9-15
9.7	REFERENCES.....	9-17
10	DECOMMISSIONING.....	10-1
10.1	PURPOSE OF REVIEW	10-1
10.2	RESPONSIBILITY FOR REVIEW.....	10-2
10.3	AREAS OF REVIEW.....	10-2
10.4	ACCEPTANCE CRITERIA.....	10-3
10.4.1	Regulatory Requirements.....	10-3
10.4.2	Regulatory Guidance.....	10-3
10.5	REVIEW PROCEDURES	10-3
10.6	EVALUATION FINDINGS	10-4
10.7	REFERENCES	10-5
11	MANAGEMENT MEASURES	11-1
11.1	PURPOSE OF REVIEW	11-1
11.2	RESPONSIBILITY FOR REVIEW.....	11-1
11.3	AREAS OF REVIEW.....	11-1
11.4	ACCEPTANCE CRITERIA.....	11-5
11.4.1	Regulatory Requirements.....	11-5
11.4.2	Regulatory Guidance.....	11-6
11.4.3	Regulatory Acceptance Criteria.....	11-6
11.5	REVIEW PROCEDURES	11-19
11.6	EVALUATION FINDINGS	11-23
11.7	REFERENCES	11-28
	APPENDIX A CHECKLIST FOR PROCEDURES	11-A-1
	APPENDIX B INCIDENT INVESTIGATION PROGRAMS AND PROCEDURES	11-B-1
	APPENDIX C RECORDS	11-C-1

EXECUTIVE SUMMARY

This “Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility” (NUREG-1520) 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 also applies to the review and evaluation of proposed amendments and license renewal applications for nuclear fuel cycle facilities.

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 Title 10, Parts 20 and 70, of the *Code of Federal Regulations* (10 CFR Part 70 and 10 CFR Part 20), as well as the newer accident safety requirements reflected in the new Subpart H of 10 CFR Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are primarily set by regulations that remain unaffected by the recent revision to 10 CFR Part 70. Review criteria applicable to the safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1065 which are standard format and content guides for Fundamental Nuclear Material Control Plans for high enriched uranium facilities and low enriched uranium facilities, respectively.

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 (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.

Each nuclear fuel cycle facility license application should contain a safety program description that addresses all of the topics listed in the table of contents of this SRP, in the same order in which they are presented in this document. In general terms, the requirements in 10 CFR Part 70 specify the information that an applicant must supply in its safety program description. This SRP compliments 10 CFR Part 70 by identifying the specific information to be submitted by an applicant and evaluated by the staff.

The major topics addressed within the safety program description of a facility license application are discussed in separate chapters of this SRP, including general information, organization and administration, integrated safety analysis, radiation safety, nuclear criticality safety, chemical process safety, fire safety, emergency management, environmental protection, decommissioning, and management measures. Each of these chapters contains seven sections including (1) purpose of review, (2) responsibility for review, (3) areas of review, (4) acceptance criteria, (5) review procedures, (6) evaluation findings, and (7) references. Prospective applicants should study the topic areas treated in the chapters of this SRP, paying particular attention to the sections entitled “Areas of Review” and “Acceptance Criteria.” In

addition, in accordance with 10 CFR 70.62 and 70.65, applicants are required to submit an ISA Summary in conjunction with the application.

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 to the license. If the staff determines that an application contains inadequate information 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 do not represent the only means of satisfying those objectives. Rather 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 demonstrate 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.

ACRONYMS AND ABBREVIATIONS

AEC	active engineered control
AEGL	acute exposure guideline level
ALARA	as low as is reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BDC	baseline design criteria
CAAS	criticality accident alarm system
CFR	<u>Code of Federal Regulations</u>
CM	configuration management
DFP	decommissioning funding plan
DP	decommissioning plan
EA	environmental assessment
EAL	emergency action level
EIS	environmental impact statement
ERPG	Emergency Response Planning Guidelines
FHA	fire hazards analysis
FM	facility maintenance
FONSI	finding of no significant impact
HEPA	high efficiency particulate
HS&E	health, safety, and environment
ICRP	International Commission on Radiological Protection
IROFS	item(s) relied on for safety
ISA	integrated safety analysis

ISO	International Organization for Standardization
LIB	Licensing and International Safeguards Branch
MDC	minimum detectable concentration
MOU	memorandum of understanding
NCS	nuclear criticality safety
NCRP	National Council on Radiation Protection and Measurements
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NMSS	Nuclear Material Safety and Safeguards, Office of (NRC)
NRC	U.S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
PEC	passive engineered control
PEL	permissible exposure limit
PHA	process hazard analysis
P&ID	piping and instrumentation diagram
PM	preventive maintenance
QA	quality assurance
QC	quality control
RAI	request for additional information
RWP	radiation work permits
SECY	Office of the Secretary of the Commission (NRC)
SER	safety evaluation report
SNM	special nuclear material

SRP	standard review plan
TEDE	total effective dose equivalent
TWA	time-weighted average
UA	Underwriters Laboratories

GLOSSARY

This glossary defines technical/industry terms that are used consistently throughout this SRP, or references the related definitions in either 10 CFR 20.1003 or 10 CFR 70.4. This glossary does not define terms that may have different connotations in different contexts; such terms are defined in the various chapters of this SRP.

Active engineered control (AEC)	A physical device that uses active sensors, electrical components, or moving parts to maintain safe process conditions without any required human action.
Accident sequence	An unintended sequence of events that, given the failure of certain IROFS identified in the sequence, would result in environmental contamination, radiation exposure, release of radioactive material, inadvertent nuclear criticality, or exposure to hazardous chemicals (provided that the chemicals are produced from licensed radioactive material). The term “accident” may be used interchangeably with “accident sequence.”
Acute	This term is defined in 10 CFR 70.4.
Administrative control	Either an augmented administrative control or a simple administrative control, as defined herein.
Augmented administrative control	A procedurally required or prohibited human action, combined with a physical device that alerts the operator that the action is needed to maintain safe process conditions, or otherwise adds substantial assurance of the required human performance.
Available and reliable to perform their function when needed	This term is defined in 10 CFR 70.4.
Baseline design criteria	A set of criteria specifying design features and management measures that are required and acceptable under certain conditions for new processes or facilities specified in 10 CFR 70.64. In general, these criteria are the acceptance criteria that apply to safety design for new facilities and new processes, as described in the chapters of this SRP.
Configuration management (CM)	This term is defined in 10 CFR 70.4.
Controlled area	This term is defined in 10 CFR 20.1003.

Controlled parameter	A measurable parameter that is maintained within a specified range by one or more specific controls to ensure the safety of an operation.
Consequence	Any result of interest caused by an event or sequence of events. In this context, “adverse consequence” refers to adverse health or safety effects on either workers, the public, or the environment.
Critical mass of special nuclear material (SNM)	This term is defined in 10 CFR 70.4.
Double contingency protection	A characteristic or attribute of a process that has incorporated sufficient safety factors so that at least two unlikely, independent, and concurrent changes in process conditions are required before a nuclear criticality accident is possible.
Engineered control	See active engineered control or a passive engineered control.
External event	An event for which the likelihood cannot be altered by changes to the regulated facility or its operation. This would include all natural phenomena events, plus airplane crashes, explosions, toxic releases, fires, etc., occurring near or on the plant site.
Hazardous chemicals produced from licensed materials	This term is defined in 10 CFR 70.4.
Integrated safety analysis (ISA)	This term is defined in 10 CFR 70.4.
Integrated safety analysis summary	This term is defined in 10 CFR 70.4.
Items relied on for safety (IROFS)	This item is defined in 10 CFR 70.4. All safety controls, as defined in this SRP, are IROFS.
Management measures	This term is defined in 10 CFR 70.4.
Mitigative control	A control intended to reduce the consequences of an accident sequence, not to prevent it. When a mitigative control works as intended, the results of the sequence are called the mitigated consequences.

Natural phenomena event	Earthquakes, floods, tornadoes, tsunamis, hurricanes, and other events that occur in the natural environment and could adversely affect safety. Natural phenomena events may be credible or incredible, depending on their likelihood of occurrence.
New processes at existing facilities	Systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. Generally, this definition does not include component-level design changes or equipment replacement.
Passive engineered control	A device that uses only fixed physical design features to maintain safe process conditions without any required human action.
Preventive control	A control intended to prevent an accident (i.e., any of the radiological or chemical consequences described in 10 CFR 70.61).
Safety control	A system, device, or procedure that is intended to regulate a device, process, or human activity to maintain a safe state. Controls may be engineered controls or administrative (procedural) controls, and may be either preventive or mitigative, as defined herein.
Safe process conditions	The defined ranges or sets of acceptable values of one or more controlled parameters.
Simple administrative control	A procedural human action that is prohibited or required to maintain safe process conditions.
Unacceptable performance deficiencies	This term is defined in 10 CFR 70.4.
Worker	This term is defined in 10 CFR 70.

INTRODUCTION

This “Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility” (NUREG-1520) 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 also applies to the review and evaluation of proposed amendments and license renewal applications for nuclear fuel cycle facilities.

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 Title 10, Parts 20 and 70, of the *Code of Federal Regulations* (10 CFR Part 70 and 10 CFR Part 20), as well as the newer accident safety requirements reflected in the new Subpart H of 10 CFR Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are primarily set by regulations that remain unaffected by the recent revision to 10 CFR Part 70. Review criteria applicable to the safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1065 which are standard format and content guides for Fundamental Nuclear Material Control Plans for high enriched uranium facilities and low enriched uranium facilities, respectively.

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 11 (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.

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.

For licensing a facility under 10 CFR Part 70, technical information on the proposed equipment and facility must be provided in the application in accordance with 10 CFR 70.22(a)(7), which states that each application shall contain:

“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 10 CFR Part 70 licensing, the staff uses a reasonable assurance standard and focuses on the programmatic provisions of the applicant’s proposed activities. This is reflected in the above licensing requirements that talk about, “sufficient detail to understand the theory of operation,” or a list “briefly describing each item relied on for safety ... in sufficient detail to understand their functions in relation to the performance requirements.” Based on this understanding, the licensing review should focus on the applicant’s programmatic commitments and, consequently, the licensing decision is ultimately based on a sufficient level of detail to understand process system functions and functionally how items relied on for safety can perform their intended function and be reliable. The reasonable assurance standard is applied such that the staff decision pertains to a reasonable assurance that the integrated safety analysis summary is complete and the licensee will follow its integrated safety analysis approach and maintain it consistent with the regulations. The level of detail required for a licensing decision, therefore, does not require a final facility design or an absolutely complete identification of all items relied on for safety and accident sequences, but instead sufficient information has to be provided to understand the process and functions of items relied on for safety and reasonable assurance that the integrated safety analysis 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, the regulations in 10 CFR 40.41(g) and 10 CFR 70.32(k) state that:

“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 prior to operation to verify that the new part of the facility has been constructed in

accordance with the requirements of the license. In order to facilitate the planning and accomplishment of a risk-informed ORR, the staff relies upon the licensee to provide a complete set of information concerning items relied upon for safety (IROFS). This information is referred to as IROFS boundary definition packages.²

In the development of the performance requirements in 10 CFR Part 70, it was anticipated that, in the future, changes will be made to the facility design and processes and, therefore, a process for addressing these changes is described in 10 CFR 70.72. 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. 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. The safety program must be described 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, 10 CFR 70.23, and Subpart H to 10 CFR Part 70 specify, in general terms, the information to be supplied in a safety program description. This SRP supersedes and replaces draft Regulatory Guide 3.52, "Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication." As such, this SRP identifies the specific information to be submitted by an applicant and evaluated by the staff. Prospective applicants should study the topic areas treated in the chapters of this SRP and the sections within each chapter (specifically, the sections headed "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

² IROFS boundary definition packages are documents that contain the physical descriptions and parameters of structures, systems, components which are used to meet the performance requirements of 10 CFR 70.61. IROFS boundary definition packages are also prepared for administrative procedures or worker actions which 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 (i.e., P&IDs, schematics, etc.).

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

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

Open items which affect reliability and/or effectiveness 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.

this SRP in the same order as presented in this document. Material submitted in one location in a license application may be referenced at another location to avoid unnecessary duplication.

In accordance with 10 CFR 70.62 and 70.65, applicants are also required to submit an ISA Summary in conjunction with the application. However, the ISA Summary will not be incorporated in the license or license amendment issued by the NRC. In addition, 10 CFR 70.61 requires each applicant to evaluate, in an integrated safety analysis performed in accordance with 10 CFR 70.62, 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 an integrated safety analysis summary that is required to be submitted with the application. The requirements in 10 CFR 70.65(b)(3) require that the integrated safety analysis contain:

“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 integrated safety analysis contain:

“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 integrated safety analysis summary provided as required under 10 CFR 70.65, licensing decisions are made as required under 10 CFR 70.21, 70.22, 70.23, and 70.60 through 70.66. 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 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 review (1) purpose, (2) responsibility, (3) areas, (4) acceptance criteria, (5) procedure, (6) 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. The overall application review is performed by this team of specialist reviewers. 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, i.e., "Acceptance Criteria" and "Review Procedures", which 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.

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, they are not considered the only acceptable positions or approaches, and others may be proposed by an applicant.

The requirements for approval of an application are provided in 10 CFR 70.23(a). These requirements state that an application will be approved upon a 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, it is for NMSS to 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. Suggestions and recommendations in the standards (so called "should" statements) will not be considered by the staff as binding commitments by the applicant, unless the applicant specifically states an intent to treat the "should" statements as binding commitments (i.e., treat as if they are "shall" statements). The applicant may make such commitments as part of the 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 Nuclear Society Standard 8.1, which relates to nuclear criticality safety, 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 to not 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 small risk. The key element in the staff's evaluation is the applicant's adequate demonstration of acceptable control of risk, which then supports a competent and informed review by the NRC staff.

Review Procedures

This section describes how the staff will perform the review. It generally 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 could include identifying which licensee commitments the reviewer needs to verify, and could include directing the reviewer to coordinate with others having review responsibilities for other portions of the application than those 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.

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 will be included in the staff's SER, in which the staff publishes the results of its review. The SER will also contain a description of the review, including aspects that received special emphasis, matters that the applicant modified during the review, matters that require additional information or will be resolved in the future, aspects where the facility'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 may recommend in the SER, license conditions to address any issues that were not previously resolved by an applicant's commitments. Such conditions are discussed with an applicant before issuing the license (or license amendment) and become commitments to performance in addition to those commitments that the applicant presented in the application.

References

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

Appendix A to this SRP provides additional guidance on filing standards for applications.