FINAL

Interim Staff Guidance Augmenting

NUREG-1537, Part 2,

"Guidelines for Preparing and

Reviewing Applications for the

Licensing of Non-Power Reactors:

Standard Review Plan and Acceptance Criteria,"

for Licensing Radioisotope Production Facilities and

Aqueous Homogeneous Reactors

October 17, 2012

INTRODUCTION TO THE INTERIM STAFF GUIDANCE

Purpose

This interim staff guidance (ISG) augments the following:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," Revision 0, February 1996

- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," Revision 0, February 1996

This ISG updates and expands the content of both NUREG-1537 Part 1 and Part 2 , respectively, to provide guidance in preparing a license application and for the U.S. Nuclear Regulatory Commission (NRC) staff in evaluating the application and issuing a license for any of the following:

- A heterogeneous or an aqueous homogeneous (AHR) non-power reactor as a utilization facility pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

- A production facility for the separation of byproduct material from special nuclear material (SNM) pursuant to 10 CFR Part 50. The production facilities addressed in this ISG are facilities that will separate isotopes from the following sources:

  - targets irradiated in a non-power reactor

  - the core of an AHR

  - the content of a subcritical multiplier solution tank or reaction vessel containing SNM and fission products resulting from incident accelerator-generated neutrons

Overview of Medical Isotope Production

For the past two decades, the U.S. has relied on imported medical radioisotopes to perform approximately 40,000 medical procedures daily. Simultaneously, U.S. policy has been to reduce the use of highly enriched uranium (HEU). The Energy Policy Act of 2005 called for the National Research Council to study ways to ensure a reliable supply of medical isotopes and, furthermore, to do so without the use of HEU. Global shortages of medical isotopes during 2009 and 2010 have underscored the need for prompt action to ensure a reliable domestic supply. The U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA) has subsequently entered into agreements with domestic commercial firms to encourage the expeditious construction of medical isotope production facilities, which will require NRC operating licenses. Potential license applicants have filed letters of intent or otherwise expressed their intent to obtain NRC licenses to operate such facilities. While licensing regulations are in place that can be applied to all technologies proposed to date, the NRC has not developed and published guidance on application content and a standard review plan that addresses each of these technologies. The ISG presented in this document augments existing guidance to define a means to license medical isotope production facilities in a manner

that ensures adequate protection of public health and safety, promotes the common defense and security and protects the environment.

While many isotopes are commonly used as radiopharmaceuticals today, the isotope currently in highest demand is molybdenum-99 (Mo-99). Mo-99 decays with a 66-hour half-life to technetium-99m (Tc-99m), which in turn decays with a 6-hour half-life to Tc-99. Common practice is to produce bulk Mo-99 and ship it to a manufacturer of generators, which are sent to hospitals, medical centers, or radiopharmacies. The generator manufacturer loads the Mo-99 onto a chromatographic-separation or ion-exchange column where it decays to Tc-99m which is periodically washed (i.e., eluted) from the column with isotonic saline solution, leaving the Mo-99 in place for subsequent decay and production of additional Tc-99m. This ISG applies only to the bulk production of isotopes and not to the manufacture of devices to dispense radiopharmaceuticals such as generators.

Two techniques commonly used for the production of Mo-99 are neutron activation of natural molybdenum, which is 24 percent Mo-98, and the fissioning of uranium-235 (U-235), which has a fission yield of 6 percent Mo-99. Fission-product Mo-99 has become the most common method of production because it has very high specific activity. Mo-99 is produced using the fission process when neutrons fission U-235 in a target placed in a reactor, in the fuel solution of an AHR, or in a solution tank containing U-235 used as a subcritical multiplier of neutrons produced by accelerator interactions. Other techniques of producing Mo-99 have been studied (e.g., the removal of a neutron from enriched stable Mo-100 accelerator targets) but have not been used for its bulk production.

A history and analysis of medical isotope research and development and descriptions of the development of an international isotope production industry and the U.S. role appear in the report by the Nuclear and Radiation Studies Board of the National Research Council, *Medical Isotope Production Without Highly-Enriched Uranium*, issued by the National Academies Press in 2009. Among its findings, the report characterizes Mo-99 production before 2009 as follows:

Reactor	Country	Date of Initial Criticality	Supply of U.S. Demand	Supply of World Demand
National Research Universal	Canada	1957	60%	40%
High-Flux Reactor	Netherlands	1961	40%	25%
Belgian Reactor 2	Belgium	1961	0	20%
Others	na	na	0	15%

The following findings of the report and subsequent events characterize the environment in which potential applicants have expressed interest in NRC licenses to construct and operate domestic radioisotope production facilities:

- Serious shortages of medical isotopes were experienced domestically and internationally during 2009 and 2010.

- The National Research Universal Reactor (NRU) experienced an unscheduled 15-month (May 2009 to August 2010) outage to repair a coolant leak.

- The High-Flux Reactor simultaneously required a scheduled 3-month (February 2010 to September 2010) piping repair outage. This event occurred simultaneously with the NRU reactor outage.

- The majority of the world isotope supply comes from reactors 50 years old or older.

- Only a small fraction of medical isotopes are produced from low-enriched uranium (LEU) (Australia and South Africa).

- 100 percent of the U.S. isotope demand comes from two sources; 85 percent of the world isotope demand comes from three sources.

- The April 2010 volcano in Iceland disrupted air transport in Europe, interfering with medical isotope distribution.

It should be noted that while the above characterized the 2009 environment in which this ISG was envisioned and initiated, the environment has evolved rapidly since then with new producers entering the market and with advances in non-HEU production of radioisotopes.

Characterization of Potential Applications and Licensing Requirements

The NRC staff has researched various isotope production technologies and facilities that it may be asked to license. Technical information has come from letters of intent, verbal and written inquiries regarding the licensing process, cooperative agreements announced by NNSA, and technical presentations at professional society meetings. Five technologies under consideration are identified below along with an outline of the licensing requirements for each:

(1) Production of Mo-99 by accelerator interaction with enriched Mo-100 targets.

  – This requires a byproduct materials license issued by an Agreement State or, if the facility is located in a Non-Agreement State, by the NRC under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." No additional NRC staff guidance to NUREG-1537 is needed in this situation.

(2) Production of Mo-99 by the activation of natural Mo in existing non-power and power reactors.

  – Most non-power reactors are licensed to perform experiments which may include the activation of targets. This constitutes normal utilization of the reactor. If the proposed utilization cannot be authorized under 10 CFR 50.59, "Changes, Tests and Experiments," or is outside the scope of the technical specifications (TS) for approved experiments, a routine license amendment will be required.

  – Power reactor licenses generally do not allow the intentional activation of targets and the insertion and removal of targets from the core. Therefore, a routine

amendment will be required for a power reactor. No additional NRC staff guidance to NUREG-1537 is needed to clarify the licensing path in this situation.

(3) Production of Mo-99 by fissioning special nuclear material (SNM) in LEU targets in existing or newly constructed non-power reactors. Mo-99 is then separated from the irradiated targets. These irradiations are governed by the facility license and TS.

- Heterogeneous reactors are addressed by the existing standard review plan for non-power reactors (NUREG-1537) and fueled experiments can be licensed based on that document with minimal additional guidance as discussed later in this introduction.

- The facility where the isotope separation process occurs may be considered a production facility subject to licensing under 10 CFR Part 50. NRC staff guidance for licensing a production facility is discussed later in this introduction.

(4) Construction and operation of an LEU-fueled AHR and a facility to separate the fission product Mo-99 from the liquid core after a short period of operation.

- The existing standard review plan for non-power reactors (NUREG-1537) does not specifically address homogeneous fuels. NRC staff guidance for licensing an AHR is discussed later in this introduction.

- The facility where the isotope separation process occurs may be considered a production facility subject to licensing under 10 CFR Part 50. NRC staff guidance for licensing a production facility is discussed later in this introduction.

(5) Construction of a reaction vessel containing a subcritical solution of LEU for the multiplication of accelerator-generated neutrons by fission of the uranium and a facility to separate the fission product Mo-99 from the solution after a short period of operation.

- The subcritical multiplier reaction vessel containing SNM by definition is not a nuclear reactor because it cannot sustain a chain reaction. It may be included in a 10 CFR Part 50 production facility license as an assembly containing SNM that is authorized for use in conjunction with the production facility. A safety analysis report (SAR) accompanying the application must evaluate the performance of the reaction vessel relative to many of the same phenomena identified as licensing concerns for an AHR.

- The facility where the radioisotope separation process occurs may be considered a production facility and, if so, may be subject to licensing under 10 CFR Part 50. NRC staff guidance for licensing a production facility is discussed later in this introduction.

This ISG was prepared for evolving technologies that were not fully developed and demonstrated at the time of publication. This is especially true for the accelerator-driven solution tank and to some degree new generation AHRs. Where technology in this ISG does not properly characterize new technology, applicants should introduce appropriate substitute terminology and provide definitions.

Licensing of 10 CFR Part 50 Utilization Facilities

NUREG-1537 presents guidance for the licensing of non-power reactors. While AHRs had been licensed and operated in the U.S. before 1996, no AHRs were in operation and none were anticipated to be built in the foreseeable future when NUREG-1537 was written. As a result, NUREG-1537, Part 1, Chapter 4, "Reactor Description," Section 4.2.1, states; "Most non-power reactors contain heterogeneous fuel elements consisting of rods, plates, or pins, which are addressed in the following sections. Homogeneous fuels should be described and analyzed in a comparable way." In anticipation of an AHR application for the production of medical isotopes, the NRC staff has prepared this ISG to augument NUREG-1537, where appropriate.

The content of NUREG-1537 Chapter 4, "Reactor Description," Chapter 5, "Reactor Coolant Systems," Chapter 6 "Engineered Safety Features," Chapter 7, "Reactor Instrumentation," Chapter 12, "Conduct of Operations," Chapter 13, "Accident Analyses," and Chapter 14, "Technical Specifications," have been supplemented significantly. This ISG contains guidance for all other chapters indicating how the remainder of NUREG-1537 as published can be effectively applied to an AHR application for a 10 CFR Part 50 utilization and radioisotope production facility license.

This ISG also provides guidance on applications for a new heterogeneous non-power reactor license. In this case, NUREG-1537 remains generally applicable, but changes in regulations (e.g., 10 CFR 50.33(k)(1) and 10 CFR 50.75 related to decommissioning requirements) and updated reference documents are addressed.

Licensing of 10 CFR Part 50 Production Facilities

Facilities separating radioisotopes from irradiated SNM will be licensed as production facilities under 10 CFR Part 50 unless an exemption is applied for and granted, or the facility meets one of the subpart (3) exceptions to the definition for *Production facility* found in 10 CFR 50.2.

A facility meeting any of these exceptions is by definition not a production facility and is therefore not subject to the 10 CFR Part 50 production facility requirements; rather, it would be considered an SNM fuel cycle facility subject to the requirements of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, issued May 2010, presents the standard review plan for a 10 CFR Part 70 facility.

The NRC staff has not previously developed guidance in the form of a standard review plan for a 10 CFR Part 50 production facility, therefore this ISG will provide such guidance. This ISG follows the structure of that prepared for a 10 CFR Part 50 utilization facility, which is contained in NUREG-1537. Certain topics such as site characterization and conduct of operations were found relevant to both production facilities and utilization facilities and are incorporated by reference. Other topics such as facility description and accident analysis were found to be significantly different; for these topics, the NRC staff engaged personnel with expertise in fuel cycle facilities and drew extensively from their expertise and the standard review plan in NUREG-1520.

Production facilities that employ the reaction vessel subcritical neutron multiplier method for producing radioisotopes present a special licensing situation. The isotope separation facility must be licensed as a production facility (unless it falls under one of the exceptions listed in subpart (3) of the definition of a Production facility found in 10 CFR 50.2). Meanwhile, the

reaction vessel is not, by definition, a reactor because the fission process occurring within the vessel is not self-sustaining. The SNM in the solution tank may therefore be licensed as material possessed by the licensee used in conjunction with the operation of the production facility.

While the reaction vessel is not a nuclear reactor, its safety analysis must consider phenomena analogous to those of an AHR. The reaction vessel can achieve relatively high power levels from the fission process. The production of reasonable and practical quantities of radioisotopes on a commercial scale may require operating power levels on the order of 50 to 75 kilowatts. While the assembly is maintained subcritical, it will have to be operated very much like an AHR with controls for managing temperature and pressure of the fuel solution, maintaining radiolytic gases at safe levels, and containing fission products, some of which are volatile, in the solution. It will have to have the same protective structures, systems, and components that are required for an AHR. Many of the hazards and concerns associated with AHRs that are addressed in this ISG will also apply to the reaction vessel subcritical neutron multiplier. Applicants for licensing this type of facility should therefore follow the guidance in this ISG, as appropriate, for developing a safety analysis for both the reaction vessel containing the fission process and the associated radioisotope separation and purification processes involved in the radioisotope production process.

This ISG provides guidance to the NRC staff reviewers who perform safety reviews of applications to construct or modify and operate medical isotope production facilities. The standard review plan (SRP) is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the NRC staff has found acceptable for meeting NRC requirements. The ISG also makes information available to interested members of the public and the regulated industry and is intended to provide an understanding of the NRC staff review process.

This ISG is not a substitute for NRC regulations and compliance with the ISG is not required. The approaches and methods in this ISG are provided as an acceptable means to meet the NRC regulations. Methods different from those described in this final ISG should provide a basis for the staff to make a determination that an applicant is able to meet NRC regulations.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in this ISG, the term “performance requirements”, when referencing 10 CFR Part 70, subpart H, is not intended to mean that the performance requirements of subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.

Expansion of Guidance on the Environmental Review

NUREG-1537 originally contained guidance for environmental reports in Section 12.12 of Chapter 12, “Conduct of Operations.” That topic has received increased attention over the past decades such that guidance has grown to warrant a chapter of its own. Therefore,

Section 12.12 has been vacated and a new chapter designated as Chapter 19, “Environmental Review” has been created.

Presentation of Interim Staff Guidance

Considering the preceding factors, the NRC is publishing the following documents as the ISG augmenting the 1996 version of NUREG-1537 to better inform the licensing of a heterogeneous reactor or an AHR as a utilization facility and the licensing of a radioisotope production facility for the separation of byproduct materials from the fission products of irradiated SNM pursuant to 10 CFR Part 50:

- “FINAL Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012”

- “FINAL Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012”

Contents

ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AHR	aqueous homogeneous reactor
ALARA	as low as reasonably achievable
ANSI/ANS	American National Standards Institute/American Nuclear Society
APE	area of potential effect
ASTM	American Society for Testing and Materials
BGEPA	Bald and Golden Eagle Protection Act
BLM	U.S. Bureau of Land Management
BR-2	Belgian Reactor-2
CAAS	criticality accident alarm system
CEQ	Council on Environmental Quality
CFR	*Code of Federal Regulations*
DBA	design-basis accident
DBC	design-basis criteria
DOE	U.S. Department of Energy
DP	decommissioning plan
DWMEP	Division of Waste Management and Environmental Protection
EA	environmental assessment
ECCS	emergency core cooling system
EFH	essential fish habitat
EIS	environmental impact statement
EPA	U.S. Environmental Protection Agency
ER	environmental report
ESF	engineered safety feature
FP	fission product
FM	Factory Mutual
FNMC	fundamental nuclear material control
FONSI	finding of no significant impact
FSME	Office of Federal and State Materials and Environmental Management Programs
HEU	highly enriched uranium
HFR	High-Flux Reactor
HVAC	heating, ventilation, and air conditioning
IAEA	International Atomic Energy Agency
IROFS	item(s) relied on for safety
ISA	integrated safety analysis
ISG	interim staff guidance
kW	kilowatt(s)
LCO	limiting condition for operation
LEU	low-enriched uranium
LOCA	loss-of-coolant accident
LSSS	limited safety system setting
MBTA	Migratory Bird Treaty Act

MHA	maximum hypothetical accident
MIPS	medical isotope production system
MMPA	Marine Mammal Protection Act
Mo	molybdenum
MPC	maximum permissible concentration
NCS	nuclear criticality safety
NEPA	National Environmental Policy Act of 1969
NFPA	National Fire Protection Association
NMFS	National Marine Fisheries Service
NNSA	National Nuclear Security Administration
NOAA	National Oceanic and Atmospheric Administration
NRC	U.S. Nuclear Regulatory Commission
NRCS	Natural Resources Conservation Service, U.S. Department of Agriculture
NRHP	National Register of Historic Places
NRU	National Research Universal
PSAR	preliminary safety analysis report
OSHA	Occupational Safety and Health Administration
RAM	remote area monitors
RG	regulatory guide
SAR	safety analysis report
SGI	Safeguards Information
SHPO	State Historic Preservation Office
SL	safety limits
SNM	special nuclear material
SR	surveillance requirement
Tc	technetium
TEDE	total effective dose equivalent
THPO	Tribal Historic Preservation Office
TS	technical specification(s)
U-235	uranium-235

Editorial Note on the Presentation of the Interim Staff Guidance:

This document presents Interim Staff Guidance (ISG) which augments the document NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," Revision 0, February 1996; all references to NUREG-1537 throughout this document refer to the stated 1996 edition. The ISG is presented in an order and format that mimics the original document, adding or modifying statements in the original document.

Introduction [To NUREG-1537]

The "Abstract" and "Introduction" sections of the current NUREG-1537 present background and general information that is applicable to all non-power reactors that also applies to a radioisotope production facility that is licensed under 10 CFR Part 50. Applicants preparing SARs for radioisotope production facilities can use the information in these sections of the NUREG with the understanding that where the term "reactor" appears it can be interpreted to mean "reactor and radioisotope production facility," as appropriate. When preparing a SAR, applicants for a production facility license should use the NUREG as it is augmented by this ISG.

1 THE FACILITY

NUREG-1537, Part 2, Chapter 1 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the facility for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

1.1 Introduction

This section should provide an overview of the facility being licensed.

1.2 Summary and Conclusions on Principal Safety Considerations

Areas of Review

The areas of review should include the following information about the radioisotope production facility:

- Facility Description: a general description of the purpose of each feature and the interrelationships between features

- Process Overview: a general description of the different processes at the facility involving licensed material

Acceptance Criteria

The information listed below pertaining to the radioisotope production facility should be added to the acceptance criteria.

- The application presents information at a level of detail that is appropriate for general familiarization and understanding of the proposed radioisotope production facility. This information should be consistent with that presented in the ISA summaries and accident analyses in Chapter 13 of the SAR but may be less detailed.

- The overview describes the relationship of specific facility features to the major processes that will be ongoing at the facility.

- This description includes the building locations of major process components; drawings illustrating the layout of the buildings and structures within the controlled area boundary are used to support the description.

- The application has portions marked to identify any proprietary or sensitive information related to the facility, if applicable.

- The process overview is acceptable if it summarizes the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on information presented in the ISA summary. This description should include the building locations of major process components and brief accounts of the process steps.

Review Procedures

The reviewer should confirm that the applicant submitted all information requested in the format and content guide. The information presented in this section is informational in nature and does not require technical analysis. Furthermore, the reviewer should use the information in this section only as background for the more detailed descriptions in later sections of the application.

Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria are appropriately satisfied, the staff will conclude that this evaluation is complete. The reviewer will write material suitable for inclusion in the safety evaluation report prepared for the entire application. The report will include a statement summarizing what was reviewed and why the reviewer finds the submittal acceptable. Specific topics that should be included in the reviewer's comments are given in the current headings 1 through 9 of this section in NUREG-1537.

1.3–1.4

The standard review plan and acceptance criteria of these sections are applicable if, wherever the term "reactor" appears, it is understood to mean "non-power reactor" or "radioisotope production facility," or both, as applicable.

1.5 Comparison with Similar Facilities

Areas of Review

The current content of this section of NUREG-1537 is limited to citations of heterogeneous non-power reactors. In the case of applications for other types of reactors (e.g., AHR designs), other references should be included.

For AHR applications, the following bullets may be added for related facilities:

- LOPO (Low power aqueous homogeneous reactor) at LANL (Los Alamos National Laboratory)
- HYPO (High power, an upgrade of the Los Alamos LOPO) at LANL
- SUPO (an upgrade of the HYPO reactor) at LANL
- TRACY (Transient experiment criticality facility reactor) at JAERI (Japan Atomic Energy Research Institute)
- HRE (Homogeneous Reactor Experiment reactor) at ORNL (Oak Ridge National Laboratory)

Any information about similar radioisotope production facilities or operations should also be included here.

1.6–1.8

The standard review plan and acceptance criteria of these sections are applicable if, wherever the term “reactor” appears, it is understood to mean “non-power reactor” or “radioisotope production facility,” or both, as applicable.

2 SITE CHARACTERISTICS

NUREG-1537, Part 2, Chapter 2 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the site characteristics for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

2.6 Bibliography

American National Standards Institute/American Nuclear Society, ANSI/ANS 15.16-2008 "Emergency Planning for Research Reactors," ANS, La Grange Park, IL.

U. S. Nuclear Regulatory Commission, Regulatory Guide (RG) 1.145, Rev. 1, "Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants," February 1983.

3 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

NUREG-1537, Part 3, Chapter 3 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the design of structures, systems, and components for the licensing of a radioisotope production facility a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable.

3.1–3.4

The standard review plan and acceptance criteria of these sections are applicable if wherever the term "reactor" appears it may be interpreted to mean "non-power reactor" or "radioisotope production facility," or both, as applicable.

3.5 Systems and Components

The standard review plan and acceptance criteria of these sections are applicable if wherever the term "reactor" appears it is understood to mean "non-power reactor" or "radioisotope production facility," or both, as applicable. This section has been divided into two parts, one for the reactor and one for the production facility. The guidance in NUREG-1537 for *areas of review, acceptance criteria, review procedures,* and *evaluation findings* should be used for the review of these parts in both Section 3.5a, "Reactor Facility," and Section 3.5b, "Radioisotope Production Facility."

3.5a Reactor Facility

NUREG-1537, Part 1, Section 3.5, applies to the reactor facility.

3.5b Radioisotope Production Facility

The applicant should provide the same type of information prescribed in Section 3.5a on the design, construction, and operating characteristics of all safety-related systems and components in the radioisotope production facilities.

Baseline design criteria for facilities that process SNM, and hazardous chemicals that are coincident with or result from operations with SNM, are described in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." Although compliance with 10 CFR 70.64 is not specifically required for a radioisotopes production facility licensed under 10 CFR 50, a license application that adequately addresses the baseline design critieria listed in 10 CFR 70.64 would be found acceptable by staff. These criteria are similar to those enumerated either in this chapter regarding the general considerations in designing, constructing, and operating non-power reactor facilities, or in other chapters addressing safety systems in greater detail. In lieu of reiterating these criteria in this ISG, the applicant should be aware of them and apply them appropriately to the SAR, particularly Chapters 3 through 9.

3.6 Bibliography

American National Standards Institute/American Nuclear Society, ANSI/ANS 15.2-2009, "Quality Control for Plate-Type Uranium-Aluminum Fuel Elements," ANS La Grange Park, IL.

American National Standards Institute/American Nuclear Society, ANSI/ANS 15.8-2005, "Quality Assurance Program Requirements for Research Reactors," ANS, La Grange Park, IL.

4 REACTOR AND RADIOISOTOPE PRODCUTION FACILITY DESCRIPTION

NUREG-1537, Part 2, Chapter 4 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the reactor and radioisotope production facility for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 4a1, "Heterogeneous Reactor Description"
- 4a2, "Aqueous Homogeneous Reactor Description"
- 4b, "Radioisotope Production Facility Description"

The ISG for each of these options follows.

4a1 Heterogeneous Reactor Description

NUREG-1537, Part 2, Chapter 4, should be used for guidance in preparing this chapter.

4a2 Aqueous Homogeneous Reactor Description

NUREG-1537, Part 2, Chapter 4, should be replaced in its entirety with the guidance below.

In this chapter of the SAR, the applicant should discuss and describe the principal features, operating characteristics, and parameters of the reactor. The analysis in this chapter should support the conclusion that the reactor is conservatively designed for safe operation and shutdown under all credible operating conditions. Information in this chapter of the SAR should provide the bases for many systems, subsystems, and functions discussed elsewhere in the SAR and for many TS.

In following the instructions in this chapter for the AHR, it should be noted that the fuel solution performs the function of the fuel, moderator, and target. In the following sections, any direct reference to a moderator or target applies to designs that might use a solid moderator or target. It should also be noted that no fuel cladding is used in the AHR design, and consequently, the concept of fission product barrier performed by the cladding is no longer valid. The cladding's role is now performed by the reactor vessel and the boundaries of any penetrations (coolant coils, control rod channels, and fuel solution transfer pipes) in the reactor vessel. The primary fission product barrier in a production facility consists of vessels and associated piping that contains the irradiated SNM and fission products (in solid, liquid or gaseous form) during the separation process.

The glossary below contains terms often used when discussing an AHR.

Boiling: Vapor generation due to phase change that results when a fluid is brought to its saturation temperature.

Fission Product Barrier: That portion of the primary system boundary in contact with fission products only (principally, the gas management system boundary).

Fuel Barrier: That portion of the primary system boundary in contact with the fuel solution (principally the vessel, cooling coils, control rod thimbles, piping, and valves).

Neutron Moderator: In an AHR, moderators are materials in the core that consist of light elements (preferable with hydrogen atoms) . Moderators can be either liquid or solid form. Coolant in the cooling coils also contributes to the moderating capacity.

Primary Cooling Systems: Replaces the term “primary coolant system” for an AHR. The primary cooling systems for an AHR are those components and systems that remove heat from the core.

Primary System Boundary: Consists of all structures that prevent the release of fuel, fission gas, or other fission products. For an AHR, this includes the reactor vessel, waste handling tank, pumps, valves, and piping.

Radiolytic Gas Release: The chemical process that generates hydrogen, oxygen, and nitrogen oxides (NOx) from the fuel solution due to dissociation by irradiation.

Reactor Core: In an AHR, consists of that region of the vessel occupied by the solution containing the fission power producing fissile material. In an AHR, the core geometry may change with time due to changes in density and voiding of the solution. The core does not include that part of the fuel solution that may become entrained into the gas.

Reactor Fuel: In an AHR, refers to the dissolved fissionable material and fission products and the solvent they are dissolved in.

Recombiner: Device that recombines hydrogen and oxygen.

Vessel: For an AHR, the structure containing the core.

This chapter gives guidance for evaluating the description in the SAR of the reactor and how it functions as well as the design features for ensuring that the reactor can be safely operated and shut down from any operating condition or accident assumed in the safety analysis. Information in this chapter of the SAR should provide the design bases for many systems and functions discussed in other chapters of the SAR and for many technical specifications. The systems that should be discussed in this chapter of the SAR include the reactor core, reactor vessel, gas management system, and biological shield. The nuclear design of the reactor and the way systems work together are also addressed. In this chapter the applicant should explain how the design and proper operation of an AHR make accidents extremely unlikely. This chapter of the SAR along with the analysis in Chapter 13, “Accident Analyses” should demonstrate that even the consequences of the design-basis accident would not cause unacceptable risk to the health and safety of the public.

4a2.1 Summary Description

This section of the SAR should contain a general overview of the reactor design and important characteristics of operation. The reviewer need not make any specific review findings for this section. The detailed discussions, evaluations, and analyses should appear in the following sections of the SAR.

This section should contain a brief discussion of the way the facility design principles achieve the principal safety considerations. For the items requested, this section should include summaries of the format and content guide and descriptive text, summary tables, drawings, and schematic diagrams.

4a2.2 Reactor Core

This section of the SAR should contain the design information on all components of the reactor core. The information should be presented in diagrams, drawings, tables of specifications, and text and analysis sufficient to give a clear understanding of the core components and how they constitute a functional AHR that could be operated and shut down safely.

By reviewing this section, the reviewer gains an overview of the reactor core design and assurance that the SAR describes a complete operable AHR core. Subsequent sections should contain a description and analysis of the specifications, operating characteristics, and safety features of the reactor components. Although cooling systems should be discussed in Chapter 5, "Reactor Coolant Systems," of the SAR, relevant information should also be presented or referenced in this chapter. The information in the following sections should address these systems and components:

- reactor fuel, including the use of the reactor vessel as fuel and fission product barrier
- control rods
- solid neutron moderator (if any) and neutron reflector
- neutron startup source
- core support structures
- gas treatment system

The information in the SAR for each core component and system should include the following:

- design bases
- system or component description, including drawings, schematics, and specifications of principal components, including materials
- operational analyses and safety considerations
- instrumentation and control features not fully described in Chapter 7, "Instrumentation and Control Systems," of the SAR, as well as a reference to Chapter 7
- TS requirements and their bases, including testing and surveillance, or a reference to Chapter 14, "Technical Specifications"

4a2.2.1 Reactor Fuel

Areas of Review

The information in the SAR should include a reference to the fuel development program and the operational and limiting characteristics of the specific fuel used in the reactor.

The design basis for an AHR should be the maintenance of primary system boundary integrity under any conditions assumed in the safety analysis. Loss of integrity is defined as the escape of any fuel and fission products from the primary system boundary. Since the fuel in an AHR is an aqueous solution without cladding or encapsulation, the primary barrier is the interface surface between the fuel solution, including fission products, and any egress point. During operation, this interface includes the reactor vessel, the gas management system, the cooling coils, the control rod thimbles, and any pipes used for transferring fuel from and to the core. Therefore, the fuel solution must be shown to be compatible with the materials of construction for the fuel barrier (including fission products) for any normal or upset condition. The reviewer should be able to conclude that the applicant has included all information necessary to establish the limiting characteristics beyond which fuel barrier integrity could be lost.

Within the context of the factors listed in Section 4.2 of this review plan, the information on, and analyses of fuel should include the information requested in this section of the format and content guide. Sufficient information and analyses should support the limits for operational conditions. These limits should be selected to ensure the integrity of the fuel barrier. Analyses in this section of the SAR should address mechanical forces and stresses; corrosion and erosion of the fuel barrier, or collection of fission products, decay daughters, or fuel precipitates on the fuel barrier, whether caused by changes in solution chemistry (such as pH, density, pressure, and temperature) or from normal operation; hydraulic forces, including natural convection in the fuel solution; thermal changes and temperature gradients; and internal and external pressures from fission products and the production of fission gas. The analyses should also address radiation effects, including the maximum fission densities and fission rates that the fuel is designed to accommodate. Results from these analyses should form part of the design bases for other sections of the SAR, for the reactor safety limits, and for other fuel-related TS.

Acceptance Criteria

The acceptance criteria for the information on reactor fuel include the following:

- The design bases for the fuel should be clearly presented, and the design considerations and functional description should ensure that fuel conforms to the bases. Maintaining fuel barrier integrity should be the most important design objective.

- The chemical and physical characteristics of the fuel constituents, including the solvent and any stabilizing additives, should be chosen for compatibility with each other and the anticipated environment, including interaction with the fuel barrier. Consideration should be given to fission product buildup in or precipitation from the homogeneous fuel solution.

- Fuel enrichment should be consistent with the requirements of 10 CFR 50.64, “Limitations on the Use of Highly Enriched Uranium (HEU) in Domestic Non-Power Reactors.”

- The fuel operating parameters should take into account characteristics that could limit fuel barrier integrity, such as heat capacity and conductivity, melting, softening, and blistering temperatures of the vessel and cooling coil materials; corrosion and erosion caused by coolant or fuel solution; chemical compatibility of the fuel solution with the fuel barrier; physical stresses from mechanical or hydraulic forces (internal pressures, vibration, and Bernoulli forces); fuel burn-up; radiation damage to the fuel barrier; and retention of fission products.

- The fuel design should include the nuclear features of the reactor core, such as structural materials with small neutron absorption cross-sections and minimum impurities, neutron reflectors, and burnable poisons, if used.

- The various phenomena that result in changes to the initial fuel composition and properties should be considered. The submittal should include information on radiolytic gas formation, the transport, changes in void fraction, and removal of gas, the return of condensate following recombination and condensation of gas or bubbles outside the core vessel, associated pH changes, potential fuel and fission product precipitation, and the addition of fuel and acid, along with the reactivity implications of these items.

- The discussion of the fuel should include a summary of the fuel development, qualification, and production program.

- The applicant should propose TS as discussed in Chapter 14 of the format and content guide to ensure that the fuel meets the safety-related design requirements. The applicant should justify the proposed TS in this section of the SAR.

Technical Rationale

The parameters included in the technical review have been identified as important, based on experience with previous operating AHRs, as discussed in References 2 and 3.

Review Procedures

The reviewer should confirm that the information on the reactor fuel includes a description of the required characteristics. The safety-related parameters should become design bases for the reactor operating characteristics in other sections of this chapter, especially Section 4.6 on the thermal-hydraulic design of the core.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the NRC staff's safety evaluation report:

- The applicant has described in detail the fuel solution to be used in the reactor. The discussion includes the design limits (chemical and physical) and clearly gives the technological and safety-related bases for these limits.

- The applicant has discussed the constituents, materials, components, and preparation specifications for the fuel. Compliance with these specifications for all fuel used in the reactor will ensure uniform characteristics and compliance with design bases and safety-related requirements.

- The applicant has referred to the fuel development program under which all fuel characteristics and parameters that are important to the safe operation of the reactor were investigated. The design limits are clearly identified for use in design bases to support TS.

- Information on the design and development program for the fuel offers reasonable assurance that the fuel can function safely in the reactor without adversely affecting the health and safety of the public.

4a2.2.2 Control Rods

Areas of Review

The control rods in an AHR are designed to change reactivity by changing the amount of neutron absorber (or fuel) in or near the reactor core. Depending on their function, control rods can be designated as regulating, safety, shim, or transient rods. To trip the reactor, the negative reactivity of the control rods is usually added passively and quickly when the rods drop into the core, although gravity can be assisted by spring action. Because the control rods serve a dual function (control and safety), control and safety systems for non-power reactors are usually not completely separable. In non-power reactors, a reactor trip does not challenge the safety of the reactor or cause any undue strain on any systems or components associated with the reactor.

This section of the format and content guide discusses the areas of review.

Acceptance Criteria

The acceptance criteria for the information on control rods include the following:

- The control rods, blades, followers (if used), and support systems should be designed conservatively to withstand all anticipated stresses and challenges from mechanical, hydraulic, and thermal forces and the effects of their chemical and radiation environment.

- The control rods should be sufficient in number and reactivity worth to comply with the "single stuck rod" criterion; that is, it should be possible to shut down the reactor and comply with the requirement of minimum shutdown margin with the highest worth scrammable control rod stuck out of the core. The control rods should also be sufficient to control the reactor in all designed operating modes and to shut down the reactor safely from any operational condition. The design bases for redundancy and diversity should ensure these functions.

- The control rods should be designed for rapid, fail-safe shutdown of the reactor from any operating condition. The discussion should address conditions under which normal electrical power is lost.

- The control rods should be designed so that tripping them does not challenge their integrity or operation or the integrity or operation of other reactor systems.

- The control rod design should ensure that positioning is reproducible and that a readout of positions is available for all reactor operating conditions.

- The drive and control systems for each control rod should be independent from other rods to prevent a malfunction in one from affecting insertion or withdrawal of any other.

- The drive speeds and scram times of the control rods should be consistent with reactor kinetics requirements, considering mechanical friction, hydraulic resistance, and the electrical or magnetic system.

- The control rods should allow replacement and inspection, as required by operational requirements and the TS.

- The action of the control rod (manual or automatic) should be such that it does not affect the stability of the core, which has been known to show significant variations in the power level but a return to a stable state following small perturbations (including physical ones from radiolytic gas formation and changes in void fraction), if the core is designed within an acceptable power density limit.

- TS should be proposed according to the guidance in Chapter 14 of the format and content guide, which describes important design aspects and proposes limiting conditions for operations (LCOs) and surveillance requirements, and they should be justified in this section 4a2.2.2 of the SAR.

Review Procedures

The reviewer should confirm that the design bases for the control rods define all essential characteristics and that the applicant has addressed them completely.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The applicant has described the control and safety rod systems for the reactor and included a discussion of the design bases, which are derived from the planned operational characteristics of the reactor. All functional and safety-related design bases can be achieved by the control rod designs.

- The applicant has included information on the materials, components, and fabrication specifications of the control rod systems. These descriptions offer reasonable assurance that the control rods conform to the design bases and can control and shut down the reactor safely from any operating condition.

- Information on scram design for the control rods has been compared with designs at other non-power reactors having similar operating characteristics. Reasonable assurance exists that the reactor trip features designed for this facility will perform as necessary to ensure fuel barrier integrity and to protect the health and safety of the public.

- The control rod design includes reactivity worths that can control the excess reactivity planned for the reactor, including ensuring an acceptable shutdown reactivity and margin, as defined and specified in the TS.

- Changes in reactivity caused by control rod dynamic characteristics are acceptable. The staff evaluations include maximum scram times and maximum rates of insertion of positive reactivity for normal and ramp insertions caused by system malfunctions.

- The applicant has justified appropriate design limits, LCOs, and surveillance requirements for the control rods and included them in the TS.

4a2.2.3 Solid Neutron Moderator and Neutron Reflector

Areas of Review

In this section of the SAR, the applicant should describe moderators and reflectors and their special features. The fuel solution of the AHR is self-moderating. The information pertinent to this section is, therefore, that for any *solid* moderator that might be added to the AHR design. The core of the aqueous homogeneous reactor is an aqueous fuel solution that self-moderates, surrounded by either a liquid or solid neutron reflector. The primary coolant is kept separate from the fuel material in cooling coils; these provide heterogeneous moderation within the homogeneous core solution. The solid reflectors are chosen primarily for favorable nuclear properties and physical characteristics. Section 4.2.1 of the SAR should contain a description of the relationship of all moderators to the core. Buildup of contaminating radioactive material in the moderator or coolant and reflector during reactor operation should be discussed in Chapter 1, “Radiation Protection Program and Waste Management,” of the SAR.

Areas of review should include the following:

- Geometry

- Materials

- compatibility with the operational environment

- structural designs

- response to radiation heating and damage

- capability to be moved and replaced, if necessary

Section 4a2.5 of the SAR should discuss nuclear characteristics of the moderator.

Acceptance Criteria

The acceptance criteria for the information on neutron moderators and reflectors include the following:

- The nonnuclear design bases, such as reflector encapsulations, should be clearly presented, and the nuclear bases should be briefly summarized. Nonnuclear design

considerations should ensure that the moderator and reflector can provide the necessary nuclear functions.

- The design should ensure that the moderator and reflector are compatible with their chemical, thermal, mechanical, and radiation environments. The design specifications should include cooling coil and core vessel material and construction methods to ensure primary barrier integrity. If the barrier should fail, the applicant should either show that the reactor can continue to be operated safely until the barrier is repaired or replaced or propose that the reactor be shut down until the barrier is repaired or replaced.

- The design should allow for dimensional changes from radiation damage and thermal expansion to avoid malfunctions of the moderator or reflector.

- The design should provide for removal or replacement of solid moderator or reflector components and systems, if required by operational considerations.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which describes important design aspects and proposes LCOs and surveillance requirements. The proposed TS should be justified in this section of the SAR.

Review Procedures

The reviewer should confirm that the information on the neutron moderator and reflector completely describes the required systems. The bases for the nuclear characteristics should appear in Section 4.5 of the SAR.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will appear in the staff's safety evaluation report:

- The moderator and reflector are integral constituents of a reactor core; the staff's evaluation of the nuclear features appears in Section 4a2.5. The designs take into account interactions between the moderator or reflector and the reactor environment. Reasonable assurance exists that degradation rates of the moderator or reflector will not affect safe reactor operation, prevent safe reactor shutdown, or cause uncontrolled release of radioactive material to the unrestricted environment.

- Graphite moderators or reflectors are clad in (state cladding material) if they are located in an environment where coolant or fuel solution infiltration could cause changes in neutron scattering and absorption, thereby changing core reactivity. Reasonable assurance exists that leakage will not occur. In the unlikely event coolant or fuel solution infiltration occurs, the applicant has shown that this infiltration will not interfere with safe reactor operation or prevent safe reactor shutdown.

- The moderator or reflector is composed of materials incorporated into a sound structure that can retain size and shape and support all projected physical forces and weights. Therefore, no unplanned changes to the moderator or reflector would occur that would interfere with safe reactor operation or prevent safe reactor shutdown.

- The applicant has justified appropriate design limits, LCOs, and surveillance requirements for the moderator and reflector and included them in the TS.

4a2.2.4 Neutron Startup Source

Areas of Review

Each nuclear reactor should contain a neutron startup source that ensures the presence of neutrons during all changes in reactivity. This is especially important when starting the reactor from a shutdown condition. Therefore, the reviewer should evaluate the function and reliability of the source system.

Areas of review should include the following:

- type of nuclear reaction
- energy spectra of neutrons
- source strength
- interaction of the source and holder, while in use, with the chemical, thermal, and radiation environment
- design features that ensure the function, integrity, and availability of the source
- TS

Acceptance Criteria

Acceptance criteria for the information on the neutron startup source include the following:

- The source and source holder should be constructed of materials that will withstand the environment in the reactor core and during storage, if applicable, with no significant degradation.
- The type of neutron-emitting reaction in the source should be comparable to that at other licensed reactors, or test data should be presented in this section of the SAR to justify use of the source.
- The natural radioactive decay rate of the source should be slow enough to prevent a significant decay over 24 hours or between reactor operations.
- The design should allow easy replacement of the source and its holder and a source check or calibration.
- Neutron and gamma radiation from the reactor during normal operation should not cause heating, fissioning, or radiation damage to the source materials or the holder.
- If the source is regenerated by reactor operation, the design and analyses should demonstrate its capability to function as a reliable neutron startup source in the reactor environment.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements, and should be justified in this section of the SAR.

Review Procedures

The reviewer should confirm that the information on the neutron startup source and its holder includes a complete description of the components and functions. In conjunction with Chapter 7 of the SAR, the information should demonstrate the minimum source characteristics that will produce the required output signals on the startup instrumentation.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The design of the neutron startup source is of a type (i.e., neutron-emitting reaction) that has been used reliably in similar reactors licensed by the NRC (or the design has been fully described and analyzed). The staff concludes that this type of source is acceptable for this reactor.

- The source will not degrade in the radiation environment during reactor operation. Either the levels of external radiation are not significant or the source will be retracted while the reactor is at high power to limit the exposure.

- Because of the source holder design and fabrication, reactor neutron absorption is low and radiation damage is negligible in the environment of use. When radiation heating occurs, the holder temperature does not increase significantly above the ambient water temperature.

- The source strength produces an acceptable count rate on the reactor startup instrumentation and allows for a monitored startup of the reactor under all operating conditions.

- The applicant has justified appropriate LCOs and surveillance requirements for the source and included them in the TS.

- The source and holder operate safely and reliably.

4a2.2.5 Reactor Internals Support Structures

Areas of Review

An AHR fuel core is composed of the homogeneous fuel solution and off gas inside a reactor vessel; the core does not require a support structure beyond the reactor vessel. However, all other reactor core components must be secured firmly and accurately, because the capability to maintain a controlled chain reaction depends on the relative positions of the components. Controlling reactor operations safely and reliably depends on the capability to locate components and reproduce responses of instrument and control systems, including nuclear detectors and control rods. Predictable fuel barrier integrity depends on stable and reproducible

control rod action and coolant flow patterns. Generally, the control rods of non-power reactors are suspended from a superstructure, which allows gravity to rapidly change core reactivity to shut down the reactor.

Areas of review include the design of the support structure for the core components and reactor vessel, including a demonstration that the design loads and forces are conservative compared with all expected loads and hydraulic forces and that relative positions of components can be maintained within tolerances.

This section of the format and content guide discusses additional areas of review.

Acceptance Criteria

Acceptance criteria for the information on the core support structure should include the following:

- The design should show that the support structure will conservatively hold the weight of all core-related components with and without the buoyant forces of the water in the tank or pool.

- The design should show that the support structure will conservatively withstand all hydraulic forces from anticipated coolant flow with negligible deflection or motion.

- The design should consider the methods by which core components (reflector pieces, control rods, and coolant systems, and the fuel transport pipe) are attached to the core support structure. The information should include tolerances for motion and reproducible positioning. These tolerances should ensure that variations will not cause reactivity design bases, coolant design bases, safety limits, or LCOs in the TS to be exceeded.

- The design should consider the effect of the local environment on the material of the support structure. The impact of radiation damage, mechanical stresses, chemical compatibility with the coolant and core components, and reactivity effects should not degrade the performance of the supports sufficiently to prevent safe reactor operation for the design life of the reactor.

- The design should show that stresses or forces from reactor components other than the core could not cause malfunctions, interfere with safe reactor operation or shutdown, or cause other core-related components to malfunction.

- The core of an AHR used for radioisotope production could vary in dimension, based on the purpose of the facility. Fuel can be transferred to and from the core during planned operations; consequently, there are devices to ensure that such operations do not occur inadvertently. The design for a changing core configuration should contain such features as position tolerances, to ensure safe and reliable reactor operation within all design limits, including reactivity and cooling capability. The description should include the interlocks that keep the reactor core configuration from changing while the reactor is critical or while forced cooling is required, if applicable. The design should show how the reactor is shut down if unwanted action occurs.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements, and should be justified in this section of the SAR.

Review Procedures

The reviewer should confirm that the design bases define a complete support system.

Evaluation findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will appear in the staff's safety evaluation report:

- The applicant has described the support system for the reactor core, including the design bases, which are derived from the planned operational characteristics of the reactor and the core design. All functional and safety-related design bases can be achieved by the design.

- The support structure includes acceptable guides and supports for other essential core components, such as control rods, nuclear detectors, and neutron reflectors.

- The support structure provides sufficient coolant flow to conform to the design criteria and to prevent loss of fuel barrier integrity from overheating.

- The support structure is composed of materials shown to be resistant to radiation damage, coolant or fuel solution erosion and corrosion, thermal softening or yielding, and excessive neutron absorption.

- The core support structure is designed to ensure a stable and reproducible core configuration for all anticipated conditions (e.g., reactor trips, coolant flow change, and core motion) through the reactor life cycle.

- The applicant has justified appropriate LCOs and surveillance requirements for the core support structure and included them in the TS.

4a2.3 Reactor Vessel

Areas of Review

The vessel of the AHR is an essential part of the primary fuel system and is the primary fuel barrier (including fission products). The vessel may also provide some support for components and systems mounted to the core supports.

The areas of review are the design bases of the vessel and the design details needed to achieve those bases. This section of the format and content guide discusses the information that the applicant should submit for review.

Acceptance Criteria

The acceptance criteria for information on the reactor vessel should include the following:

- The vessel dimensions should include thickness and structural supports, and fabrication methods should be discussed. The vessel should be conservatively designed to withstand all mechanical and hydraulic forces and stresses to which it could be subjected during its lifetime.

- The construction materials and vessel treatment should resist chemical interaction with the fuel solution and be chemically compatible with other reactor components in the primary system. The compatibility between the vessel material and fuel solution should be addressed to prevent fuel solution leakage.

- The dimensions of the vessel and the materials used to fabricate it should ensure that radiation damage to the vessel is minimized, so that the vessel will remain intact for its projected lifetime.

- The construction materials and vessel treatment should be appropriate for preventing fuel solution from corroding the vessel interior and pool water from corroding the exterior.

- A plan should be in place to assess irradiation of and chemical damage to the vessel materials. Remedies for damage or a replacement plan should be discussed.

- All penetrations and attachments to the vessel below the fuel solution level should be designed to avoid malfunction and loss of fuel solution.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements, and should be justified in this section of the SAR.

Technical Rationale

Fuel chemistry has been shown to affect corrosion and result in possible loss of vessel integrity, based on the experience from the operation of previous reactors, as described in References 2 and 3.

Review Procedures

The reviewer should confirm that the design bases describe the requirements for the vessel and that the detailed design is consistent with the design bases and acceptance criteria for the vessel.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will appear in the staff's safety evaluation report:

- Information has been provided on gas composition (hydrogen, oxygen, nitrogen (NOx), and fission gases) from radiolytic decomposition of fuel solution, as well as gas handling and condensate return.

- The vessel system can withstand all anticipated mechanical and hydraulic forces and stresses to prevent loss of integrity, which could lead to a loss of fuel solution or other malfunctions that could interfere with safe reactor operation or shutdown.

- The penetrations and attachments to the vessel are designed to ensure safe reactor operation. Safety and design considerations of any penetrations below the fuel solution level include analyses of potential malfunction and loss of fuel solution. The applicant discusses credible fuel spill and leak scenarios in Chapter 13, "Accident Analyses," Section 13.1.4.

- The construction materials, treatment, and methods of attaching penetrations and components are designed to prevent chemical interactions among the vessel and the fuel solution, pool water, and other components.

- The outer and inner surfaces of the vessel are designed and treated to avoid corrosion in locations that are inaccessible for the life of the vessel. Vessel surfaces will be inspected in accessible locations.

- The applicant has considered the possibility that fuel solution may leak into unrestricted areas, including ground water, and has included precautions to avoid the uncontrolled release of radioactive material.

- The design considerations include the shape and dimensions of the vessel to ensure sufficient radiation shielding to protect personnel and components. Exposures have been analyzed, and acceptable shielding factors are included in the vessel design.

- The applicant has justified appropriate LCOs and surveillance requirements for the vessel and included them in the TS.

- The design features of the vessel offer reasonable assurance of its reliability and integrity for its anticipated life. The design of the vessel is acceptable to avoid undue risk to the health and safety of the public.

4a2.4 Biological Shield

Areas of Review

The radiation shields around non-power reactors are called biological shields and are designed to protect personnel and reduce radiation exposures to reactor components and other equipment. The principal design and safety objective is to protect the employees and the public. The second design objective is to make the shield as thin as possible, consistent with acceptable protection factors. The radioisotope production AHR uses the neutron flux for fissioning and direct production of Mo-99. Access to this radioactive Mo-99 within a few days to a week is necessary because of the relatively short half-life of the material. This necessitates the transfer of the fuel solution to the separations facility at the plant site, and this should be addressed in the shield design. Traditional methods of improving protection factors without increasing shield thickness are to use materials with higher density, higher atomic numbers for gamma rays, and higher hydrogen concentration for neutrons. The optimum shield design should consider all of these.

This section of the format and content guide discusses areas of review.

Acceptance Criteria

The acceptance criteria for the information on the biological shields include the following:

- The principal objective of the shield design should be to ensure that the projected radiation dose rates and accumulated doses in occupied areas do not exceed the limits of 10 CFR Part 20, "Standards for Protection Against Radiation," and the guidelines of the facility's ALARA (as low as reasonably achievable) program discussed in Chapter 11 of the SAR.

- The shield design should address potential damage from radiation heating and induced radioactivity in reactor components and shields. The design should limit heating and induced radioactivity to levels that could not cause significant risk of failure.

- The pool design and the solid shielding materials should be apportioned to ensure protection from all applicable radiation and all conditions of operation.

- Shielding materials should be based on demonstrated effectiveness at other non-power reactors with similar operating characteristics, and the calculational models and assumptions should be justified by similar comparisons. New shielding materials should be justified by calculations, development testing, and the biological shield test program during facility startup.

- The analyses should include specific investigation of the possibilities of radiation streaming or leaking from shield penetrations, inserts, and other places where materials of different density and atomic number meet. Any such streaming or leakage should not exceed the stated limits.

- Supports and structures should ensure shield integrity, and quality control methods should ensure that fabrication and construction of the shield exceed the requirements for similar industrial structures.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements. The applicant should justify the proposed TS in this section of the SAR.

Review Procedures

The reviewer should confirm that the objectives of the shield design bases are sufficient to protect the health and safety of the public and the employees and that the design achieves the design bases. The reviewer should compare design features, materials, and calculational models with those of similar non-power reactors that have operated acceptably.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The analysis in the SAR offers reasonable assurance that the shield designs will limit exposures from the reactor and reactor-related sources of radiation so as not to exceed the limits of 10 CFR Part 20 and the guidelines of the facility's ALARA program.

- The design offers reasonable assurance that the shield can be successfully installed with no radiation streaming or other leakage that would exceed the limits of 10 CFR Part 20 and the guidelines of the facility's ALARA program.

- Reactor components are sufficiently shielded to avoid significant radiation-related degradation or malfunction.

- The applicant has justified appropriate LCOs and surveillance requirements for the shield and included them in the TS.

4a2.5 Nuclear Design

In this section of the SAR, the applicant should show how the systems described in this chapter function together to form a nuclear reactor that can be operated and shut down safely from any operating condition. The analyses should address all possible operating conditions throughout the reactor's anticipated life cycle. Because the information in this section describes the characteristics necessary to ensure safe and reliable operation, it will determine the design bases for most other chapters of the SAR and the TS. The text, drawings, and tables should completely describe the reactor's operating characteristics and safety features.

4a2.5.1 Normal Operating Conditions

Areas of Review

In this section of the SAR, the applicant should discuss the configuration for a functional reactor that can be operated safely.

This section of the format and content guide discusses the areas of review.

Acceptance Criteria

The acceptance criteria for information on normal operating conditions include the following:

- The information should show a complete, operable reactor core. Control rods should be sufficiently redundant and diverse to control all proposed excess reactivity safely and to safely shut down the reactor and maintain it in a shutdown condition. Reactivity analyses should include individual and total control rod effects.

- The information should describe anticipated power oscillations and their effects on safety-related equipment and systems. These oscillations should be shown to be self-damping and controllable.

- Anticipated core evolution should account for uranium burn-up; actinide and fission product buildup; changes in fuel solution chemical stability caused by radiolysis, including changes in pH, temperature, pressure, density, and specific heat capacity; and poisons, both from fission products and those added by design, for the life of the reactor.

The information should also include an analysis of the total fuel solution volume as a function of total burn-up.

- The analyses should show initial and changing reactivity conditions, control rod reactivity worths, and reactivity worths of reflector units, as well as in-core components for all anticipated configurations. There should be a discussion of administrative and physical constraints that would prevent inadvertent movement that could suddenly introduce more than one dollar of positive reactivity or an analyzed safe amount, whichever was larger. These analyses should address movement, flooding, and voiding of core components, including fission gas generation and failure of the gas recombiners.

- The reactor kinetic parameters and behavior should be shown, along with the dynamic reactivity changes caused by the instrumentation and control systems. Analyses should prove that the control systems will prevent nuclear transients from causing the loss of fuel barrier integrity or an uncontrolled addition of reactivity (e.g., the reactivity control system shall be designed with appropriate limits on the rate and amount of reactivity increase that may occur during a reactivity insertion accident so as to prevent compromise of the primary barrier).

- The information should include calculated core reactivities for the possible and planned configurations of the control rods. The reactivity impacts of radiolytic gas and void formation, fission product gas removal, fuel solution and acid addition, and condensate return to the core should be provided. If only one core configuration will be used over the life of the reactor, the applicant should clearly indicate this. The limiting core configuration during reactor life should be indicated. This information should be used for the analyses in Section 4.6 of the SAR. The information should also include reactivities for fuel solution storage and handling outside the reactor, fuel transport to and from the core, and the effects of core recycling after isotope removal processing.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements, and should be justified in this section of the SAR.

Technical Rationale

Power oscillations in AHRs are expected and usually are self-limiting because of the large negative reactivity feedback coefficients. It is necessary to ensure that oscillations are bounded for proper operation of the reactor, based on the operation of previous AHRs found in References 2 and 3.

Review Procedures

The reviewer should confirm that a complete, operable core has been analyzed.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which should appear in the staff's safety evaluation report:

- The applicant has described the proposed initial core configuration and analyzed all reactivity conditions. These analyses also include other possible core configurations

planned during the life of the reactor. The assumptions and methods used have been justified and validated.

- The analyses include reactivity and geometry changes resulting from burn-up; plutonium buildup; the buildup and removal of fission products, both in solution and in the gas management system; fuel solution condensate return to the core; fuel solution and acid addition; and the use of poisons, as applicable.

- The reactivity analyses include the reactivity values for the in-core components, such as control rods or cooling coils, and the ex-core components, such as the reflector and pool. The assumptions and methods have been justified.

- The analyses address the steady power operation and kinetic behavior of the reactor and show that the dynamic response of the control rods and instrumentation is designed to prevent reactor transients that cause the reactor to exceed operating limits.

- The analyses show that any in-core components that could be flooded or voided could not cause reactor transients beyond the capabilities of the instrumentation and control systems to prevent fuel damage or other reactor damage. This also should include failure of radiolytic gas recombiners and subsequent pressure pulses resulting from deflagration or explosions of radiolytic gas.

- The analyses address a limiting core that is the minimum size possible with the planned fuel. Since this core configuration has the highest power density, the applicant uses it in Section 4.6 of the SAR to determine the limiting thermal-hydraulic characteristics for the reactor.

- The analyses and information in this section describe a reactor core system that could be designed, built, and operated without unacceptable risk to the health and safety of the public.

- The applicant has justified appropriate LCOs and surveillance requirements for minimal operating conditions and included them in the TS. The applicant has also justified the proposed TS.

4a2.5.2 Reactor Core Physics Parameters

In this section of the SAR, the applicant should present information on core physics parameters that determine reactor operating characteristics and are influenced by the reactor design. The principal objective of an AHR is to produce isotopes for use, while not posing an unacceptable risk to the health and safety of the public. By proper design (sufficiently low power density), the reactor will operate at steady power; however, power oscillation in AHRs is expected, and the reactor systems will be able to terminate or mitigate transients without reactor damage.

Areas of Review

Areas of review should include the design features of the reactor core that determine the operating characteristics and the analytical methods for important contributing parameters. The results presented in this section of the SAR should be used in other sections of this chapter.

This section of the format and content guide further discusses the areas of review.

Acceptance Criteria

The acceptance criteria for the information on reactor core physics parameters include the following:

- The calculational assumptions and methods should be justified and traceable to their development and validation, and the results should be compared with calculations of similar facilities and previous experimental measurements. The ranges of validity and accuracy should be stated and justified.

- Uncertainties in the analyses should be provided and justified.

- Methods used to analyze neutron lifetime, effective delayed neutron fraction, and reactor periods should be presented, and the results should be justified. Comparisons should be made with similar reactor facilities. The results should agree within the estimates of accuracy for the methods.

- Coefficients of reactivity (temperature, void, and power) should all be negative over the significant portion of the operating ranges of the reactor. The results should include estimates of accuracy. If any parameter is not negative within the error limits over the credible range of reactor operation, the combination of the reactivity coefficients should be analyzed and shown to be sufficient to prevent reactor damage and risk to the public from reactor transients, as discussed in Chapter 13 of the SAR.

- Changes in feedback coefficients with core configurations, power level, and fuel burn-up should not change the conclusions about reactor protection and safety, nor should they void the validity of the analyses of normal reactor operations.

- The methods and assumptions for calculating the various neutron flux densities should be validated by comparisons with results for similar reactors. Uncertainties and ranges of accuracy should be given for other analyses requiring neutron flux densities, such as fuel burn-up, thermal power densities, radiolytic gas production, control rod reactivity worths, and reactivity coefficients. This should include a description of the method of calculating and verifying the burn-up and the fuel composition after isotope removal. It also should include methods to analyze gas evolution and the generation of void spaces and predict their reactivity effects.

- TS, if required, should be proposed according to the guidance in Chapter 14 of the format and content guide, which proposes LCOs and surveillance requirements, and should be justified in this section of the SAR.

Review Procedures

The reviewer should confirm that generally accepted and validated methods have been used for the calculations, evaluate the dependence of the calculational results on reactor design features and parameters, review the agreement of the methods and results of the analyses with the acceptance criteria, and consider the derivation and adequacy of uncertainties and errors.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which should appear in the staff's safety evaluation report:

- The analyses of neutron lifetime, effective delayed neutron fraction, and coefficients of reactivity have been completed, using methods validated at similar reactors and experimental measurements.

- The effects of fuel burn-up and reactor operating characteristics for the life of the reactor are considered in the analyses of the reactor core physics parameters.

- The numerical values for the reactor core physics parameters depend on features of the reactor design, and the information given is acceptable for use in the analyses of reactor operation.

- The applicant has justified appropriate LCOs and surveillance requirements for the reactor core physics parameters and included them in the TS. The applicant has also justified the TS.

4a2.5.3 Operating Limits

Areas of Review

In this section of the SAR, the applicant should present the nuclear design features necessary to ensure safe operation of the reactor core and safe shutdown from any operating condition. The information should demonstrate a balance between fuel loading, control rod worths, and number of control rods. The applicant should discuss and analyze potential accident scenarios, as distinct from normal operation, in Chapter 13 of the SAR.

This section of the format and content guide discusses the areas of review.

Acceptance Criteria

The acceptance criteria for the information on operating limits include the following:

- All operational requirements for excess reactivity should be stated, analyzed, and discussed. These could pertain to at least the following:

    - temperature coefficients of reactivity

    - fuel burn-up between reloads or shutdowns

    - void coefficients

    - fission product poison (e.g. samarium and or dissolved xenon)

    - overall power coefficient of reactivity if not accounted for in the items listed above

    - fuel processing, handling, and recycling, and implications for reactor safety

- effects of experiments

- Credible inadvertent insertion of excess reactivity should not damage the reactor or fuel barrier; this event should be analyzed in Sections 4.5 and 4.6 and Chapter 13 of the SAR.

- The minimum amount of total control rod reactivity worth to ensure reactor subcriticality should be stated.

- A transient analysis should be performed that assumes that an instrumentation malfunction drives the most reactive control rod out in a continuous ramp mode in its most reactive region. The analysis should show that the reactor would not be damaged and fuel barrier integrity would not be lost. Chapter 13 of the SAR should analyze reactivity additions under accident conditions.

- An analysis should be performed that examines reactivity, assuming that the reactor is operating under its maximum licensed conditions, normal electrical power is lost, and the control rod of maximum reactivity worth and any non-scrammable control rods remain fully withdrawn. The analysis should show how much negative reactivity must be available in the remaining scrammable control rods so that, without operator intervention, the reactor can be shut down safely and remain subcritical without risk of fuel damage, even after temperature equilibrium is attained and all transient poisons, such as xenon, are reduced, with consideration for the most reactive core loading.

- On the basis of analysis, the applicant should justify a minimum negative reactivity (shutdown margin) that will ensure the safe shutdown of the reactor. This discussion should address the methods and the accuracy with which this negative reactivity can be determined to ensure its availability.

- The core configuration with the highest power density possible for the planned fuel should be analyzed as a basis for safety limits and limiting safety system settings (LSSSs) in the thermal-hydraulic analyses. The core configuration should be compared with other configurations to ensure that a limiting configuration is established for steady power.

- The effects of surface frothing as an intermittent reflector or moderator should be considered.

- Analysis should show that power oscillations will not exceed the operational or safety limits and may include operational limits on parameters such as power density.

- The applicant should propose and justify TS for safety limits, LSSSs, LCOs, and surveillance requirements, as discussed in Chapter 14 of the format and content guide.

Review Procedures

The reviewer should confirm that the methods and assumptions used in this section of the SAR have been justified and are consistent with those in other sections of this chapter.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will appear in the staff's safety evaluation report:

- The applicant has discussed and justified all excess reactivity factors needed to ensure a readily operable reactor. The applicant has also considered the design features of the control systems that ensure that this amount of excess reactivity is fully controlled under normal operating conditions.

- The discussion of limits on excess reactivity shows that a credible rapid withdrawal of the most reactive control rod or other credible failure that would add reactivity to the reactor would not lead to loss of fuel barrier integrity. Therefore, the information demonstrates that the proposed amount of reactivity is available for normal operations but that it would not cause unacceptable risk to the public from a transient.

- The definition of the shutdown margin is negative reactivity obtainable by control rods to ensure reactor shutdown from any reactor condition, including a loss of normal electrical power. With the assumption that the most reactive control rod is inadvertently stuck in its fully withdrawn position, and non-scrammable control rods are in the position of maximum reactivity addition, the analysis derives the minimum negative reactivity necessary to ensure safe reactor shutdown. The applicant conservatively proposes a shutdown margin of xx (the reviewer should insert the margin specified in the SAR) in the TS. The applicant has justified this value; it is readily measurable and is acceptable.

- The SAR contains calculations of the peak thermal power density achievable with any core configuration. This value is used in the calculations in the thermal-hydraulic section of the SAR to derive reactor safety limits and LSSSs, which are acceptable.

4a2.6 Thermal-Hydraulic Design

Areas of Review

The information in this section should enable the reviewer to determine the limits on cooling conditions necessary to ensure that fuel barrier integrity will not be lost under any reactor conditions, including accidents. In the case of a low-power AHR, there is no concern about damaging fuel; however, there is concern about damaging the fuel barrier (and fission product barriers).

Since the fuel solution is free to move in an aqueous form, the temperature within the fuel can more readily equalize; however, the power shape may still cause some hot spots, which may have adverse safety impacts in terms of instability and/or fuel and fission product precipitation, a potential that the applicant's safety analysis should address. Because some of the factors in the thermal-hydraulic design are based on experimental measurements and correlations that are a function of coolant conditions, the analyses should confirm that the values of such parameters are applicable to the reactor conditions analyzed.

The AHR design may contain a flow loop that circulates radiolysis gas, fission gases, water vapor, and a cover gas. The reviewer needs to determine the constituents in the bubbly mixture and cover gas. The capacity of recombiners and condensers in the system may limit achievable stable and safe operation. The reviewer needs to determine if the makeup and flow rate of the

circulating mixture is within the design limits of any recombiners for radiolysis gases or condensers of water vapor. The reviewer should also ensure that any sources and sinks of energy in the flow loop are within the design capacities of any heat exchangers in the loop.

This section of the format and content guide discusses the areas of review.

Acceptance Criteria

The acceptance criteria for the information on thermal-hydraulic design should include the following:

- The applicant should propose criteria and safety limits based on the criteria for acceptable safe operation of the reactor, thus ensuring fuel barrier integrity under all analyzed conditions. The discussion should include the consequences of these conditions and justification for the alternatives selected. It should also include the limiting power density to offset the onset of instability following perturbation to the system (including from radiolytic gas generation). These criteria could include the following:

  – There should be no coolant flow instability in any cooling coil that could lead to a significant decrease in fuel cooling. This can be ascertained using a suitable onset-of-flow-instability correlation.

  – The departure-from-nucleate-boiling ratio should be no less than 2.0 along any coolant coil. This could apply to the inner surfaces of cooling coils that might be internal to an AHR.

- Safety limits, as discussed in Chapter 14 of the format and content guide, should be derived from the analyses described above, the analyses in Section 4.5.3 of the SAR, and any other necessary conditions. The safety limits should include conservative consideration of the effects of uncertainties or tolerances and should be included in the TS.

- LSSSs, as discussed in Chapter 14 of the format and content guide of the SAR, should be derived from the analyses described above, the analyses in Section 4.5.3 of the SAR, and any other necessary conditions. These settings should be chosen to maintain fuel barrier integrity when safety system protective actions are conservatively initiated at the LSSSs.

- A forced-flow reactor should be capable of switching to natural-convection flow without jeopardizing safe reactor shutdown. Loss of normal electrical power should not change this criterion. These limits should be based on the thermal-hydraulic analyses and appear in the TS.

- For AHRs, undercooling may change the pH of the system, resulting in fuel or fission product plate-out or precipitation; this should be considered in the thermal-hydraulic design.

- The gas treatment system, including recombiners, will contain fission product gas and hazardous chemicals. Since this forms part of the primary system boundary, this section

should consider the associated cooling systems and show their ability to maintain their functions and primary system boundary integrity under normal and abnormal operations.

- The pool water surrounding the reactor vessel is expected to provide some heat removal during steady-state operation. An analysis of the effects of loss of pool cooling should show that it would not affect fuel barrier (vessel) integrity under normal and abnormal operations.

Technical Rationale

Previous experience with AHRs has indicated the importance of the interrelationship of temperature of the fuel solution, chemical pH, and radiolytic gas recombination rates, as described in References 2 and 3 of section 4a2.8.

Review Procedures

The reviewer should confirm that the thermal-hydraulic analyses for the reactor are complete and address all issues that affect key parameters (e.g., flow, temperature, pressure, power density, pH, and peaking). The basic approach is an audit of the SAR analyses, but the reviewer may also perform independent calculations to confirm SAR results or methods.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will appear in the staff's safety evaluation report:

- The information in the SAR includes the thermal-hydraulic analyses for the reactor. This includes radiolytic gas generation, changes in void fraction, and fuel solution mixing, which might minimize precipitation with the fuel volume or frothing on the fuel solution surface, and a subsequent core transient. The applicant has justified the assumptions and methods and validated their results.

- All necessary information on the primary coolant hydraulics and thermal conditions of the fuel solution is specified for this reactor. The analysis has considered the various approaches and systems for heat removal, such as the cooling coils, the pool, and the gas management system. The analyses give the limiting conditions of the features that ensure fuel barrier integrity.

- Safety limits and LSSSs are derived from the thermal-hydraulic analyses. The values have been justified and appear in the TS. The thermal-hydraulic analyses on which these parameters are based ensure that overheating or overcooling during any operation or credible event will cause neither a loss of fuel barrier integrity and unacceptable radiological risk to the health and safety of the public nor fuel or fission product plate-out or precipitation that could lead to a loss of fission product integrity. The analysis includes methods for calculating the induced natural convection within the homogeneous fuel solution.

4a2.7 Gas Management System

Areas of Review

This section of the SAR should contain the design information on all components of the gas management system. The design information should be presented in drawings, diagrams, text, and analysis in sufficient detail for the staff to understand the flow of evolved gases and fission products from their generation in the reactor core to their ultimate release. Using this information, the staff should determine whether there is reasonable assurance that the gas management system can prevent a hydrogen deflagration or detonation hazard; contain hazardous chemicals and volatile fission products until they can be released safely, in accordance with environmental release criteria; and withstand any pressure transients within the reactor system.

In evaluating the analysis demonstrating these capabilities, the staff should ensure that these criteria can be met for the maximum power density that is considered credible during power oscillations. The applicant should justify the maximum fission product and radiolytic gas generation rates during power oscillations.

This section of the format and content guide discusses the areas of review.

Technical Rationale

Areas of review, acceptance criteria, and evaluation findings are all dictated by five hazards: an inadvertent criticality outside the reactor core, a radiolytic gas deflagration or detonation, an NOx release, a release of gaseous fission products, and an increase in the pressure in the headspace over the core. Although the reactor will operate in a steady-state mode, power oscillations may be possible. Therefore, the design must be sufficiently robust to sustain fission product and NOx generation, heat generation, and pressures that will occur at peak power. The dynamics of criticality accidents show that a sudden spike in power of several orders of magnitude can occur in solution systems. This can occur when there is a rapid reactivity insertion that causes the solution to go prompt critical. The spike is generally terminated by the negative reactivity effect of void formation caused by radiolytic gas generation. The actual first spike yield and total fission yield during accidents and planned critical excursions can vary widely, so fairly conservative assumptions should be made concerning the assumed dynamics during a prompt critical excursion.

Acceptance Criteria

The design of the gas management system should be found acceptable if it meets the following acceptance criteria:

- The geometry of all equipment and piping should be favorable (e.g., subcritical when filled with optimally moderated reactor core solution).

- If any portions of the equipment or piping are not favorable geometry, the applicant's analysis should demonstrate that no single failure can result in a criticality outside the core.

- Monitoring should be provided periodically for the long-term accumulation of fissionable material entrained in the system.

- The radiolytic gas recombiner must be capable of preventing a hydrogen deflagration or detonation anywhere within the gas confinement boundary, especially in the reactor vessel.

- The cooling system for the recombiner must be sufficient to dissipate the reaction heat.

- The construction materials must be compatible with the chemical environment (e.g., NOx gases), such that corrosion cannot lead to a loss of confinement.

- The maximum pressure resulting from heat and radiolytic gas generation must not exceed the design pressure for the system, unless redundant pressure relief features are described.

- The maximum release of fission gases must not exceed applicable regulatory criteria.

- The maximum release of hazardous chemicals must not exceed applicable regulatory criteria (this should include any potential effect on workers in the production facility).

- Monitoring should be provided for concentrations of hazardous chemicals and fission products to detect buildup and leaks.

Chapter 5 contains acceptance criteria for any credited cooling function of the gas management system.

Technical Rationale

Most of these are events that can result in release pathways through the loss of confinement (e.g., by deflagration or detonation, corrosion, or overpressurization). The exception to this is criticality, which will result in the generation of more fission products (although they will be small compared to those generated during normal reactor operations). Criticality should not be allowed outside the reactor vessel, because there are no means to control it or adequately protect personnel outside such an environment. Ideally, all equipment that is connected to the reactor vessel should have favorable geometry (i.e., the contained SNM will always have a sub-critical multiplication factor), although at some point a connection might need to be made to non-favorable geometry. Maintaining solution and aerosolized fuel within the reactor core (ideally) or the favorable geometry part of the gas management system (as an anticipated upset) is crucial. For chemical releases, both the effects of NOx on personnel and on equipment must be considered.

Review Procedures

The reviewer should confirm that the design of the gas management system and the associated analysis are sufficient to provide reasonable assurance of safe operation of the reactor and compliance with all applicable chemical and radiological release criteria.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The applicant has described the system in sufficient detail to prevent criticality outside the reactor vessel, caused by the entrainment of uranium in the gas, slow accumulation over time, or backflow of solution from the reactor vessel.

- The applicant has described the system in sufficient detail to prevent the occurrence of a radiolytic hydrogen deflagration or detonation that could breach confinement and result in exceeding the applicable regulatory limits on hazardous chemical or fission product releases.

- The applicant has designed the system to withstand the maximum pressure that could occur during credible power oscillations, so as to avoid breaching confinement and exceeding applicable regulatory limits.

- The applicant has designed the system to allow for control of the reactor during possible explosions or increases in pressure.

- The applicant has designed the system to be compatible with the chemical environment to which it will be exposed, avoiding corrosion that could result in a release of hazardous chemicals or fission products exceeding applicable regulatory limits.

- The applicant has designed sufficient surge capacity to contain hazardous chemicals and allow for the decay of fission products until they can be released in accordance with applicable regulatory limits.

Technical Rationale

These conclusions are driven by the consideration of hazards discussed previously.

4a2.8 References

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2. Fluid Fueled Reactors "Part 1 Aqueous Homogeneous Reactors," James A. Lane, editor, Addison Wesley, 1958, http://moltensalt.org/references/static/downloads/pdf/.

3. C. Cappiello, T. Grove, and R. Malenfant, "Lessons Learned from 65 Years of Experience with Aqueous Homogenous Reactors," LA-UR-10-02947, Los Alamos National Laboratory, May 2010.

4. Barbry, F., "French solution reactor experience and contribution to the Feasibility of the use of LEU Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes," IAEA-CRP/RCM, February 2010.

5. Botts, J.L., Raridon, R.J., Costanzo, D.A., "Density, Acidity, and Conductivity Measurements of Uranyl Nitrate/Nitric Acid Solutions," ORNL/TM-6491, Oak Ridge National Laboratory, Oak Ridge, TN, October 1978.

6. Bunker, M.E. "Status Report on the Water Boiler Reactor," LA-2854, Los Alamos Scientific Laboratory, Los Alamos, NM,1963.

7. Jerden, J.L. and Vandegrift, G.F., "Predictive Modeling of Solution Chemistry in an Aqueous Homogenous Reactor Used For Mo-99 Production," 30th International Meeting on Reduced Enrichment for Research and Test Reactors," Washington D.C., October 5-9, 2008.

8. Kimpland, R., Hayes, D., Grove, T., "Stability Analysis of the SUPO Reactor," LA-UR-04318, Los Alamos National Laboratory, Los Alamos, NM, June 2010.

9. McLaughlin, T.P., Monahan, S.P., Pruvost, N.L., Frolov, V.V., Ryazanov, B.G., Svirdov, V.I., "A Review of Criticality Accidents," LA-13638, Los Alamos, NM.

10. Mishosi Y. Yamane Y., Okubo K, Reverdy, L., Grivot, P., Konishi, H., Mitake, S., Liem, P.H. "Inter-code Comparison Exercise for Criticality Excursion Analysis [Benchmark Phase I: Pulse Mode Experiments with Uranyl Nitrate Solution in the TRACY and SILENE Facilities]," Nuclear Energy Agency, Organization for Economic Co-operation and Development, 2009.

11. Parkins, W.E., Wilson, R.F., McElroy, W.N., Henry, J.O., Williams, R.O., "Aqueous Homogenous Type Research Reactors," Second United Nations International Conference on the Peaceful Uses of Atomic Energy," 1958.

12. Remley, M.E., Flora, J.W., Hetrick, D.L., Muller, D.R., Gardner, E.L., Wimmer, R.E., Stitt, R.K., Gamble, D.P., "Experimental Studies on the Kinetic Behavior of Water Boiler Type Reactors," Proc. 2nd United Nations Int. Conf. Peaceful Uses of Atomic Energy, Geneva, Switzerland, Vol. 11, United Nations, September 1958.

13. Souto, F.J., Kimpland, R.H., Hegar, A.S., "Analysis of the Effects of Radiolytic-Gas Bubbles on the Operation of Solution Reactors for the Production of Medical Isotopes," Nuclear Science Engineering, Vol. 150, 2005.

14. Spiegler, P., Bumpus, C.F., Norman, A., "Production of Void and Pressure By Fission Track Nucleation of Radiolytic Gas Bubbles During Power Bursts in a Solution Reactor," NAA-SR-7086, Atomics International, Canoga Park, CA, 1962.

15. Williams M.M.R., "Calculation of the Void Fraction and Void Coefficient in an Aqueous Homogeneous Reactor," Nuclear Science and Engineering, Vol. 168, 2011.

4b Radioisotope Production Facility Description

The structures, systems, and components that should be discussed in this section shall include processes containing SNM, particularly when material is separate from the reactor.

4b.1 Facility and Process Description

This section of the SAR expands the reactor summary description to include an isotope production facility. It should include the principal safety considerations that were factored into the design, construction, and operation. The design bases and functions of the systems and components should be presented in sufficient detail to allow a clear understanding and to ensure that the facility can be operated for its intended purpose and within regulatory limits for ensuring the health and safety of the operating staff and the public. Drawings and diagrams

should be provided as necessary to allow a clear and general understanding of the physical facility features and of the processes involved.

Areas of Review

The summary should include the name, amount, and specifications (including chemical and physical forms) of the SNM that will be in process. The license application should include a list of byproduct materials (identity and amounts) in the process solutions, finished products, and wastes from the process.

It should also include a detailed description of the design and construction of the equipment that will be used while processing SNM outside the reactor. It should include enough detail to identify materials that may have moderating, reflecting, or other nuclear-reactive properties.

Acceptance Criteria

The summary should be found acceptable if it includes the following:

- The summary describes the chemical and physical forms of SNM in process, including the maximum amounts of SNM in process in various building locations.

- The application presents a summary description of the raw materials, byproducts, wastes, and finished products of the facility. This information should include data on expected levels of trace impurities or contaminants (particularly fission products or transuranic elements) characterized by identity and concentration.

- The application contains a general description of provisions for criticality control including adherence to the double-contingency principle.

- The application contains a description of adequate protections against chemical risks produced from licensed material, facility conditions, which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

Review Procedures

The information submitted by the applicant in this section is informative in nature and requires no technical analysis. In addition, the reviewers use the information in this section only as background for the more detailed descriptions in later sections of the application. Therefore, the primary reviewer ascertains whether the descriptive information is consistent with the information presented in the accident analysis and emergency management plan.

Evaluation Findings

If the license application includes sufficient information to provide a general understanding of the production facility, the radioisotope production process and assurance that the regulatory acceptance criteria can be achieved, the staff should conclude that this evaluation is complete.

4b.2 Processing Facility Biological Shield

Biological shields are designed to protect personnel and minimize radiation exposures. The principal design objective is to protect the workers and the public. This section should present the design bases and a detailed description of the biological shield.

Areas of Review

The guidance provided in NUREG-1537, Part 2, Section 4.4, is applicable, provided that any reference to a reactor facility is understood to mean a radioisotope production facility, as appropriate.

Acceptance Criteria

In addition to the acceptance criteria provided in NUREG-1537, Part 2, Section 4.4, applicable to a radioisotope production facility, the following criteria should be considered:

- The shield design should include a detailed description of the design and construction of the biological shield in which radiochemical processes will be conducted. The shielding design basis, including any calculations that were used to prescribe the required form and substance of the shield, should be provided. It should also describe the functional design of the biological shield, showing entry and exit facilities for products, wastes, process equipment, and operating staff.

- The objective of the shield design should be to ensure that the projected radiation dose rates and accumulated doses do not exceed the limits of 10 CFR Part 20 and the guidelines of the facility's ALARA program.

- The application should include a detailed description of the ventilation system for the biological shield structure, including (1) the design basis and function, (2) the design and location of vent ducting, filters, and fans, (3) details on vent system operating limits under both normal and emergency operating conditions, and (4) the design basis and function of all filtering and sequestration systems provided to control release of particulate and gaseous airborne radioactive contaminants to the environment under normal and emergency conditions of operation.

All of the essential physical and operational features of the biological shield that are required to prevent the release of radioactive material and to maintain radiation levels below applicable radiation exposure limits prescribed in 10 CFR Part 20 for the protection of the staff and the public should be identified and included in the proposed technical specifications in Chapter 14.

Review Procedures

The guidance in the "*Review Procedures"* part of NUREG-1537, Part 2, Section 4.4, is applicable.

Evaluation Findings

The guidance in the "*Review Procedures"* part of NUREG-1537, Part 2, Section 4.4, is applicable.

4b.3 Radioisotope Extraction System

This section of the SAR should provide the design and detailed description of the radioisotope extraction process. The specific information required by Part 1, "Standard Format and Content," of this ISG should be the subject of this review.

Areas of Review

The information should provide a complete description, including diagrams and drawings, as necessary, in sufficient detail to give a clear understanding of the extraction process and how the process can be performed safely within regulatory limits.

Acceptance Criteria

The application should provide processing details such as the following:

- description of the SNM in terms of physical and chemical form, volume in process, and radioactive inventory in process.
- description of the sequence of radioisotope extraction and the time increments involved.
- description of the processing apparatus, including tanks, piping, separation columns, reagent vessels, materials of construction, and process monitoring or control equipment.
- description of any required criticality control measures that are designed into the process systems and components. A detailed description of the Criticality Safety Program (CSP) is given in Chapter 6b.3, Part 2 of this ISG.
- description of any hazardous chemicals that are used or that may evolve during the process along with a description of provisions to protect the staff and the public from exposure.
- all of the essential physical and operational features of the radioisotope extraction system that are required to prevent the release of radioactive material and to maintain radiation levels below applicable radiation exposure limits prescribed in 10 CFR Part 20 and that would limit the consequences of the release of chemicals in a manner consistent with the criteria set forth in 10 CFR 70.61, or alternative limits proposed and justified by the applicant, for the protection of the staff and the public should be identified and included in the proposed technical specifications in Chapter 14.

Review Procedures

The primary reviewer should ascertain whether the descriptive information presented is sufficient to satisfy the objective of providing a clear understanding of the processes and whether it is consistent with the information presented in the accident analysis, engineered safety features (ESFs), and TS that are included in other chapters of the application.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions for the safety evaluation report:

- The process description(s) in the SAR provide a detailed account of the SNM in process along with any included fission-product radioactivity. The description of the post-irradiation processing after the fuel is removed from the reactor gives a clear understanding that these operations can be conducted safely in this facility.

- The processing facilities and apparatus have been described in sufficient detail to provide confidence that the SNM and byproduct material can be controlled throughout the process so that the health and safety of the public will be protected.

- The criticality control measures provided throughout the process are in accordance with double-contingency principle and the processing facility provides suitable defense-in-depth for the contained processes.

- Sufficient technical specifications and ESFs have been developed that provide safe margins for all safety-related process variables.

4b.4 SNM Processing and Storage

The contents of this section describe the processing components and procedures involved in handling, processing, and storing SNM.

4b.4.1 Processing of Irradiated Special Nuclear Material

Areas of Review

This section of the SAR should contain information about processes with irradiated SNM as follows:

- The summary should specify the maximum amounts of SNM in storage or in process in various facility locations. It should describe the chemical and physical forms of SNM in process. The application presents a summary description of the process(es). This information should include data on expected levels of radioactivity, broken down by radionuclide (particularly volatile and long-lived fission products and transuranic elements). The radionuclide inventory should be projected with decay time and tabulated at various times throughout the process. The description should identify points in the process where major separations are performed and describe the pathway of the separated radionuclides or other constituents.

- The application should provide a clear description of the process systems and components to allow a good understanding that the facility can be operated safely within regulatory limits. In particular, this summary should identify the proposed possession at the facility of any moderator or reflector with special characteristics, such as beryllium or graphite. The processing materials should be compatible with the process material contained to withstand the effects of corrosion and radiation. The processing system should be designed to manage any fission-product or radiolysis gases that evolve in the process.

- The application should include a detailed description of any required criticality control measures that are designed into the process systems and components

- The application should include a description of any hazardous chemicals that are used or that may evolve during the process along with a description of provisions to protect the staff and the public from exposure.

Acceptance Criteria

The application should provide processing details such as:

a. Description of the SNM in terms of physical and chemical form, volume in process, and radioactive inventory in process.

b. Description of the sequence of process steps and the time increments involved.

c. Description of the processing apparatus including any piping, separation columns, reagent vessels, materials of construction, process monitoring or control equipment.

d. Description of auxiliary equipment or apparatus that is required to remove or control heat and volatile gases that could evolve from the process.

e. The application includes a detailed description of any required criticality control measures that are designed into the process systems and components. A detailed description of the Criticality Safety Program (CSP) is given in Section 6b.3, Part 2 of this ISG.

f. The application includes a description of any hazardous chemicals that are used or that may evolve during the process along with a description of provisions to protect the staff and the public from exposure.

All of the essential physical and operational features of the irradiated SNM processing system that are required to prevent the release of radioactive material and to maintain radiation levels below applicable radiation exposure limits prescribed in 10 CFR Part 20 for the protection of the staff and the public should be identified and included in the proposed technical specifications in Chapter 14.

Review Procedures

The primary reviewer should ascertain whether the descriptive information presented is sufficient to satisfy the objective of providing a clear understanding of the processes and that it is consistent with the information presented in the accident analysis, engineered safety features and technical specifications that are included in other chapters of the application.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions for the safety evaluation report:

- The process description(s) in the SAR provides a detailed account of the SNM in process along with any included fission-product radioactivity. The process descriptions for reconditioning fuel for continued use, for disposal as waste or for some other appropriate purpose are sufficient to provide a clear understanding that these operations can be conducted safely in this facility.

- The processing facilities and apparatus have been described in sufficient detail to provide confidence that the SNM and byproduct material can be controlled throughout the process so that the health and safety of the public will be protected.

- The criticality control measures provided are in accordance with double-contingency principle and the processing facility provides suitable defense-in-depth for the contained processes.

- Sufficient technical specifications and ESFs have been developed that provide safe margins for all safety-related process variables.

4b.4.2 Processing of Unirradiated Special Nuclear Material

Operations with unirradiated SNM in the form of reactor fuel are generally addressed in NUREG-1537, Chapter 9, "Auxiliary Systems." This discussion may be located in Chapter 9 or in this section of Chapter 4. This ISG presents it in Section 4b.4.2 in the interest of maintaining the continuity of discussion of all operations with SNM in the radioisotope production facility.

Regarding new fuel entering the facility, the application should provide a narrative describing all operations involving receipt, qualification, movement, storage, and preparation for use in the reactor. The application should explain the technical basis for the design and implementation of each operation.

Areas of Review

Areas of Review are prescribed in this section of Part 1, format and content of this ISG

Acceptance Criteria

The reviewer should ascertain that the application includes the information prescribed in Part 1 of this section of the ISG as follows:

- A description of all operations involving SNM before it is used as fuel in the reactor (e.g., receipt, storage, transfer and preparation for use in the reactor).

- A description of the detailed procedures used in each operation including a description of the quantity, physical form and chemical form of the SNM involved in each operation and enough detail to enable development and analysis of potential accident sequences in Chapter 13.

- The location of each operation with SNM.

- A description of the equipment employed in each operation.

- A description of any criticality safety features and management measures per the requirements of Section 6b, Parts 1 & 2 of this ISG.

- A description of any preventive or mitigative features and management measures to control the use of hazardous chemicals that are used with or evolve from operations with SNM (refer to ISG section 12.1.6, “Production Facility Safety Program”).

All of the essential physical and operational features of the unirradiated SNM processing system that are required to prevent the release of radioactive material and to maintain radiation levels below applicable radiation exposure limits prescribed in 10 CFR Part 20 for the protection of the staff and the public should be identified and included in the proposed technical specifications in Chapter 14.

Review Procedures

The primary reviewer should ascertain whether the descriptive information presented is sufficient to satisfy the objective of providing a clear understanding of the processes and that it is consistent with the information presented in the accident analysis, engineered safety features and technical specifications that are included in other chapters of the application.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions for the safety evaluation report:

- The process description(s) in the SAR provide a detailed account of the SNM in process. Each operation with SNM in receipt, transport, storage or preparation for use is described in sufficient detail to show that there is reasonable assurance that these operations can be conducted safely.

- The storage, transport and processing facilities and apparatus have been described in sufficient detail to provide confidence that the SNM can be controlled throughout the process so that the health and safety of the public will be protected.

- The criticality control measures provided are in accordance with double-contingency principle and the processing facility provides suitable defense-in-depth for the contained processes.

- Sufficient technical specifications and ESFs have been developed that provide safe margins for all safety-related process variables.

5 COOLANT SYSTEMS

NUREG-1537, Part 2, Chapter 5 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the coolant system for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 5a1, "Heterogeneous Reactor Coolant Systems "
- 5a2, "Aqueous Homogeneous Reactor Cooling Systems"
- 5b, "Radioisotope Production Facility Cooling Systems"

This document specifies the ISG for each of these options below.

5a1 Heterogeneous Reactor Coolant Systems

NUREG-1537, Part 2, Chapter 5 should be used for guidance in preparing this chapter.

5a2 Aqueous Homogeneous Reactor Cooling Systems

Replace Chapter 5 of NUREG-1537, Part 2, in its entirety with the following guidance: This chapter contains guidance for evaluating the design bases, descriptions, and functional analyses of the AHR cooling systems. The principal purpose of the cooling system is to safely remove the fission and decay heat from the fuel and dissipate it to the environment. In an AHR, the primary cooling systems are those components and systems that remove heat from the core, where the core consists of that region of the vessel occupied by the solution containing the fission power producing fissile material. In an AHR, the core geometry may change with time, because of changes in density and voiding of the solution. The core does not include that part of the fuel solution that may become entrained into the cover gas or the vapor above the core.

For an AHR, the applicant should describe and discuss, in this chapter, all systems that remove and dispose of the heat from the reactor. The design bases of the core cooling systems for the full range of normal operation should be derived from Chapter 4 of the SAR.

For an AHR, the primary cooling system removes heat from the core by being in direct contact with the fuel solution through a structural barrier or by the heat removal accompanying the fluid mass transport out of and into the fuel solution (i.e., evaporation and condensation); it is the cooling system that removes the largest fraction of the core heat.

The AHR may include other cooling systems that remove a significant fraction of the total heat produced by the core and fission products, however. Cooling systems may include core heat removal by radiolysis gas management systems or passive heat removal through the reactor vessel to a surrounding pool. Reactors operating at very low power levels may be cooled solely by passive heat removal through the vessel wall.

In addition, the "Secondary Coolant Systems" for an AHR are defined as those systems and components that transfer heat from the primary cooling systems to the environment or intermediate heat sink(s). Secondary cooling systems may consist of additional heat

exchangers and pumps to circulate the coolant. The secondary coolant system is that which removes the heat from the primary cooling system to the environment.

In this chapter, the applicant should identify and discuss reactor cooling systems, including auxiliary and reactor core subsystems, that remove heat from the reactor core, as well as major components. The description should include, for example, information on core cooling coils that might be the primary cooling system, and the partition of heat removal by additional reactor cooling systems that remove core heat directly, such as the radiolysis gas management system, or passively, through the reactor vessel. These additional reactor cooling systems should be summarized in Section 5a2.1 and discussed in detail in Chapter 4, "Reactor Description," if reactor core systems such as gas management systems, are involved. Chapter 9, "Auxiliary Systems," should discuss details of auxiliary systems using coolant, other than the primary cooling system, such as passive core cooling by the pool surrounding the vessel.

This chapter should also describe and discuss all auxiliary systems and subsystems that use and contribute to the heat load of either the primary or secondary cooling system. Chapter 9, "Auxiliary Systems," should discuss any auxiliary systems using coolant from other sources, such as building service water. The design bases of any features of the core cooling system designed to respond to potential accidents or to mitigate the consequences of potential accidents should be derived from the analyses in Chapter 13, "Accident Analyses." These features should be summarized in this chapter and discussed in detail in Chapter 6, "Engineered Safety Features," of the SAR. In this chapter, the applicant should discuss and reference the TS needed to ensure operability consistent with the assumptions in the SAR analyses.

This chapter gives the review plan and acceptance criteria for information on the heat removal systems. The information suggested for this section of the SAR is outlined in Chapter 5 of the format and content guide.

5a2.1 Summary Description

In this section, the applicant should give a brief description of reactor cooling systems, including the supplementary core heat removal pathways, summarizing the principal features. Information should include the following:

- type of coolant: liquid, gas, or solid (conduction to surrounding structures)
- type of cooling system: open or closed to the atmosphere
- type of coolant flow in the primary and secondary cooling systems and the method of heat disposal to the environment
- capability to provide sufficient heat removal to support continuous operation at full licensed power
- special or facility-unique features

The applicant should summarize the principal features of the reactor cooling systems unique to the AHR. In addition to the primary cooling system, other means of heat transport from the core should be described, including the corresponding amount of heat transported from the core and

the fraction of total core heat removed. These are the supplementary core heat removal pathways.

5a2.2 Primary Cooling System

Areas of Review

For an AHR, the term “primary cooling system” replaces the term “primary coolant system.” The primary cooling systems for an AHR are those components and systems that remove heat from the core.

The primary cooling system is a key component in the overall design and should have the capability to do the following:

- remove the fission and decay heat from the core during normal reactor operation and decay heat during reactor shutdown
- transfer the heat to a secondary cooling system for controlled dissipation to the environment
- maintain high water quality to limit corrosion of cooling coils, control and safety rods, reactor vessel or pool, and other essential components
- prevent uncontrolled leakage or discharge of contaminated coolant to the unrestricted environment

The basic requirements for these functions are generally derived and analyzed in other chapters of the SAR. In this chapter, the applicant should describe how the cooling system provides these functions. Section 5a2.2 of the format and content guide discusses specific areas of review for this section.

The liquid fuel solution in an AHR may be highly corrosive and will contain mobile radioactive fission product species. In addition, no fuel cladding barrier exists for the fuel solution, as is characteristic of solid fuel elements in conventional non-power reactors. Therefore, it may be appropriate to consider solid material barriers that isolate the primary coolant from the fuel (such as cooling tube walls) as analogous to fuel cladding. Because this could affect the design of AHR cooling systems, consideration should be given to the following:

- construction materials of components and fabrication specifications of safety-related components as they relate to corrosion resistance to the fuel solution.
- coolant quality requirements for operation and shutdown conditions, given the presence of liquid fuel solution on the core side of components (due to the fluid and potentially volatile nature of the fuel and its constituents, prevention of corrosion on either side of the cooling system components is of major concern).
- locations, designs, and functions of essential components, such as cooling coils located in the reactor vessel, as these components ensure that the primary cooling system is operable and that uncontrolled loss or discharge of fuel solution from the fuel core tank into the primary cooling system does not occur.

Section 5a2.2 of the format and content guide discusses specific areas of review for this section. For an AHR, the applicant should provide information in this section on the reactor cooling systems unique to these principal features of AHRs.

Acceptance Criteria

The acceptance criteria for the information on the primary cooling system include the following:

- Chapter 4 of the SAR should contain analyses of the reactor core, including coolant parameters necessary to ensure removal of heat from the core. Safety limits (SLs) and LSSSs and limiting conditions for operation (LCOs) should be derived from those analyses and be included in the TS. Examples of cooling system variables on which LSSSs and LCOs may be established are maximum thermal power level for operation, minimum and maximum coolant temperatures, minimum and maximum coolant flow rates, and coolant pressure range. The analyses in this section should show that the components and the functional design of the primary cooling system will ensure that no LSSS will be exceeded through the normal range of reactor operation. The analyses should address forced flow or natural-convection flow in the primary cooling system, as applicable.

- The functional design should show that safe reactor shutdown and decay heat removal are sufficient to ensure fuel boundary integrity for all possible reactor conditions, including potential accident scenarios. Scenarios that postulate loss of flow or loss of coolant should be analyzed in Chapter 13 and the results summarized in this section of the SAR.

- The descriptions and discussions should show that sufficient instrumentation, coolant parameter sensors, and control systems are provided to monitor and ensure stable coolant flow, respond to changes in reactor power levels, and provide for a rapid reactor shutdown in the event of loss of cooling. There should also be instrumentation for monitoring the radiation of the primary coolant, because elevated radiation levels could indicate a loss of primary coolant barrier integrity. There should be routine sampling for gross radioactivity in the coolant and less frequent radioactive spectrum analysis to identify the isotopes and concentrations found in the coolant. This spectrum analysis may also detect primary cooling system integrity failure at its earliest stages.

- The primary coolant should provide a chemical environment that limits corrosion of the primary coolant barrier, control and safety rod surfaces, reactor vessels or pools, and other essential components. Other requirements for water purity should be analyzed in the SAR, and proposed values of conductivity and pH should be justified. Experience in non-power reactors has shown that the primary water conditions, electrical (conductivity ≤5 μmho/cm) (micro-mho is a measure of electrical conductivity in water, and the reciprocal of micro-ohm — both terms are a measure of water purity) and pH between 5.5 and 7.5 can usually be attained with good housekeeping and a good filter and demineralizer system. Chemical conditions should be maintained, as discussed in Section 5a2.4 of this standard review plan.

- Radioactive species, including nitrogen-16 and argon-41, may be produced in the primary coolant. Additional radioactivity may occur as a result of neutron activation of

coolant contaminants and fission product leakage from the fuel. Provisions for limiting radiological hazards for personnel should maintain potential exposures from coolant radioactivity below the requirements of 10 CFR Part 20 and should be consistent with the facility's ALARA program. To ensure that facilities or components for controlling, shielding, or isolating nitrogen-16 are acceptable, potential exposures should not exceed the requirements of 10 CFR Part 20 and should be consistent with the facility's ALARA program. Section 5a2.6 of this standard review plan discusses the nitrogen-16 control system.

- Argon-41 is another radionuclide that can be produced in the primary cooling system. Because it may be an important radionuclide released to the environment during a reduction-in-cooling event, special analyses and discussion of its production and consequences should be provided in Chapter 11 of the SAR. If any special design or operational features of the primary cooling system modify or limit exposures from argon-41, they should be discussed in this section of the SAR. This discussion should demonstrate that any facilities or components added to the primary cooling system to modify argon-41 releases can limit potential personnel exposures to the values found acceptable in Chapter 11.

- Closed systems also may experience a buildup of hydrogen in air spaces in contact with the coolant. The discussion should show that it is not possible to have hydrogen build up to concentrations that are combustible. This may require gas sweep systems and hydrogen concentration monitoring. Chapter 9 should discuss these systems.

- Because the primary cooling system may provide essential heat removal from the core, the system design should avoid uncontrolled release or loss of coolant. Some design features to limit losses include locating components of the primary cooling system above the core level, avoiding drains or valves below core level in the pool or tank, providing siphon breaks in piping that enters the primary vessel or pool, and providing check valves to preclude backflow. The designs and locations of such features should provide reasonable assurance that primary system boundary failure is very unlikely. A potential accident of rapid loss of coolant should be analyzed in Chapter 13 and summarized in this section of the SAR.

- If contaminated coolant were lost from the primary cooling system, the design and analyses should ensure that potential personnel exposures and uncontrolled releases to the unrestricted environment do not exceed acceptable radiological dose consequence limits derived from the accident analyses. The radiological consequences from the contaminated coolant should be discussed in Chapter 11 and summarized in this section of the SAR. Necessary surveillance provisions should be included in the TS.

- The primary coolant should provide a chemical environment that limits corrosion of primary coolant barrier material and components of the primary cooling system, given the presence of liquid fuel solution on the core side of the primary coolant barrier material. The barrier should prevent the fuel solution from contaminating the primary coolant, and the primary coolant from diluting the fuel solution, with accompanying reactivity and chemistry effects.

- The design of the primary cooling system components ensures that the system is operable and that uncontrolled loss or discharge of fuel solution from the fuel core tank

into the primary system does not occur. The system design should avoid uncontrolled release of fuel solution to the primary coolant. If contaminated coolant were lost from the primary cooling system, the design and analyses should ensure that potential personnel exposures and uncontrolled releases to the unrestricted environment do not exceed acceptable radiological dose consequence limits derived from the accident analyses. The designs and locations of such essential components as fuel tank core cooling coils should provide this reasonable assurance. The application should demonstrate that the design of the primary cooling system can limit potential personnel exposures to the values found acceptable in Chapter 11.

- Acceptance criteria for fuel integrity and fuel cladding integrity limits should be limits unique to the AHR liquid fuel solution core, as defined in Chapter 4. These criteria provide the acceptable margin to the breach of the fuel solution boundary integrity.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should compare the functional design and operating characteristics of the primary cooling system with the bases for the design presented in this and other relevant chapters of the SAR. The system design should meet the appropriate acceptance criteria presented above, considering the specific facility design under review.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which should be included in the staff's safety evaluation report:

- The primary cooling system is designed in accordance with the design bases derived from all relevant analyses in the SAR.

- Design features of the primary cooling system and components give reasonable assurance of primary system boundary integrity under all possible reactor conditions. The system should be designed to remove sufficient fission heat from the core to allow all licensed operations without exceeding the established LSSSs that are included in the TS.

- The design and location of primary cooling system components have been specifically selected to avoid coolant loss that could lead to primary system boundary failure or to an uncontrolled release of excessive radioactivity.

- The primary cooling system is designed to convert, in a passive or fail-safe method, to natural-convection flow sufficient to avoid loss of fuel integrity *(this feature is evaluated in conjunction with the reviews of the reactor description and accidents. It is applicable to licensing AHRs to operate with forced-convection coolant flow).*

- The chemical quality of the primary coolant will limit corrosion of the primary cooling coils, the control and safety rod cladding or thimbles, the outside of the reactor vessel

and other essential components of the primary cooling system for the duration of the license and for the projected utilization time of the fuel.

- Systems are present that will prevent hydrogen concentrations from reaching combustible limits.

- Primary cooling system instrumentation and controls are designed to provide all necessary functions and to transmit information on the operating status to the control room.

- The TS, including testing and surveillance, provide reasonable assurance of necessary primary cooling system operability for reactor operations, as analyzed in the SAR.

- The design bases of the primary cooling system provide reasonable assurance that the environment and the health and safety of the public will be protected.

5a2.3 Secondary Cooling System

Areas of Review

The secondary cooling system of an AHR should be designed to transfer reactor heat from the primary and possibly other cooling systems to the environment. The secondary cooling system should be designed for continuous operation at the licensed power level. Therefore, the secondary cooling system in these reactors must be designed to dissipate heat continuously. In this section of the SAR, the applicant should justify how any necessary heat dissipation is accomplished. Section 5a2.3 of the format and content guide discusses specific areas of review for this section.

Acceptance Criteria

The acceptance criteria for the information on the secondary cooling system include the following:

- The analyses and discussions in Section 5a2.3 should demonstrate that the secondary cooling system is designed to allow the primary cooling system to transfer heat, as necessary, to ensure fuel integrity. The analyses should address primary cooling systems operating with forced flow, natural-convection flow, or both, for reactors licensed for both modes. The design should show that the secondary cooling system is capable of dissipating all necessary fission and decay heat for all potential reactor conditions, as analyzed in the SAR.

- The primary coolant will usually contain radioactive contamination. The design of the total cooling system should ensure that release of such radioactivity through the secondary cooling system to the unrestricted environment would not lead to potential exposures of the public in excess of the requirements of 10 CFR Part 20 and the ALARA program guidelines. Designs should ensure that the primary cooling system pressure is lower than the secondary cooling system pressure across the heat exchanger under all anticipated conditions, that the secondary cooling system is closed, or that radiation monitoring and an effective remedial capability are provided. The secondary cooling system should prevent or acceptably mitigate an uncontrolled release of radioactivity to

the unrestricted environment. Periodic samples of secondary coolant should be analyzed for radiation. Action levels and required actions should be discussed.

- The secondary cooling system should accommodate any heat load required of it in the event of a potential ESF operation or accident conditions, as analyzed in Chapters 6 and 13 of the SAR.

- The secondary cooling system design should provide for any necessary chemical control to limit corrosion or other degradation of the heat exchanger and prevent chemical contamination of the environment.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should verify that all reactor conditions, including postulated accidents, requiring transfer of heat from the primary cooling system to the secondary cooling system have been discussed. The reviewer should verify that the secondary cooling system is capable of removing and dissipating the amount of heat and the thermal power necessary to prevent accidents. The reviewer should also confirm the analyses of secondary cooling system malfunctions, including the effects on reactor safety, fuel integrity, and the health and safety of the public.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- Design features of the secondary cooling system and components will allow the transfer of the necessary reactor heat from the primary cooling system under all possible reactor conditions.

- Locations and design specifications for secondary cooling system components ensure that malfunctions in the system will not lead to reactor damage, fuel failure, or an uncontrolled release of radioactivity to the environment.

- Secondary cooling system instrumentation and controls are designed to provide all necessary functions and to transmit information on the operating status to the control room.

- The secondary cooling system is designed to respond, as necessary, to such postulated events as a reduction in cooling caused by either a loss of primary coolant or primary coolant flow.

- The TS, including testing and surveillance, provide reasonable assurance of necessary secondary cooling system operability for normal reactor operations.

5a2.4 Primary Coolant Cleanup System

Areas of Review

Experience has shown that potable water supplies are usually not sufficiently pure for use as a reactor primary coolant without additional cleanup. The AHR concepts considered here consist of a configuration with a primary cooling system immersed in fuel solution. The primary coolant is separated from the fuel solution by a material barrier that isolates the mobile fission products from the cooling system components. The primary cooling coil material is an example of a primary coolant barrier. The purity of the primary coolant should be maintained as high as reasonably possible for the following reasons:

- to limit the chemical corrosion of primary cooling coils, control and safety rod cladding, reactor vessel or pool, and other essential components in the primary cooling system

- to limit the concentrations of particulate and dissolved contaminants that might become radioactive by neutron irradiation

Section 5a2.4 of the format and content guide discusses specific areas of review for this section.

Acceptance Criteria

The acceptance criteria for the information on the primary coolant cleanup system include the following:

- The primary coolant quality should be maintained in the ranges established as acceptable in Chapters 4 and 11 of the SAR. Experience has shown that water quality conditions and electrical conductivity ≤5 μmho/cm and pH between 5.5 and 7.5, can usually be achieved by good housekeeping and a cleanup loop with particulate filters and demineralizers. These water quality conditions would be acceptable unless the SAR analyses establish other purity conditions as acceptable.

- Radioactively contaminated resins and filters should be disposed of or regenerated in accordance with radiological waste management plans discussed in Chapter 11, and potential exposures and releases to the unrestricted environment shall not exceed the requirements of 10 CFR Part 20 and should be consistent with the facility's ALARA program.

- The location, shielding, and radiation monitoring of the water cleanup system for routine operations and potential accidental events should be such that the operating staff and the public are protected from radiation exposures exceeding the requirements of 10 CFR Part 20 and acceptable radiological consequence dose limits for accidents.

- The location and functional design of the components of the water cleanup system should ensure the following:

  – Malfunctions or leaks in the system do not cause uncontrolled loss or release of primary coolant.

– Personnel exposure and release of radioactivity do not exceed the requirements of 10 CFR Part 20 and are consistent with the facility's ALARA program.

– Safe reactor shutdown is not prevented.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should compare the design bases for the primary coolant water quality with the design bases by which the primary cooling cleanup system will achieve the requirements. The comparison should include performance specifications, schematic diagrams, and discussion of the functional characteristics of the cleanup system. The reviewer should evaluate (1) design features, to ensure that leaks or other malfunctions would not cause inadvertent damage to the reactor or personnel exposure, and (2) the plan for control and disposal of radioactive filters and demineralizer resins.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which should be included in the staff's safety evaluation report:

- The design bases and functional descriptions of the primary water cleanup system give reasonable assurance that the required water quality can be achieved. The design ensures that corrosion and oxide buildup of cooling coils and other essential components in the primary cooling system will not exceed acceptable limits.

- The primary coolant cleanup system and its components have been designed and selected so that malfunctions are unlikely. Any malfunctions or leaks will not lead to radiation exposure to personnel or releases to the environment that exceed the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines.

- The plans for controlling and disposing of radioactivity accumulated in components of the primary water cleanup system, which results from normal operations and potential accident scenarios, conform to applicable regulations, including 10 CFR Part 20 and acceptable radiological consequence dose limits for accidents.

- The TS, including testing and surveillance, provide reasonable assurance of necessary primary water cleanup system operability for normal reactor operations.

5a2.5 Primary Coolant Makeup Water System

Areas of Review

During operations, it may be necessary to replace or replenish the primary coolant. Coolant may be lost through radiolysis, leaks from the system, and other operational activities. It might also be plausible that primary coolant is bled off to storage or holding tanks where evaporation would reduce makeup inventory. Although each reactor should have a makeup water system or procedure to meet projected operational needs, the system need not be designed to provide a

rapid, total replacement of the primary coolant inventory. Section 5a2.5 of the format and content guide discusses specific areas of review for this section.

Acceptance Criteria

The acceptance criteria for the information on the primary coolant makeup water system include the following:

- The projected loss of primary coolant inventory for anticipated reactor operations should be discussed. The design or plan for supplying makeup water should ensure that those operational requirements are satisfied.

- If storage of treated makeup water is required by the design bases of the primary cooling system, the makeup water system or plan should ensure that such water is provided.

- Not all AHRs must provide makeup water through hardware systems directly connecting the reactor to the facility's potable water supply. However, for those that do, the makeup water system or plan should include components or administrative controls that prevent potentially contaminated primary coolant from entering the potable water system.

- The makeup water system or plan should include features to prevent loss or release of coolant from the primary cooling system.

- The makeup water system or plan should include provisions for recording the use of makeup water to detect changes that indicate leakage or other malfunctions of the primary cooling system.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should compare the design bases and functional requirements for replenishing primary coolant, including the quantity and quality of water, the activities or functions that remove primary coolant, and the systems or procedures to accomplish water makeup with the acceptance criteria. The review should focus, as applicable, on safety precautions to prevent overfilling the reactor cooling system, loss of primary coolant through the nonradioactive service drain system, and the release of primary coolant back through the makeup system into potable water supplies.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The design bases, functional descriptions, and procedures for the primary coolant makeup water system give reasonable assurance that the quantity and quality of water required will be provided.

- The system design or procedures will prevent overfilling the primary cooling system or a malfunction of the makeup water system, as well as the loss or release of contaminated primary coolant that would exceed the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines.

- The system design or procedures will prevent contaminated primary coolant from entering the potable water system through the makeup water system.

- The TS, including testing and surveillance, provide reasonable assurance of necessary makeup water system operability for normal reactor operations.

5a2.6 Nitrogen-16 Control System

Areas of Review

Nitrogen-16, a high-energy beta and gamma ray emitter with a half-life of approximately 7 seconds, is a potential source of high radiation exposure at water-cooled reactors. It tends to remain dissolved in the coolant water as it leaves the core. The quantity and concentration of nitrogen-16 should be considered and provisions made to control personnel exposure. Because of the relatively short half-life, potential doses can be decreased by delaying the coolant within shielded regions. If the reactor makes use of natural-convection cooling to a large open pool, stirring or diffusing the convection flow to the surface can produce a delay. For forced-flow cooling, passing the coolant through a large shielded and baffled tank can produce the delay. Section 5a2.6 of the format and content guide discusses specific areas of review for this section.

Acceptance Criteria

The acceptance criteria for information on the nitrogen-16 control system include the following:

- The reduction in personnel exposure to nitrogen-16 should be consistent with the nitrogen-16 analyses in Chapter 11 of the SAR. The total dose should not exceed the requirements of 10 CFR Part 20 and should be consistent with the facility's ALARA program.

- The system design should not decrease cooling efficiency so that any LSSS would be exceeded, or lead to an uncontrolled release or loss of coolant if a malfunction were to occur, or prevent safe reactor shutdown and removal of decay heat sufficient to avoid damage to core components and other components of the primary fission product barrier.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should evaluate the design bases and functional requirements of the system that controls personnel exposures to nitrogen-16 by (1) confirming the amount of nitrogen-16 predicted by the SAR analysis at the proposed power level and the potential personnel exposure rates, including exposures from direct radiation and airborne nitrogen-16;

(2) reviewing the type of system control and the anticipated decrease in exposure rates; (3) reviewing the effect of the proposed system on the full range of normal reactor operations; and (4) reviewing the possible effects of malfunctions of the nitrogen-16 control system on reactor safety, safe reactor shutdown, and release of contaminated primary coolant.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- Design bases and design features give reasonable assurance that the nitrogen-16 control system can function as proposed and can reduce potential doses to personnel, so that they do not exceed the requirements of 10 CFR Part 20 and are consistent with the facility's ALARA program.

- Design and functional operation of the nitrogen-16 control system give reasonable assurance that the system will not interfere with reactor cooling under anticipated reactor operating conditions and will not reduce cooling below the acceptable thermal-hydraulic performance discussed in Chapter 4 of the SAR.

- Design features give reasonable assurance that malfunction of the nitrogen-16 control system will not cause uncontrolled loss or release of primary coolant and will not prevent safe reactor shutdown.

- The TS, including testing and surveillance, provide reasonable assurance of necessary nitrogen-16 control system operability for normal reactor operations.

5a2.7 Auxiliary Systems Using Primary Coolant

Areas of Review

The primary coolant may serve functions other than cooling the reactor core. Some of these auxiliary functions could involve cooling other heated components, which may affect the heat load of the primary cooling system. Auxiliary uses of the primary coolant could affect its availability as a fuel coolant, which is its principal use. Although the principal discussions of these auxiliary systems should be located in other sections of the SAR, their effects on the coolant systems should be summarized in this section.

Acceptance Criteria

The acceptance criteria for the information on the auxiliary systems using primary coolant include the following:

- The system should remove sufficient projected heat to avoid damage to the cooled device.

- The system should not interfere with the required operation of the primary core cooling system.

- Any postulated malfunction of an auxiliary system should not cause the uncontrolled loss of primary coolant or prevent a safe reactor shutdown.

- The shielding system using primary coolant should provide sufficient protection factors to prevent personnel exposures that exceed the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines.

- The system should not cause radiation exposures or release of radioactivity to the environment that exceed the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines.

- The applicant should identify operational limits, design parameters, and surveillances to be included in the TS.

Review Procedures

The reviewer should verify that auxiliary cooling or shielding using primary coolant is described in this section of the SAR for any component (other than the core) in which potentially damaging temperature increases or excessive radiation exposures are predicted. If the potential exists for radiation heating of components near the reactor core, the reviewer should verify that the heat source, temperature increases, heat transfer mechanisms, and heat disposal have been discussed and analyzed. The reviewer should verify that the potential personnel radiation exposures from sources shielded by the primary coolant have been analyzed and that the protection factors provided by the coolant have been discussed.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, which will be included in the staff's safety evaluation report:

- The applicant has described and analyzed auxiliary systems that use primary coolant for functions other than core cooling, has derived the design bases from other chapters of the SAR, has analyzed any reactor components located in high-radiation areas near the core for potential heating that could cause damage to the reactor core or failure of the component, and has planned acceptable methods to remove sufficient heat to ensure the integrity of the components. The coolant for these systems is obtained from the purified primary cooling system without decreasing the capability of the system below its acceptable performance criteria for core cooling.

- The applicant has analyzed any reactor components or auxiliary systems for which primary coolant helps shield personnel from excessive radiation exposures. The use of the coolant for these purposes is acceptable, and the estimated protection factors limit the exposures to the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines. There is reasonable assurance that credible and postulated malfunctions of the auxiliary cooling systems will not lead to an uncontrolled loss of primary coolant, radiation exposures, or the release of radioactivity to the unrestricted environment that exceed the requirements of 10 CFR Part 20 and the facility's ALARA program guidelines.

- The TS, including testing and surveillance, provide reasonable assurance of necessary auxiliary cooling system operability for normal reactor operations.

5b Radioisotope Production Facility Cooling Systems

Add the following guidance to NUREG-1537, Part 2, Chapter 5:

The reviewer should ascertain that the application has either provided an adequate analysis to ensure that there is no need for auxiliary cooling during the course of any part of the radioisotope production process or has provided a complete description of the design and operation of any required cooling system.

Areas of Review

The reviewer should ascertain that the application includes a complete analysis of the thermal characteristics of the material in process during all phases of the radioisotope production process. If required, the design, construction and operation of the auxiliary cooling system should be clearly and completely explained in text, drawings, or diagrams, as necessary.

Acceptance Criteria

The acceptance criteria specified in NUREG-1537, Part 2, Section 5a2.7, may be used as they would apply to any required radioisotope processing cooling system.

In the event that cooling of the SNM solution is required during the radioisotope extraction process adequate precautionary measures are in place to prevent detrimental changes to the physical or chemical characteristics of the SNM solution. As an example, precautions against exceeding the soluble limits of the SNM in solution due to overcooling should be in place.

Review Procedures

The review procedures specified in NUREG-1537, Part 2, Section 5a2.7, may be used as they would apply to the radioisotope processing cooling system.

Evaluation Findings

The evaluation and findings specified in NUREG-1537, Part 2, Section 5a2.7, may be used as they would apply to the radioisotope processing system.

6 ENGINEERED SAFETY FEATURES

NUREG-1537, Part 2, Chapter 6 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the engineered safety features for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 6a1, "Heterogeneous Reactor Engineered Safety Features"
- 6a2, "Aqueous Homogeneous Reactor Engineered Safety Features"
- 6b, "Radioisotope Production Facility Engineered Safety Features and Items Relied on for Safety"

6a1 Heterogeneous Reactor Engineered Safety Features

NUREG-1537, Part 2, as written, applies to a heterogeneous reactor. This chapter of the SAR needs no additional guidance.

6a2 Aqueous Homogeneous Reactor Engineered Safety Features

This ISG augments NUREG-1537, Part 2, to include application to an AHR.

Introduction

The third paragraph, fourth bullet, should read: "loss of reactor vessel integrity or fuel mishandling."

Add a ninth bullet to read: "criticality accident".

6a2.1 Summary Description

This section, as written, applies to an AHR facility.

6a2.2 Detailed Description

This section, as written, applies to an AHR facility.

6a2.2.1 Confinement

This section of the current NUREG applies to an AHR facility with the following modifications:

Replace the first, second, and third sentences of the second paragraph with: "During normal operations, the reactor may release small amounts of radioactive material. Specifically, relatively small amounts of fission-product gaseous and iodine radionuclides and some argon-41 could escape from the reactor primary fission product barrier. The applicant should describe how these releases to the environment will be controlled so that neither the public nor the facility's operating staff will receive radiation doses greater than regulatory limits".

Areas of Review

This section, as written, applies to an AHR facility.

Acceptance Criteria

This section, as written, applies to an AHR facility.

Review Procedures

This section, as written, applies to an AHR facility.

Evaluation and Findings

This section, as written, applies to an AHR facility.

6a2.2.2 Containment

The current wording in this section of the NUREG generally applies to an AHR.

6a2.3 Emergency Core Cooling

The current version of this section of the NUREG applies to an AHR.

Areas of Review

Where reference is made to the fuel cladding, it is understood to mean the primary fission-product barrier in an AHR.

If the conclusion in other chapters of the SAR is that areas outside the core will require primary cooling (e.g., recombiner), this section must also evaluate a loss of coolant in these systems.

Acceptance Criteria

This section, as written, applies to an AHR.

Review Procedures

This section should read: "The reviewer should evaluate the accidents in Chapter 13 of the SAR to determine the scenario and consequences for a LOCA and to ascertain if the integrity of the reactor vessel or the FP gas management system can be compromised. The reviewer should verify that the proposed ECCS can prevent or mitigate the degradation of the reactor vessel and, if applicable, the FP gas management system. The reviewer should compare the design details of the ECCS with the design and functional requirements of the SAR LOCA and also the mitigated radiological consequences with 10 CFR Part 20 or 10 CFR Part 100 (for an AHR with a power level greater than 1 MW(t)) as applicable, to determine if the design is acceptable."

Evaluation Findings

The first bullet should read: "The applicant has identified a potential maximum hypothetical LOCA that could lead to unacceptable reactor vessel degradation or loss of FP gas management system integrity and unacceptable radiological consequences."

The second bullet should read: "The applicant's analysis of this accident in Chapter 13 includes a proposed ECCS whose design and function is to cool the fuel (and the FP gas management system, as appropriate) to prevent failure of the reactor vessel and associated containment."

6b Radioisotope Production Facility Engineered Safety Features and Items Relied on for Safety

The radioisotope production process involves the separation of certain fission-product isotopes from irradiated SNM. Certain operations with SNM are similar to processes performed by facilities that are licensed under 10 CFR Part 70, although a radioisotope production facility may be licensed under 10 CFR Part 50, NRC has determined that the Integrated Safety Analysis (ISA) methodology and designation of IROFS described in 10 CFR Part 70 Subpart H would be found acceptable by NRC staff for certain operations with SNM . Under 10 CFR Part 70 IROFS are identified from the ISA. Some IROFS may be comparable or equivalent to the ESFs required under 10 CFR Part 50. This ISG will include such IROFS in the ESFs and will refer to them as such.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotopes production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in this chapter and elsewhere in this ISG, the term "performance requirements" is not intended to suggest that Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria by radioisotope production facilities would be found acceptable by NRC staff. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.

Introduction

This section of NUREG-1537 generally applies to a radioisotope production facility, with the understanding that wherever the term "reactor" or "non-power reactor" appears, it is understood to mean "radioisotope production facility," as appropriate. Other changes that will make this section more appropriate for a production facility are as follows:

- The bullets in the third paragraph should be changed to the following:

  - loss of cooling (if it is required)
  - loss of primary fission-product barrier
  - failure of process control equipment
  - operator error
  - loss of electric power
  - criticality accident
  - hazardous chemical release
  - external events, such as fire, flood, earthquake, or wind

In addition to the radiological exposure limits prescribed in 10 CFR Part 50 and 10 CFR Part 20 (by reference in Part 50), the license application for a radioisotope production facility should include consequence and likelihood criteria for potential accidents resulting in chemical exposure to workers or members of the public. The chemical performance requirements in 10 CFR 70.61(b)(4) and (c)(4) have been found to be acceptable criteria for chemical-related accident sequences

6b.1 Summary Description

The current version of this section of NUREG-1537 applies, provided the term "reactor" is understood to mean "radioisotope production facility," as appropriate.

6b.2 Detailed Descriptions

The current version of this section of NUREG-1537 applies, provided the term "reactor" is understood to mean "radioisotope production facility," as appropriate.

In addition to any radiological hazards associated with operations in a production facility, 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," specifies limits regarding exposure to hazardous chemicals. Although not required of Part 50 licensees, these limits should also be considered when reviewing this section of the SAR.

6b.2.1 Confinement

The wording in this section of NUREG-1537 generally applies to a radioisotope production system, provided the term "reactor facility" is understood to mean "radioisotope production facility," as appropriate.

Areas of Review

The current wording in NUREG-1537 applies. Consider the consequences of hazardous chemical exposures, if they are possible.

Acceptance Criteria

The fourth bullet should read: "Where reference is made to radiological exposure limits, it is understood to mean radiological and chemical exposure limits".

Review Procedures

Wherever the term “radiological exposures” appears, it is understood to mean “radiological and chemical exposures.”

Evaluation Findings

Wherever the terms “reactor facility” and “radiological exposure” appear, it is understood that they mean “non-power reactor” or “radioisotope production facility” and “radiological or chemical exposure,” respectively.

The fourth bullet should read: “The risks from accidents to workers, the public, and the environment should not exceed the performance requirements of 10 CFR 70.61 with regard to radiological and chemical exposures or alternative criteria proposed and justified by the applicant. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.”

6b.2.2 Containment

The wording in this section of NUREG-1537 generally applies to a radioisotope production facility, provided the term “reactor facility” is understood to mean “radioisotope production facility,” as appropriate.

Areas of Review

With the above interpretation of terminology, this section, as written, applies to a production facility.

Acceptance Criteria

With the above interpretation of terminology, this section, as written, applies to a production facility.

Review Procedures

The last sentence should be replaced with the words: “The reviewer should verify that the risks from accidents to workers, the public, and the environment do not exceed the performance requirements of 10 CFR 70.61 with regard to radiological and chemical exposures or alternative criteria proposed and justified by the applicant. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.”

Evaluation Findings

The first bullet should read: “The applicant has either identified a potential or maximum hypothetical accident that results in projected exposures to the staff or the public that, without

containment, would be greater than acceptable limits, or the applicant has elected to provide containment for adherence to the ALARA principle."

The second bullet should read: "The design and functional features proposed for a containment reasonably ensure that risks from accidents to workers, the public, and the environment should not exceed the performance requirements of 10 CFR 70.61 with regard to radiological and chemical exposures or alternative criteria proposed and justified by the applicant. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property."

6b.2.3 Emergency Cooling System

This section (6.2.3) of NUREG-1537 is applicable to a radioisotope production facility with the following changes:

- reference to ECCS in this section 6b.2.3 is interpreted to mean emergency cooling for the radioisotope production and irradiated fuel processing systems.

- reference to reactor or non-power reactor in this section 6b.2.3 is interpreted to mean radioisotope production and irradiated fuel processing facilities.

- reference to fuel cladding in this section 6b.2.3 is interpreted to mean primary fission product barrier.

Areas of review:

Replace the first paragraph with:

In the event it is necessary to provide cooling to the radioisotope production and irradiated fuel processing systems to maintain the primary fission product barrier, emergency cooling must be provided.

Acceptance criteria:

The current wording of this section of NUREG-1537, Part 2 is applicable to a radioisotope production facility provided that the fourth bullet is replaced with the words: "The risks from accidents to workers, the public, and the environment should not exceed the performance requirements of 10 CFR 70.61 with regard to radiological and chemical exposures or alternative criteria proposed and justified by the applicant. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property."

Review Procedures:

The current wording of this section of NUREG-1537, Part 2 is applicable to a radioisotope production facility provided the above mentioned interpretations of ECCS and fuel cladding are applied and the last sentence is replaced with the words: "The reviewer should verify that the risks from accidents to workers, the public, and the environment do not exceed the performance requirements of 10 CFR 70.61 with regard to radiological and chemical exposures or alternative criteria proposed and justified by the applicant. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property."

Evaluation Findings:

The current wording of this section of NUREG-1537, Part 2 is applicable to a radioisotope production facility provided the above mentioned interpretations of ECCS and fuel cladding are applied.

6b.3 Nuclear Criticality Safety for the Processing Facility

The primary purpose of this section is to determine, with reasonable assurance, that the applicant has designed a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of licensed materials. The facility design must adequately protect the health and safety of workers and the public during normal operations and credible accident conditions from the accidental criticality risks in the facility. It should also protect against facility conditions that could affect the safety of licensed materials and thus present an increased risk of criticality or radiation release.

Another purpose of this review is to determine, with reasonable assurance, whether the licensee's or applicant's nuclear criticality safety (NCS) program, as described in the license application, is adequate to ensure compliance with the regulatory requirements and will support safe possession and use of nuclear material at the facility. The review should examine the parts of the license application that describe the NCS program. The review should ensure that either the license application for a new facility or the license amendment to an existing facility meets the applicable regulatory requirements.

Areas of Review

- The general organization and administration methods used by the applicant that relate to NCS should be met, including the experience, educational requirements, responsibilities, and authorities of NCS management and staff.

- Process descriptions are narrative descriptions of the site, facility, and processes with respect to criticality safety for normal operations. The criticality process description can include flow diagrams, major process steps, and major pieces of equipment, with emphasis on the criticality safety control.

- Criticality accident evaluations should include accident analyses involving licensed materials and an interpretation of the sequence of events. It is presumed that all

criticality accident analyses would assume high consequences; therefore, the applicant should include every credible event that could result in an uncontrolled criticality event.

- Criticality accident analyses should be identified, including the assumption that all criticality accidents are high-consequence events and that the applicant's bases and methods are based on using preventive controls.

- Criticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical.

- Criticality management measures should ensure that the reliability and availability of the safety controls are adequate to maintain subcriticality.

Acceptance Criteria

The reviewer should find the applicant's criticality safety program information acceptable if it provides reasonable assurance that the acceptance criteria discussed below are adequately addressed and satisfied:

- The applicant describes a facility criticality accident alarm system (CAAS) is capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within one minute. Coverage of all areas is provided by two detectors.

- The applicant describes a facility CAAS that uses gamma- or neutron-sensitive radiation detectors which will energize clearly audible alarm signals if accidental criticality occurs.

- The applicant commits to American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.3-1997, "Criticality Accident Alarm System," as modified by RG 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," issued October 2005 by the NRC. RG 3.71 lists the following exceptions to the standard:

  – At or above the mass limits, the applicant should require CAAS coverage in each area where SNM is handled, stored, or used.

  – A requirement that two detectors cover each area needing CAAS coverage.

  – A requirement that a CAAS be capable of detecting a nuclear criticality that produces an absorbed dose in soft tissue of 0.2 Gy (20 rads) of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute.

- The applicant provides a description of a CAAS that is appropriate for the facility for the type of radiation detected, the intervening shielding, and the magnitude of the minimum accident of concern.

- The CAAS is designed to remain operational during credible events, such as a seismic shock equivalent to the site-specific, design-basis earthquake or the equivalent value specified by the Uniform Building Code.

- The CAAS is designed to remain operational during credible events, such as a fire, an explosion, a corrosive atmosphere, or other credible conditions.

- The criticality accident alarm is clearly audible in areas that must be evacuated or there are alternative notification methods that are documented to be effective in notifying personnel that evacuation is necessary.

- The applicant either, commits to the following national standards, as they relate to these requirements: ANSI/ANS-8.7-1975, "Guide for Nuclear Criticality Safety in the Storage of Fissile Materials"; ANSI/ANS-8.9-1987, "Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials"; ANSI/ANS-8.10-1983, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement"; ANSI/ANS-8.12-1987, "Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors"; ANSI/ANS-8.15-1981, "Nuclear Criticality Control of Special Actinide Elements"; and ANSI/ANS-8.17-1984, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors" or, the applicant specifies safety limits based on validated calculational methods.

- The applicant commits to rendering operations safe, by shutdown and quarantine, if necessary, in any area where CAAS coverage has been lost and not restored within a specified number of hours. The number of hours should be determined on a process-by-process basis, because shutting down certain processes, even to make them safe, may carry a larger risk than being without a CAAS for a short time. The applicant should commit to compensatory measures (e.g., limiting access, halting SNM movement) when the CAAS system is not functional. These provisions are included in the technical specifications governing the operational requirements for the CAAS.

- The applicant shall institute emergency procedures to include the following management provisions:

    - The applicant has an emergency plan that comports with the guidance in ANS/ANSI 8.23-1997, "Nuclear Criticality Accident Emergency Planning and Response"

    - The applicant commits to providing fixed and personnel accident dosimeters in areas that require a CAAS. These dosimeters should be readily available to personnel responding to an emergency, and there should be a method for prompt onsite dosimeter readouts.

    - The applicant commits to providing emergency power for the CAAS or providing justification for the use of continuous monitoring with portable instruments.

    - The applicant commits to maintaining emergency procedures for each area in which this licensed special nuclear material is handled, used, or

stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm. These procedures must include conducting drills to familiarize personnel with the evacuation plan, designation of responsible individuals for determining the cause of the alarm, and placement of radiation survey instruments in accessible locations for use in such an emergency. The applicant commits to retaining a copy of current procedures for each area as a record for as long as licensed special nuclear material is handled, used, or stored in the area. The applicant commits to retaining any superseded portion of the procedures for three years after the portion is superseded.

- The applicant describes a program that ensures compliance with the double-contingency principle, where practicable. Processes in which there are no credible accident sequences that lead to criticality meet the double-contingency principle by definition. This principle, as given in ANSI/ANS-8.1-1998, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," states that at least two changes in process conditions must occur before criticality is possible. If there are no process changes leading to criticality, then the principle is satisfied. Each process that has accident sequences leading to criticality should have sufficient controls in place to ensure double-contingency protection. This may be provided by either (1) control of two independent process parameters, or (2) control of a single process parameter, such that at least two independent failures would have to occur before criticality is possible. The first method is preferable because of the inherent difficulty in preventing common-mode failure when controlling only one parameter.

- The applicant meets the acceptance criteria in Section 13b of the standard review plan, as they relate to the identification, consequences, and likelihood of NCS accident sequences, as well as descriptions of IROFS for NCS accident sequences.

- The applicant should consider the upsets listed in Appendix A to ANSI/ANS-8.1-1983 in identifying NCS accident sequences.

- The applicant describes how it performed the safety analyses for the new process and how the process provides for criticality control including adherence to the double-contingency principle. The applicant also explains how it applies defense-in-depth to higher risk accident sequences. Acceptable defense-in-depth principles for the criticality safety design are those that support a hierarchy of controls: prevention, mitigation, and operator intervention, in order of preference.

- The applicant describes proposed facility-specific or process-specific relaxations or additions to baseline design criteria, along with justifications for such relaxations.

- The safety analysis describes how the applicant used criticality safety in baseline design criteria establishing the design principles, features, and control systems of the new process.

- The application states the NCS program objectives, which should include those listed in this chapter.

- The application outlines an NCS program structure that is consistent with current industry practices (e.g., ANSI/ANS-8.1-1998 and ANSI/ANS-8.19-1996, “Administrative Practices for Nuclear Criticality Safety”) and that defines the responsibilities and authorities of key program personnel.

- The NCS program requires the applicant (licensee) to establish and maintain NCS safety limits and operating limits for the possession and use of fissile material and to maintain management measures to ensure the availability and reliability of the controls. Criticality control limits and management measures are included in the technical specifications as required by 10 CFR 50.36.

- The SAR specifies that modifications to the facility or safety program will be evaluated for their impact on criticality as required by 10 CFR 50.59.

- The reviewer should find the applicant’s NCS organization and administration acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

  – The applicant meets the acceptance criteria as they relate to NCS, including organizational positions, functional responsibilities, experience, and qualifications of personnel responsible for NCS.

  – The applicant meets the intent of ANSI/ANS-8.1 and ANSI/ANS-8.19 (see RG 3.71), as they relate to organization and administration.

  – The NCS organization should be independent of operations to the extent practical.

  – The applicant commits to providing distinctive NCS postings in areas, operations, work stations, and storage locations relying on administrative controls for NCS.

  – The applicant commits to requiring its personnel to perform activities in accordance with written, approved procedures when the activity may affect NCS. Unless a specific procedure deals with the situation, personnel shall take no action until the NCS staff has evaluated the situation and provided recovery procedures.

  – The applicant commits to requiring its personnel to report defective NCS conditions to the NCS program management.

  – The applicant describes organizational positions, experience of personnel, qualifications of personnel, and functional responsibilities.

  – The applicant commits to designating an NCS program director who will be responsible for implementing the NCS program.

- The applicant’s NCS surveillance requirements should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

– Training and Procedures

a. The applicant meets the intent of ANSI/ANS-8.19-1996 and ANSI/ANS-8.20, “Nuclear Criticality Safety Training,” as they relate to training.

b. The applicant commits to training all personnel to recognize the CAAS signal and to evacuate promptly to a safe area.

c. The applicant commits to providing instruction and training regarding the policy in the SRP guidance for NCS organization procedures.

d. The applicant commits to ANSI/ANS-8.18-1996 as it relates to procedures.

– Audits and Assessments

- The applicant commits to ANSI/ANS-8.19-1996, as it relates to audits and assessments.

i. The applicant commits to conducting and documenting walkthroughs (i.e., observation of operations to ensure compliance with criticality limits) of all operating SNM process areas, so that all such areas will be reviewed at some specified frequency. The reviewer should consider the complexity of the process, the degree of process monitoring, and the degree of reliance on administrative controls in assessing the acceptability of the specified frequency. Identified weaknesses should be referred to those responsible for facility corrective actions and should be promptly and effectively resolved. A graded approach may be used to establish an NCS walkthrough schedule.

ii. The applicant commits to conducting and documenting periodic NCS audits (such that all NCS aspects of surveillance requirements will be audited at least every 2 years). A graded approach may be used to justify an alternative NCS audit schedule.

iii. Audit requirements will be included in the Administrative Controls section of the facility technical specifications

- The reviewer should consider the applicant’s NCS technical practices acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

– NCS evaluations will be performed using industry-accepted and peer-reviewed methods.

- NCS limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety.

- Methods used to develop NCS limits will be validated to ensure that they are used within acceptable ranges and that the applicant used both appropriate assumptions and acceptable computer codes.

- The applicant commits to demonstrating (1) the adequacy of the margin of subcriticality for safety by ensuring that the margin is large compared to the uncertainty in the calculated value of K effective (K_{eff}) (effective multiplication factor); (2) that the calculation of K_{eff} is based on a set of variables within the method's validated area of applicability; and (3) that trends in the bias support the extension of the methodology to areas outside the area or areas of applicability.

- The reviewer must use judgment in assessing whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality. The reviewer should consider the following factors:

  - conservatism in the calculations, beyond that needed to accommodate uncertainties in the modeled parameters (e.g., geometric tolerances).

  - confidence in subcriticality generated by the applicant's validation process, including the following:

    a. similarity between the benchmark experiments and calculations to be performed.

    b. sufficiency of the benchmark data (both quality and quantity).

    c. rigor of the validation methodology (e.g., trending, statistical testing).

    d. conservatism in the statistical parameters.

  - sensitivity of the system to changes in modeled parameters, and therefore sensitivity to errors.

  - corroborating evidence of subcriticality from other sources (e.g., knowledge of neutron physics for well-characterized systems, such as finished fuel).

  - risk considerations, including the likelihood of actually attaining an abnormal condition.

- The applicant includes a summary description of a documented, reviewed, and approved validation report (by NCS function and management) for each methodology that will be used to perform an NCS analysis. The summary description of a reference manual or validation report should include the following:

- a summary of the theory of the methodology that is sufficiently detailed and clear to be understood, including the method used to select the benchmark experiments, determine the bias and uncertainty in the bias, and determine the upper subcritical limit.

- a summary of the physical systems and area(s) of applicability covered by the validation report, noting that it is not necessary to include the full range of numerical parameters that defines the area of applicability.

- a description of the methods used to justify applying the methodology outside the area or areas of applicability.

- a summary of the plant-specific benchmark experiments used to validate the methodology.

- a description of the margin of subcriticality for safety and its justification.

- a description of the controlled software and hardware.

- a description of the verification process, including verification upon changes to the calculational system and upon some specified period.

- The applicant's validation methodology, as described above, should be found acceptable if either (1) the applicant commits to following ANSI/ANS-8.24-2006, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations," as endorsed by RG 3.71; or (2) the methodology follows current industry practices in terms of selecting the benchmark experiments, assessing their applicability, determining the area(s) of applicability, extending the area(s) of applicability beyond the range of benchmark data, and statistically analyzing the data. This requires that the NCS reviewer remain aware of current practices in the area of criticality code validation.

- The reviewer should consider the applicant's commitment to NCS technical practices acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

  - The applicant's use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet double-contingency protection.

  - In general, the applicant should commit to the following order of preference for NCS controls: (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) simple administrative. When using other than a passive engineered control, the applicant should justify the choice of the type and manner.

  - When they are relevant, the applicant should consider heterogeneous effects. Heterogeneous effects are particularly relevant for LEU processes where, all other parameters being equal, heterogeneous systems are more reactive than homogeneous systems.

- The use of mass as a controlled parameter should be considered acceptable in the following circumstances:

  - When mass limits are derived for a material that is assumed to have a given weight percent of SNM, determinations of mass are based on either (1) weighing the material and assuming that the entire mass is SNM; or (2) conducting physical measurements to establish the actual weight percent of SNM in the material.

  - When fixed geometric devices are used to limit the mass of SNM a conservative process density is assumed in calculating the resulting mass.

  - Instrumentation used to measure mass is subject to facility surveillance requirements.

- The use of geometry as a controlled parameter should be considered acceptable if, before beginning operations, all dimensions and nuclear properties that use geometry control are verified.

- The use of density as a controlled parameter should be considered acceptable in the following circumstances:

  - When process variables can affect the density, the accident analysis shows them to be controlled by surveillance requirements.

  - Instrumentation used to measure density is subject to facility surveillance requirements.

- The use of enrichment as a controlled parameter should be considered acceptable if the following apply:

  - Either a method of segregating enrichments is used to ensure that differing enrichments will not be interchanged or the most limiting enrichment is applied to all material.

  - Measurements of enrichment are obtained by using instrumentation subject to facility management measures.

- The use of reflection as a controlled parameter should be considered acceptable in the following circumstances:

  - In the evaluation of an individual unit, the wall thickness of the unit and all reflecting adjacent materials of the unit are considered. The materials adjacent to the unit should be farther than 30 centimeters (12 inches).

  - After all fixed reflectors are accounted for, the controls to prevent the presence of any transient reflectors (e.g., personnel) in the accident analysis are identified as ESFs or TS, or both.

- The use of moderation as a controlled parameter should be considered acceptable if the following apply:
  - When using moderation, the applicant commits to ANSI/ANS-8.22-1997, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators."
  - When process variables can affect the moderation, the accident analysis shows them to be controlled by ESFs or TS, or both.
  - Moderation is measured by using instrumentation subject to facility surveillance requirements.
  - The design of physical structures prevents the ingress of moderators.
  - When moderation needs to be sampled, dual independent sampling methods are used.
  - Firefighting procedures for use in a moderation-controlled area evaluate the use of moderator material.
  - After all credible sources of moderation are evaluated, measures are instituted to prevent or control the inadvertent introduction of moderating materials into a moderation-controlled area.
- The use of concentration as a controlled parameter should be considered acceptable in the following circumstances:
  - When process variables can affect the concentration, the accident analysis shows them to be controlled by ESFs or TS, or both.
  - Concentrations of SNM in a process are limited unless the process is determined to be safe at any credible concentration.
  - When using a tank containing a concentration-controlled solution, the tank is normally closed and locked to prevent unauthorized access.
  - When concentration needs to be sampled, dual independent sampling methods are used.
  - After identification of possible precipitating agents, precautions are taken to ensure that such agents will not be inadvertently introduced.
- The use of interaction as a controlled parameter should be considered acceptable if the following applies:
  - To maintain a physical separation between units, engineered controls are used to ensure a minimum spacing. If engineered controls are not feasible, augmented administrative controls are used.

- The structural integrity of the spacers or racks should be sufficient for normal and credible abnormal conditions.

- The use of neutron absorption as a controlled parameter should be considered acceptable in the following circumstances:

  - When using borosilicate-glass raschig rings, the applicant commits to ANSI/ANS-8.5-1996, "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."

  - When using fixed neutron absorbers, the applicant commits to ANSI/ANS-8.21-1995, "Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."

  - In the evaluation of absorber effectiveness, neutron spectra are considered (e.g., cadmium is an effective absorber for thermal neutrons but ineffective for fast neutrons).

- The use of volume as a controlled parameter should be considered acceptable if the following apply:

  - Fixed geometry is used to restrict the volume of SNM.

  - When the volume is measured, the instrumentation used is subject to facility surveillance requirements.

- The reviewer should consider the applicant's description of additional commitments for the NCS program acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

  - The applicant commits to using the NCS program to promptly detect any NCS deficiencies by means of operational inspections, audits, or investigations and report those deficiencies in ESFs or TS, or both; NCS function; or surveillance requirements to those individuals who are responsible for the facility's corrective actions, so as to prevent recurrence.

  - The applicant commits to supporting the facility change mechanism process by performing NCS evaluations per the requirements of 10 CFR 50.59 to determine changes to processes, operating procedures, criticality controls, ESFs, TS, and surveillance requirements will require a license amendment.

  - The applicant commits to retaining records of NCS deficiencies and documenting any corrective actions taken.

- The applicant's description of measures to implement the reporting requirements for criticality safety-related commitments should be considered acceptable if the commitments are consistent with the overall program commitments and the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

- The applicant has a program for evaluating the criticality significance of NCS events and an apparatus in place for making the required notification to the NRC Operations Center. Qualified individuals should make the determination of significance for NCS events. The determination of loss or degradation of double-contingency protection should be made against the license.

- The applicant incorporates the reporting criteria and the report content requirements into the facility emergency procedures.

- The applicant commits to issuing the necessary report, based on whether the criticality controls credited were lost (i.e., they were unreliable or unavailable to perform their intended safety functions), irrespective of whether the safety limits of the associated parameters were actually exceeded.

- If the applicant intends to conduct activities to which an NRC-endorsed standard applies, the intent of the standard should be met by satisfying the following acceptance criteria:

  - The license application contains a commitment to follow the requirements (i.e., "shall" statements) of the standard, subject to any exceptions taken by the NRC. The application clearly specifies the version of the standard and the specific provisions to which the applicant is committing, and,

  - If there are requirements in a standard to which the applicant does not commit, it provides sufficient information for the staff to determine if the requirements are not relevant to the applicant's activities or the license application contains other commitments that are equivalent.

- If the licensee commits to a standard that the NRC has not endorsed, is not the most current version endorsed by the NRC, or is an unendorsed version of a previously endorsed standard, the license application should include justification for this commitment.

- The reviewer should find the applicant's criticality safety information acceptable if it provides reasonable assurance that the acceptance criteria presented below are adequately addressed and satisfied. The applicant may elect to incorporate some or all of the requested process information in the facility and process description rather than in this section. Either approach is acceptable, as long as the information is adequately cross-referenced:

  - Process descriptions are sufficiently detailed to allow an understanding of the criticality to permit development of potential accident sequences.

  - The use of analysis to demonstrate compliance is acceptable in the following circumstances:

    a. The applicant provides a general description of the criticality hazards.

    b. Each hazard identified by the applicant includes a criticality-hazard evaluation of potential interactions and key assumptions, vessels, process equipment, and facility personnel.

c. The applicant provides reasonable assurance that measures to mitigate the consequences of accident sequences are consistent with actions described in the standard review plan.

d. All the credible criticality accident sequences are assumed to have high consequences.

- The application should demonstrate the management measures proposed to determine that safety controls are available and reliable to ensure subcriticality by briefly describing the following:

  – procedures to ensure the reliable operation of engineered controls (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, criteria for acceptable test results).

  – procedures to ensure that administrative controls will be correctly implemented, when required (e.g., employee training and qualification in operating procedures, refresher training, safe work practices, development of standard operating procedures, training program evaluation).

  – the configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements used by the applicant.

  – management provisions for the following:

    a. training and qualifications of NCS management and staff

    b. auditing, assessing, and upgrading the NCS program

    c. maintaining current NCS safety-basis documentation

    d. installing and maintaining a CAAS to detect and annunciate an inadvertent nuclear criticality

    e. referring NCS deficiencies to the corrective action program

    f. retaining records of the NCS program, including independent reviews, audits, and documentation of corrective actions taken

    g. preparing production facility operating staff for NRC operator license examination

Review Procedures

After the application has been accepted, the primary reviewer should conduct a complete review of the application and determine if it meets the conditions for approval specified in this section. The primary reviewer should consult with the supporting reviewers, as appropriate, to identify

and resolve any issues of concern related to the licensing review. The primary reviewer should coordinate with other primary reviewers of other standard review plans to confirm that the application meets all acceptance criteria pertinent to NCS. The reviewer should also coordinate with other primary reviewers in radiation protection, chemical safety, and fire protection, as well as other disciplines, as appropriate (e.g., seismic), to ensure consideration of any cross-cutting issues.

The primary reviewer should review the applicant's NCS information in the license application for completeness with respect to the requirements.

The reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the commitments made in the license application are implemented through procedures and training.

Nuclear Criticality Safety Program

The reviewer should review all aspects of the applicant's NCS program, including management, organization, and technical practices. The reviewer should identify and note any items or issues relating to the NCS program and commitments that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the commitments made in the license application are implemented through procedures and training.

Safety Analysis

The results of the criticality safety analysis support the overall safety basis for the criticality safety evaluation. The reviewer should assess the criticality safety risks identified and ensure that the level of safety is reflected in the design and the operational process and controls for the facility. The reviewer should establish that the applicant's facility design, operations, and criticality safety controls provide reasonable assurance that they will function as intended, be reliable and available to perform their safety function, and provide for the safe possession and use of licensed material at the facility.

Evaluation Findings

The SAR should contain sufficient information to support the following types of conclusions in the SER:

The NRC staff has reviewed the nuclear criticality safety (NCS) program and requirements for criticality safety for [name of facility] according to this standard review plan. The NRC staff has reasonable assurance of the following:

- The applicant will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures.

- The applicant's conduct of operations will be based on NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely.

- The applicant will have the capability to perform adequate safety analyses of all production processes that will be conducted in the facility. Credible postulated criticality accident scenarios can be performed and adequate preventive and mitigative controls and measures will be included in the production facility technical specifications as required by 10 CFR 50.36.

- The applicant will develop, implement, and maintain a criticality accident alarm system that meets the acceptance criteria in Section 6b.3 of this ISG. The applicant will have in place an NCS program.

Based on this review, the NRC staff should be able to conclude that the applicant's NCS program provides reasonable assurance of the protection of public health and safety, including that of workers, and the environment.

6.4 References

American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.1-1998- "Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors"

ANSI/ANS – 8.3-1997- "Criticality Accident Alarm Systems"

ANSI/ANS – 8.7 – 1975 "Guide for Nuclear Criticality Safety in the Storage of Nuclear Materials"

ANSI/ANS – 8.9 – 1987 "Nuclear Criticality Safety for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials"

ANSI/ANS – 8.10 – 1983 "Criteria for Nuclear Criticality Controls in Operations with Shielding and Confinement"

ANSI/ANS – 8.12 – 1987 "Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors"

ANSI/ANS – 8.15 - 1981 "Nuclear Criticality Control of Special Actinide Elements"

ANSI/ANS – 8.17 – 1984 "Criticality Safety Criteria for Handling, Storage and Transportation of LWR Fuel Outside Reactors

United States Nuclear Regulatory Commission (USNRC) Regulatory Guide 3.71 "Nuclear Criticality Safety Standards for Fuels and Materials", Oct. 2005 (Updated 2010)

7 INSTRUMENTATION AND CONTROL SYSTEMS

NUREG-1537, Part 2, Chapter 7 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the instrumentation and control systems for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 7a1, "Heterogeneous Reactor Instrumentation and Control Systems"
- 7a2, "Aqueous Homogeneous Reactor Instrumentation and Control Systems"
- 7b, "Radioisotope Production Facility Instrumentation and Control Systems"

As of the date of this ISG, the NRC is processing revised guidance concerning digital instrumentation and control (I&C) systems for non-power reactors (NPR). This ISG updates the original reference material so that NUREG-1537 reflects the most recent issue dates. Applicants for licenses subsequent to the issuance of this ISG should check for any new guidance at the time of application.

7a1 Heterogeneous Reactor Instrumentation and Control Systems

NUREG-1537, Part 2, Chapter 7, "should be used for guidance in reviewing this chapter. The following reference is applicable:

- ANSI/ANS 10.4, "Guidelines for the Verification and Validation of Scientific and Engineering Computer Programs for the Nuclear Industry," updated in 2008.

7a2 Aqueous Homogeneous Reactor Instrumentation and Control Systems

NUREG-1537, Part 2, Chapter 7, should be used for guidance in reviewing this chapter, as appropriate for an AHR facility. The following reference is applicable:

- ANSI/ANS 10.4, "Guidelines for the Verification and Validation of Scientific and Engineering Computer Programs for the Nuclear Industry," updated in 2008.

7b Radioisotope Production Facility Instrumentation and Control Systems

Add the following guidance to NUREG-1537, Part 2 Chapter 7:

> The radioisotope production facility may require sensors, electronic circuitry, displays, and actuating devices that provide the information and the means to safely control the radioisotope production process, the special nuclear material (SNM) fuel reconditioning process (if applicable), or other operations with SNM that are conducted outside of the reactor. I&C systems may also be employed to avoid or mitigate accidents. This section should include details regarding the design and operating characteristics of these I&C systems.

7b.1 Summary Description

Each I&C system for the radioisotope production facility should be designed to perform functions commensurate with the complexity of the processes therein. The applicant should provide a summary description of the I&C systems, including the design bases; the safety, considerations, and objectives; the operational characteristics of the production facility that determine or limit the I&C design; and the ways in which the various subsystems constitute the whole and interact to contribute to its essential functions. This summary should also include schematic, logic, and flow diagrams illustrating the various subsystems.

7b.2 Design of Instrumentation and Control Systems

This section should address the following as they relate to the I&C systems for the radioisotope production and SNM fuel reconditioning processes:

- Design criteria
- Design bases
- System description
- System performance analysis
- Conclusion

The remaining subsections discuss specific information that should be included in this section for each of the systems and how the reviewer should evaluate each subsystem.

7b.3 Process Control Systems

Areas of Review

The process control systems contain most of the I&C subsystems and components designed for normal operation of the radioisotope production and SNM fuel or target reconditioning processes, if applicable. The areas of review for the process control systems should discuss the factors requested in Section 7b.2, above, but only as they relate to the radioisotope production and SNM fuel reconditioning processes. Subtopics may include, but are not limited to, the following:

- Nuclear instruments—including radiation detectors and displays suitable for a particular process. Where SNM is in process in quantities above the thresholds stipulated in 10 CFR 70.24 a criticality alarm system (CAAS) must be provided.

- Process instruments—instruments designed to measure and display parameters critical to the radioisotope production process and the SNM fuel reconditioning processes, if applicable.

- Control elements—types, number, function, design, and operating features of process or reactivity control devices, or both (coordinated with the review of the section of Chapter 6 relating to criticality control).

- Interlocks—circuits or devices to inhibit or prevent an action unless a specified precondition exists with the intention of protecting personnel or other subsystems from harm.

The areas of review for the process control systems should also include the following:

- Bases, criteria, standards, and guidelines used for the design of the process control systems.

- Description, including logic, schematic, and functional diagrams, of the overall system and component subsystems.

- Analysis of the adequacy of the design to establish conformance to the design bases and criteria for stated critical parameters.

- Application of the functional design and analyses to the development of bases of technical specifications, including surveillance tests and intervals.

- Process control system failure modes to determine whether any malfunction of the process control system could prevent any subsystem from performing its safety function.

Acceptance Criteria

The acceptance criteria, together with the use of good engineering judgment, will help the reviewer to conclude whether the process control system is designed to provide for the reliable control of the radioisotope production and SNM fuel reconditioning processes for the full range of operation. Acceptance criteria include the following:

- The range of operation of sensor (detector) channels should be sufficient to cover the expected range of variation of the monitored variable during normal and transient process operation.

- The process control system should give continuous, redundant indication of neutron flux present during the radioisotope production and SNM fuel reconditioning processes, if applicable.

- The precision and accuracy of each sensor channel should be commensurate with the importance and the level of intensity of the variable being measured. This is particularly important for those instruments and controls monitoring parameters that are significant to safety.

- The system should give reliable and redundant neutron flux level and rate of change information from detectors or sensors that directly measure neutron flux.

- The system should give reliable information about the status and magnitude of process variable necessary for the full operating range of the radioisotope production and SNM fuel reconditioning processes, if applicable.

- The system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations and should ensure compliance with analyzed requirements on excess reactivity and shutdown margins. Review of this criterion should be coordinated with the review of the section of Chapter 6 relating to criticality control.

- The process control system should not be designed to fail or operate in a mode that would prevent any subsystem from performing its designed function.

- Hardware and software for computerized systems should meet the guidelines of Institute of Electrical and Electronics Engineers (IEEE) 7-4.3.2-2010, "IEEE Standard Criteria for Digital Computer Systems in Safety Systems of Nuclear Power Generating Stations," and Regulatory Guide (RG) 1.152, Revision 1, "Criteria for Digital Computers in Safety Systems of Nuclear Power Plans," issued January 1996 (Appendix 7.1 to Chapter 7 of NUREG-1537, Part 1, "Format and Content). Software should meet the guidelines of ANSI/ANS 10.4-2008 that apply to non-power reactor systems.

- For I&C systems that are being upgraded to systems based on digital technology, the applicant should consult U.S. Nuclear Regulatory Commission (NRC) Generic Letter 95-02, "Use of NUMARC/EPRI Report TR-102348, 'Guideline on Licensing Digital Upgrades,' in Determining the Acceptability of Performing Analog-to-Digital Replacements under 10 CFR 50.59,'" dated April 26, 1995.

- The process control system should be designed for reliable operation in the normal range of environmental conditions anticipated within the facility.

- The process control system should be designed to assume a safe state during loss of electrical power.

- The subsystems and equipment of the process control system should be readily tested and capable of being accurately calibrated.

- Technical specifications, including surveillance tests and intervals, should be based on safety analysis report (SAR) analyses and should assure availability and reliability of all safety related monitoring and control instrumentation.

- Where neutron flux is a necessary process variable that must be measured for safety or control, at least one neutron flux measuring channel should give reliable readings to a predetermined flux level. If the production facility has neutron flux as a safety limit, the measurable flux level should be above the safety limit. For production facilities without neutron flux as a safety limit, the measurable neutron flux level should be high enough to show that the basis for limiting licensed neutron flux level is not exceeded.

- The applicant should describe in the SAR the interlocks used to limit personnel hazards or prevent damage to systems during the full range of normal operations.

- If an analysis of a process indicates a hazard to the process or the production facility, direct interacting or interlocking process controls may be justified. Any such automatic limiting devices should demonstrate that a safety function of any other process control subsystem will not be compromised.

Review Procedures

This chapter of the SAR should describe the I&C subsystems that apply to all normal functions and parameters of the radioisotope production and SNM fuel reconditioning processes, if applicable. These subsystems constitute the process control system. The reviewer should confirm that this section addresses I&C information for all normal functions and systems described in the chapters of the SAR.

The process control system comprises several subsystems; therefore, the reviewer should anticipate that the information in the SAR will be further subdivided, as noted in the section describing the areas of review. The subdivisions should address all of the factors listed in Section 7b.2, above, for each subsystem and should state how and where the subsystems interact and interface and how they function as a total process control system for normal operations. The reviewer should verify that all design bases are justified and that the designs themselves accurately and completely implement the applicable bases and acceptance criteria. The reviewer should obtain the assistance of experts in the I&C branch to review computer systems.

Evaluation Findings

This section of the SAR should contain sufficient information to support the following types of conclusions, any of which may be included in the staff's safety evaluation report (SER):

- The applicant has analyzed the normal operating characteristics of the radioisotope production and SNM fuel reconditioning processes, if applicable. The applicant has also analyzed the functions of the process control system and components designed to permit and support normal production and reconditioning process operations and confirms that the process control system and its subsystems and components will convey all necessary information to the operator or to automatic devices to maintain planned control for the full range of production and reconditioning process operations.

- The components and devices of the process control system are designed to sense all parameters necessary for facility operation with acceptable accuracy and reliability and to transmit the information with high accuracy in a timely fashion. Control devices are designed for compatibility with the analyzed dynamic characteristics for the production and SNM fuel reconditioning processes.

- The applicant has ensured sufficient interlocks, redundancy, and diversity of subsystems to avoid total loss of operating information and control and to limit hazards to personnel. The applicant has also ensured compatibility among operating subsystems and components in the event of a single, isolated malfunction of equipment.

- The process control system was designed so that any single malfunction in its components, either analog or digital, would not prevent the process and facility protection systems from performing necessary functions.

- Discussions of testing, checking, and calibration provisions, and the bases of technical specifications (including surveillance tests and intervals), provide reasonable confidence that the process control system will function as designed.

7b.4 Engineered Safety Features Actuation Systems

This chapter of the SAR should follow the guidance in NUREG-1537, Part 2, Section 7.5 as it applies to the radioisotope production and SNM fuel reconditioning processes. This section should describe the actuation systems for any engineered safety features (ESFs) discussed in Chapters 6 or 13.

7b.5 Control Console and Display Instruments

This chapter of the SAR should follow the guidance in NUREG-1537, Part 2, Section 7.6 as it applies to the radioisotope production and SNM fuel reconditioning processes, with the following exceptions:

- Anywhere “reactor control system” or “RCS” is indicated, the applicant should discuss the production process control system.

- Anywhere “reactor protection system” or “RPS” is indicated, the applicant should discuss the system or means used to prevent criticality or breach of radioactive material containment in the production facility.

7b.6 Radiation Monitoring Systems

This chapter of the SAR should follow the guidance in NUREG-1537, Part 2, Section 7.7 as it applies to the radioisotope production and SNM fuel reconditioning processes. If the radiation monitoring systems for the production facility have been described in conjunction with the radiation monitoring systems for the reactor elsewhere in the SAR, the applicant should note that in this section, but the discussion does not need to be repeated. If the CAAS is described in another chapter of the SAR it should be referenced but not repeated here.

References

ANSI/ANS 10.4 – 2008, Verification and Validation of Non-Safety Related Scientific and Engineering Computer Programs for the Nuclear Industry.

IEEE 7-4.3.2, 2010, Standard Criteria for Digital Computer Systems in Safety Systems of Nuclear Power Generating Systems.

USNRC Regulatory Guide 1.152 Rev. 3, 7/2011, Criteria for Use of Computers in Safety Systems of Power Reactors.

8 ELECTRICAL POWER SYSTEMS

This chapter of NUREG-1537 was written for heterogeneous reactors and specifies the content of a chapter describing the electrical power system for the reactor facility. To expand the use of NUREG-1537 to AHRs or a radioisotope production facility. Additional sections have been added to this chapter as follows:

- 8a1, “Heterogeneous Reactor Electrical Power Systems”
- 8a2, “Aqueous Homogeneous Reactor Electrical Power Systems”
- 8b, “Radioisotope Production Facility Electrical Power Systems”

Guidance for each of these options follows.

8a1 Heterogeneous Reactor Electrical Power Systems

NUREG-1537, Part 2, Chapter 8, should be used for guidance in reviewing this chapter.

8a2 Aqueous Homogeneous Reactor Electrical Power Systems

NUREG-1537, Part 2, Chapter 8, should be used for guidance in reviewing this chapter.

8b Radioisotope Production Facility Electrical Power Systems

NUREG-1537, Part 2, Chapter 8, should be used for guidance in reviewing this chapter provided that a reference to the “reactor” should be interpreted to mean the “radioisotope production facility,” as appropriate. Where the reactor and production facility share a common electrical supply system, it is not necessary to duplicate the information in this chapter.

9 AUXILIARY SYSTEMS

NUREG-1537, Part 2, Chapter 9 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the auxiliary systems for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 9a1, "Heterogeneous Reactor Auxiliary Systems"
- 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems"
- 9b, "Radioisotope Production Facility Auxiliary Systems"

Guidance for each of these options follows.

9a1 Heterogeneous Reactor Auxiliary Systems

NUREG-1537, Part 2, Chapter 9, should be used for guidance in reviewing this chapter.

9a2 Aqueous Homogeneous Reactor Auxiliary Systems

NUREG-1537, Part 2, Chapter 9, should be used for guidance in reviewing this chapter except as described in the following subsections.

9a2.1 Heating, Ventilation, and Air Conditioning Systems

This section of NUREG-1537, although intended for a heterogeneous reactor, is general enough to apply to other reactor types. The current guidance in NUREG-1537 can be used for the reviewing of the heating, ventilation, and air conditioning (HVAC) systems of AHR's.

9a2.2 Handling and Storage of Reactor Fuel

This chapter in NUREG-1537 is written primarily for a heterogeneous reactor. Therefore, the guidance should be interpreted appropriately for the different characteristics of AHR fuel. For example, any reference to cladding should be understood to mean the primary fission-product barrier; reference to handling tools should be understood to mean any fuel-handling equipment, and mention of damage to fuel should be understood to mean any compromise of the quality or the integrity of the fuel. Other than these differences, the general guidance in NUREG-1537 is applicable to AHR fuel.

9a2.3 Fire Protection and Programs

The current guidance in NUREG-1537 should be used for reviewing this section.

9a2.4 Communication Systems

The current guidance in NUREG-1537 should be used for reviewing this section.

9a2.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The current guidance in NUREG-1537 should be used for reviewing this section.

9a2.6 Cover Gas Control in Primary Coolant Systems

The cover gas control system of an AHR, which is described in Chapter 4, is an integral part of the reactor. Additional information may be included in this chapter. The guidance in NUREG-1537 can be applied here as well.

9a2.7 Other Auxiliary Systems

The current guidance in NUREG-1537 should be used for reviewing this section as applicable.

9b Radioisotope Production Facility Auxiliary Systems

The general guidance in this chapter of NUREG-1537 can be applied to auxiliary systems for a radioisotope production facility provided that a reference to the reactor should be interpreted to mean the radioisotope production facility, as appropriate. The following subsections provide additional guidance applicable to a radioisotope production facility.

9b.1 Heating, Ventilation, and Air Conditioning Systems

The current guidance in this section of NUREG-1537 is applicable to the radioisotope production facility as well as the reactor if the HVAC systems are separate. If the HVAC system is integral and common for both facilities, that fact should be noted, and the description given for the reactor in Section 9a2.1 does not need to be duplicated in this section.

9b.2 Handling and Storage of Reactor Fuel

This section of NUREG-1537 is applicable to a radioisotope production facility provided that any reference to fuel is interpreted as SNM involved in the production process outside of the reactor facility. The applicant or licensee should clearly define that area or component in the facility that separates the reactor from the radioisotope production facility in the SAR. It should be consistent with the divergent requirements to either control a critical reactor or prevent an assembly from becoming critical. Such a reference applies to both irradiated and unirradiated SNM.

9b.3 Fire Protection Systems

This section of NUREG-1537 can be applied to the radioisotope production facility as well as the reactor if the fire protection systems are separate. If the system is integral and common to both facilities, the description given for the reactor in Section 9a2.3 does not need to be duplicated in this section.

9b.4 Communication Systems

This section of NUREG-1537 can be applied to the production facility as well as the reactor if the systems are separate. If the system is integral and common to both facilities, the description given for the reactor in Section 9a2.4 does not need to be duplicated in this section.

9b.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

This section of NUREG-1537 is applicable to the production facility as well as the reactor.

9b.6 Cover Gas Control System

The radioisotope production facility may use a cover gas in the isotope extraction process and in the irradiated SNM storage and treatment system. Gas venting and control apparatus may also be part of the radioisotope extraction and SNM processing equipment. The guidance provided in this section of NUREG-1537 can be applied to the production facility.

10 EXPERIMENTAL FACILITIES

NUREG-1537, Part 2, Chapter 10 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the experimental facilities for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term “reactor” appears, it is understood to mean a “non-power reactor facility,” a “radioisotope production facility,” or both as applicable. The result should be one or two chapters with the following titles:

The current content in NUREG-1537, Part 2, is applicable without modification or augmentation to this ISG.

11 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

NUREG-1537, Part 2, Chapter 11 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the radiation protection program and waste management for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. The result should be one or two chapters with the following titles:

11.1 Radiation Protection

The current wording of the following subsections is adequate without modification of this ISG:

11.1.1 Radiation Sources
11.1.2 Radiation Protection Program
11.1.3 ALARA Program
11.1.4 Radiation Monitoring and Surveying
11.1.5 Radiation Exposure Control and Dosimetry

A new section is added and reads as follows:

Areas of Review

> The integrated safety analysis (ISA) should clearly distinguish between trained radiation workers, who may receive specified occupational dose during an accident, and members of the public, whose consequences and likelihoods should be controlled to more stringent levels.
>
> The application should identify a controlled area, as defined in 10 CFR 20.1003. This controlled area should be identified in the boundary and area maps provided in Chapter 2, Section 2.1.1.2, of the SAR.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotope production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in this chapter and elsewhere in this ISG, the term "performance requirements" is not intended to suggest that Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria by radioisotope production facility would be found acceptable by NRC staff. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed

procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.

Acceptance Criteria

The ISA should clearly distinguish between trained radiation workers, who may receive specified occupational dose during an accident, and members of the public, whose consequences and likelihoods should be controlled to more stringent levels.

The application should identify a controlled area, as defined in 10 CFR 20.1003. This controlled area should be identified in the boundary and area maps provided in Chapter 2, Section 2.1.1.2, of the SAR. The licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of demonstrating that the operations of the facility meet the criterion of the ISA, individuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the ISA, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of 10 CFR 70.61, or alternative criterion proposed by the applicant; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)–(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of 10 CFR 70.61, or alternative criterion proposed by the applicant, may be applied to these individuals.

Evaluation Findings

The staff's evaluation should verify that the license application contains a clear definition of the controlled area, and that the radiation protection program and the ISA performance requirements clearly distinguish between workers inside the controlled area and members of the public outside the controlled area.

11.1.6 Contamination Control
11.1.7 Environmental Monitoring

11.2 Radioactive Waste Management

The current wording of this section and the following subsections is adequate without modification of this ISG:

11.2.1 Radioactive Waste Management Program
11.2.2 Radioactive Waste Control
11.2.3 Release of Radioactive Waste

11.3 Respiratory Protection Program

The following guidance for reviewing the respiratory protection program is added to NUREG-1537 for non-power reactors and radioisotope production facilities, as appropriate.

Areas of Review

The areas of review should include detailed information about the following two areas of the respiratory program:

(1) Establishment, maintenance, and implementation of a respiratory protection program.

(2) Design and implementation of programs to control airborne concentrations of radioactive material by using ventilation systems, containment systems, and respirators.

Acceptance Criteria

The applicant should do the following:

(1) Install appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed the occupational derived air concentration values specified in 10 CFR Part 20, "Standards for Protection against Radiation," Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(2) Describe surveillance requirements, including preventive and corrective maintenance and performance testing, to ensure that the ventilation and containment systems operate when required and are within their design specifications.

(3) Describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used.

(4) Describe the frequency and types of tests to measure the performance of ventilation and containment systems, the acceptance criteria, and the actions to be taken when the acceptance criteria are not satisfied.

(5) Establish a respiratory protection program that meets the requirements of 10 CFR Part 20, Subpart H, "Respiratory Protection and Controls To Restrict Internal Exposure in Restricted Areas."

(6) Prepare written procedures for the selection, fitting, issuance, maintenance, testing, training of personnel, monitoring, and recordkeeping for individual respiratory protection equipment and for specifying when such equipment is to be used.

(7) Revise the written procedures for the use of individual respiratory protection equipment, as applicable, when making changes to processing, facility, or equipment.

(8) Maintain records of the respiratory protection program, including training in respirator use and maintenance.

Review Procedures

The reviewer should determine whether the respiratory protection program provides adequate protection of personnel from airborne concentrations exceeding the limits of Appendix B to 10 CFR Part 20 and the overall adequacy of the program. The methods used for the identification and evaluation of potential hazards and estimated doses should provide realistic and accurate predictions. The applicant should evaluate potential hazards and estimated doses by performing surveys, bioassays, air sampling, or other means as necessary.

As for the respiratory protection to be used, the reviewer should ensure that the equipment has been tested and certified to provide the appropriate degree of personal protection. The applicant must also commit to testing of respirators for operability before usage. The reviewer should also examine the description of respirator usage, training, fit testing, selection, storage, maintenance, repair, and quality assurance through the written procedures.

After evaluating the acceptance criteria, the reviewer will perform a safety evaluation. The reviewer will prepare an SER on the licensing action for the licensing project manager.

Evaluation Findings

The reviewer will draft an SER addressing the topic reviewed explaining why the NRC staff has reasonable assurance that the respiratory protection program is acceptable and that the health and safety of the workers is adequately protected. The NRC staff may propose license conditions to impose requirements in those areas in which the application is deficient. The NRC staff's SER should include the following kind of statement and conclusion:

> The applicant has committed to an acceptable radiation protection program that includes a program to control airborne concentrations of radioactive material with engineering controls and respiratory protection.

Change the sequential number for the "References" section.

11.4 References

References in the current NUREG-1537, Part 1, Section 11.3, apply. The following has been updated:

U.S. Nuclear Regulatory Commission, Regulatory Guide 8.13, Revision 3, "Instruction Concerning Prenatal Radiation Exposure," June 1999.

12 CONDUCT OF OPERATIONS

NUREG-1537, Part 2, Chapter 12 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the conduct of operations for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable.

Note that this Interim Staff Guidance has significantly increased the volume of information on environmental matters to reflect requirements in 10 CFR Part 51 which implement the National Environmental Policy Act of 1969 (NEPA), as amended for NRC licensees. As a result, a new Chapter 19, "Environmental Review" has been formed to replace NUREG-1537 Section 12.12 in this ISG.

The reviewer should verify that the applicant describes and discusses the conduct of operations at any facility captured in the scope of this ISG. The conduct of operations involves the administrative aspects of facility operations, the facility emergency plan, the security plan, the quality assurance plan, the reactor operator requalification plan, the startup plan, and environmental reports as described in NUREG-1537. Wherever the document refers to "university, corporation, or facility," it should also include "processing facility."

Note that Section 12.13, "Material Control and Accounting," has been added in this ISG for compliance with 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material."

12.1 Organization

A new bullet is added to the *Areas of Review*:

- Production facility safety program

New *Acceptance Criteria* are added corresponding to Section 12.1.6 of Part 1 of this ISG,

The license application for a radioisotope production facility should describe an established facility safety program, as described in 10 CFR 70.61, "Performance Requirements" and 10 CFR 70.62, "Safety Program and Integrated Safety Analysis." This safety program may be integrated with a similar program established for other functions on site such as the reactor.

NRC staff have determined that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR 70 Subpart H and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety (IROFS), and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotope production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in this ISG, the term, "performance requirements" is not intended to mean that the performance requirements of 10 CFR 70.61 are required by regulation, only that their use as accident consequence and likelihood criteria could be found acceptable by staff.

(a) NRC staff considers the factors set forth in 10 CFR 70.62(a) an acceptable method of demonstrating an adequate safety program, as such the application is acceptable if the description of the safety program contains the following information, or alternative information proposed and justified by the applicant:

(1) The safety program described in the application demonstrates compliance with the performance requirements in 10 CFR 70.61(b), (c), and (d), or alternate performance criteria proposed in the application. The safety program may be graded such that the management measures applied are graded commensurate with the magnitude of the risks involved. Three elements of this safety program - process safety information, integrated safety analysis (ISA), and management measures - are described in paragraphs (b) through (d) of this section.

(2) The application describes a commitment to establish and maintain records that demonstrate compliance with paragraphs (b) through (d) of this section or alternate performance criteria.

(3) The description of the records management program demonstrates that the applicant will maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an IROFS or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of 10 CFR 70.61 referenced above are not satisfied. These records should identify the IROFS or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the IROFS was unable to perform its function, any other IROFS or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance criteria or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an IROFS or management measure.

(b) *Process safety information.* The application is acceptable if it includes a commitment to maintain process safety information to enable the performance and maintenance of an ISA. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

(c) *Integrated Safety Analysis.*

(1) The application is acceptable if it includes a summary of an ISA that is of appropriate detail for the complexity of the process that identifies:

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) above, and the methods used to determine the consequences and likelihoods; and

(vi) Each IROFS identified in the required accident analyses pursuant to 10 CFR 70.61(e), the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the IROFS is relied on to support compliance with the performance criteria.

(2) The application is acceptable if the description of the ISA team qualifications demonstrates that the ISA has been performed by a team with expertise in engineering and process operations to ensure the adequacy of the ISA. The team included at least one person who has experience and knowledge specific to each process being evaluated and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific accident analysis methodology being used.

(d) *Management measures.* The application is acceptable if it includes a description of management measures established to ensure compliance with the performance criteria in 10 CFR 70.61, or alternative criteria proposed and justified by the applicant. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures must ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed, and to comply with the performance requirements of 10 CFR 70.61, or alternative criteria proposed and justified by the applicant.

As used in this ISG, the term, “performance requirements” is not intended to suggest that the performance requirements found in 10 CFR 70.61 are being imposed against licensees licensed under 10 CFR Part 50, only that their use as accident consequence and likelihood criteria by radioisotope production facilities may be found acceptable by NRC staff.

A new Review Procedure is added as follows: The reviewer should review the production facility safety program description against the format and content guide (Part 1 of this ISG).
A new subsection is added to *Evaluation Findings* as follows:

- The applicant has described a production facility safety program that includes process safety information, an ISA Summary, and commitments to management measures that meet the acceptance criteria described above and applicable acceptance criteria referenced in NUREG-1520.

12.2 through 12.6

The current wording of these sections in NUREG-1537 applies to a non-power reactor and radioisotope production facility without augmentation or modification to this ISG.

12.7 Emergency Planning

1. Emergency planning is a specialized area of review. AHRs should follow the guidance in NUREG-1537. If the facility is a combined non-power reactor and a radioisotope production facility, the NRC staff expects the applicant to provide one emergency plan for the entire site. For the review and evaluation of combined non-power reactors and radioisotope production facilities, the emergency plan review should use NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," issued October 1983, for the reactor and production facility. In addition, NUREG-1520, Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, " issued May 2010, suggests additional information that should be included for the production facility, as described below.

Section 1.0, "Introduction"

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- Provide a detailed drawing of the site showing the following features:
  - Onsite and near offsite (within 1.61 kilometers (km) (1 mile (mi)) structures with building numbers and labels.
  - Roads and parking lots on site and main roads near the site.
  - Site boundaries showing fences and gates.
  - Major site features.
  - Water bodies within approximately 1.61 km (1 mi) of the site.
- Include a general area map covering a radius of approximately 16.1 km (10 mi), a U.S. Geological Survey topographical quadrangle (7.5-minute series, including the adjacent quadrangles if the site is located less than 1.61 km (1 mi) from the edge of the quadrangle), and a map or aerial photograph indicating onsite and near-site structures within a radius of approximately 1.61 km (1 mi). The map should include the location of sensitive facilities near the site, such as hospitals, schools, nursing homes, nearest residents, fire department, prisons, environmental sampling locations, and other structures and facilities that are important to emergency management.
- Detail the stack heights, typical stack flow rates, and efficiencies of any emission control devices.

- Describe, in general, the licensed and other major activities conducted at the facility and the type, form, and quantities of radioactive and other hazardous materials that are normally on the site, by locations (use and storage), building, and hazardous characteristics (exposure rates, pH, temperature, and other characteristics), that are important to emergency management.

- Provide certification by the plant manager (or the individual authorized by the applicant) that the applicant has met all responsibilities under the Emergency Planning and Community Right To Know Act of 1986 (Title III, Public Law 99-499), in accordance with 10 CFR 70.22 (i)(3)(xiii).

- For each general type of accident identified in the Integrated Safety Analysis (ISA) summary or Safety Analysis Report (SAR) for which protective actions may be needed.

  – The process and physical locations where accidents could occur.

  – Complicating factors and possible onsite and offsite consequences, including releases of nonradioactive hazardous chemicals incident to the processing of licensed material that could impact emergency response efforts.

  – The accident sequence that has the potential for the greatest radiological or toxic chemical impact.

  – Figures projecting doses and toxic substance concentrations as a function of distance and time for various meteorological stability classes, including a description of how the applicant projected such doses or concentrations (e.g., computer models and assumptions).

Section 2.0, “Definitions”

The emergency plan should define words or phrases with meanings specific or unique to the plan, reactor, or production facility.

Section 3.0, “Organization and Responsibilities”

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan should describe who will take the following actions and how he or she will act promptly and effectively:

  – The decision to declare an alert or site area emergency.

  – The activation of the onsite emergency response organization during all shifts.

  – The prompt notification of offsite response authorities that an alert or site area emergency has been declared, including the licensee’s initial recommendation for offsite protective actions (normally within 15 minutes of classification).

– The notification of the NRC Operations Center (as soon as possible and, in any case, no later than 1 hour after a declared emergency).

– The decision regarding which onsite protective actions to initiate.

– The decision regarding which offsite protective actions to recommend.

– The decision to request support from offsite organizations.

– The decision to terminate the emergency or enter recovery mode.

- The emergency plan should describe the following aspects of the applicant's plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency:

  – The methods and responsibilities for assessing the damage to and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process.

  – Key positions in the recovery organization.

Section 4.0, "Emergency Classification System"

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan classification system should include the following two classifications for the production facility:

  (1) Alert: Events that may occur, are in progress, or have occurred, that could lead to a release of radioactive material or hazardous chemicals incident to the processing of license material; however, the release is not expected to require a response by an offsite response organization to protect persons offsite.

  (2) Site Area Emergency: Events that may occur, are in progress, or have occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the processing of license material and that could require a response by offsite emergency response organizations to protect persons offsite.

- The emergency plan should identify the classification (alert or site area emergency) expected for each accident identified in the emergency plan.

Section 5.0, "Emergency Action Levels"

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan should specify emergency action levels (EALs) at which an alert or site area emergency will be declared. EALs are specific conditions that require the performance of emergency response measures. The applicant's EALs should be consistent with

Appendix A to Regulatory Guide 3.67, Revision 1, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," issued April 2011, and should be comparable to the U.S. Environmental Protection Agency's protective action guidelines described in EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," issued May 1992. Transportation accidents more than 1.61 km (1 mi) from the facility should not be classified.

Section 6.0, "Emergency Planning Zones"

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the radioisotope production facility:

- As part of emergency planning, the owner/operator of a facility that identifies radiological emergencies which result in offsite plume exposures exceeding 1 rem whole body or 5 rem thyroid should identify an emergency planning zone (EPZ). The postulated radioactive release from credible accidents provides the basis for determining the need for an EPZ. The size of the EPZ should be established so that the dose to individuals beyond the EPZ is not projected to exceed the protective action guideline. As an alternative to performing such calculations, the EPZ sizes provided in Appendix II of NUREG-0849 may be adopted according to the power level.

Section 7.0, "Emergency Response"

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan should describe the following aspects of the applicant's procedures to be used to promptly and effectively assess the release of radioactive material or hazardous chemicals incident to the processing of licensed material:
  - Procedures for estimating or measuring the release rate or source term.
  - Valid computer codes used to project doses or concentrations to the public or environment and their associated assumptions, along with adequate justifications to show the validity of the assumptions.
  - Types, methods, frequencies, implementation times, and other details of onsite and offsite sampling and monitoring that will be performed to assess a release of radioactive materials or hazardous chemicals incident to the processing of licensed material.
  - The method for assessing collateral damage to the facility (including items relied on for safety).
- The emergency plan should provide reasonable assurance that emergency notification procedures will enable the emergency organization to correctly classify emergencies, notify emergency response personnel, and initiate or recommend appropriate actions in a timely manner, on the basis of the following:

  - Notification procedures minimize distraction of shift operating personnel and include concise, preformatted messages. Appropriate follow-up messages to offsite authorities are issued promptly.

  - Radiological and chemical source term data are available to the command post, technical support center, emergency operation center, and appropriate State personnel in cooperation with the NRC.

  - When available, offsite field monitoring data are logged, compared with source term data, and used in the protective action recommendation process.

  - Protective action guides are available and are used by the appropriate personnel in a timely manner.

- The emergency plan should describe the information to be communicated during an emergency, including the following:

  - A standard reporting checklist to facilitate timely notification.

  - A description of preplanned protective action recommendations to be made to each appropriate offsite organization.

  - Recommended actions to be taken by offsite organizations for each accident treated in the emergency plan.

Section 8.0, “Emergency Facilities and Equipment”

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- For each accident identified in the ISA Summary or SAR, the emergency plan should briefly describe measures and equipment.

- For each type of accident identified, the emergency plan should describe the following:

  - The means of detecting the accident.

  - The means of detecting any release of radioactive material or hazardous chemicals incident to the processing of licensed material.

  - The means of alerting the operating staff.

- The emergency plan should list and describe onsite and offsite facilities that could be relied on in an emergency. The emergency plan should include the following:

  - A list and description of both onsite and offsite emergency facilities, by location and purpose.

- A description of emergency monitoring equipment available for personnel and area monitoring, and to assess the release to the environment of radioactive or hazardous chemicals incident to the processing of licensed material.

- A description of the onsite and offsite services that support emergency response operations, including first aid personnel, firefighters, law enforcement assistance, and ambulance services.

Section 9.0, “Recovery”

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan should describe the following aspects of the applicant’s plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency:

  - The procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive material or hazardous chemicals incident to the processing of licensed material and to prevent further incidents.

  - The provisions for promptly and effectively accomplishing required restoration actions.

Section 10.0, “Maintaining Emergency Preparedness”

The reviewer should verify that the emergency plan supplements the information suggested in NUREG-0849 with the following details regarding the production facility:

- The emergency plan should describe the frequency, performance objectives, and plans for the emergency response training that the licensee will provide to workers. The plan should include the following:

  - The topics and general content of training programs for the licensee’s onsite and offsite emergency response personnel to satisfy the objectives described above.

  - The administration of the training program including responsibility for training, the positions to be trained, the schedule for training, the frequency of retraining, the use of team training, and the estimated number of hours of initial training and retraining.

  - The training to be provided on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response.

  - The training program for onsite personnel who are not members of the emergency response staff.

  - Any special instructions and orientation tours that the licensee would offer to fire, police, medical, and other non-licensee emergency personnel who may be

required to respond to an emergency to ensure that they know the emergency plan, assigned duties, and effective response to an actual emergency.

- The emergency plan should state the applicant's commitment to conduct exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency. An adequate plan should demonstrate the following:

  – Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation.

  – Effective player, controller, evaluator, and observer pre-drill briefings are conducted.

  – Scenario data and exercise messages provided by the controllers effectively maintain the timeline and do not interfere with the emergency organization's response to exercise scenario events, except when safety considerations are involved.

  – The pre-staging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities.

  – Emergency drills demonstrate that resources are effectively used to control the site, mitigate further damage, control radiological releases, perform required onsite activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery.

  – Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events.

  – Emergency drills demonstrate that onsite communications effectively support emergency response activities.

  – Emergency drills demonstrate that the emergency public information organization disseminates accurate, reliable, timely, and understandable information.

  – Provisions are made for conducting quarterly communications checks with offsite response organizations.

  – Offsite organizations are invited to participate in the biennial onsite exercise, which tests the major elements of the emergency plan and response organizations.

Emergency planning is a specialized area of review. The technical reviewer should forward emergency planning information and proposed emergency plans to the branch in the Office of Nuclear Security and Incident Response responsible for the review and evaluation of emergency plans at non-power reactors and radioisotope production facilities. The emergency

plan reviewer should provide an evaluation for inclusion in the staff's safety evaluation report. The emergency plan reviewer should use NUREG-0849 (appears as Appendix 12.2 in NUREG-1537, Part 2).

12.8 Security

Security planning is a specialized area of review. The technical reviewer should forward security planning information and proposed security plans to the branch in the Office of Nuclear Reactor Regulation responsible for the review and evaluation of security plans at non-power reactors and radioisotope production facilities. Security planning information is considered either proprietary or safeguards information (including Safeguards Information designated as Safeguards Information-Modified Handling) and must receive special handling. The technical reviewer should ensure that this information is handled properly. The security plan reviewer should contact the branch in the Office of Nuclear Security and Incident Response responsible for Information Security regarding any questions on the proper handling of security information. The security plan reviewer should provide an evaluation for inclusion in the staffs' safety evaluation report and a license condition for inclusion in the facility license.

12.9 Quality Assurance

The second sentence of the current section 12.9 of NUREG-1537 should be ignored. Instead, all quality assurance should be sent to the NRC Document Control Desk (DCD) like all other submittals. The DCD will then forward it to the assigned project manager.

12.10 Operator Training and Qualifications

The current wording of this section predominantly addresses training requirements for the non-power reactor staff. This should be titled:

12.10a Reactor Operator Training and Requalification

The current wording of this section in NUREG-1537 is applicable to a non-power reactor and radioisotope production facility without requiring changes in this ISG.

A new section should be added to the application pertaining to training in the radioisotope production facility addressing the following:

12.10b Production Facility Operator Training and Requalification

Reviewers should ensure that license applications for radioisotope production facilities contain the technical qualifications, training, and licensing requirements for operators as addressed in the following paragraphs.

The Atomic Energy Act of 1954, Section 107 states: "The Commission shall prescribe uniform conditions for licensing individuals as operators of any of the various classes of production and utilization facilities licensed in this Act." As set out in 10 CFR 50.54(h) and (i) the license is subject to the provisions of the Act, and the licensee may not permit the manipulation of the controls of any facility by anyone who is not a licensed operator or senior operator pursuant to the regulations in 10 CFR Part 55, "Operators' Licenses." Although 10 CFR Part 55 only specifies the licensing requirements for utilization facility operators without specifically

addressing production facilities, the NRC has determined that the same technical and safety considerations apply to operators of production facilities and so will also apply the relevant 10 CFR Part 55 requirements to production facility operators by a license condition.

The NRC requires facilities licensed under 10 CFR Part 70 to employ properly qualified and trained staff and to ensure staff are trained on how to respond to emergency situations. NUREG-1520 provides further guidance for training for all personnel who perform activities relied on for safety. The staff should be trained and tested so as to provide reasonable assurance that they understand, recognize the importance of and are qualified to perform those activities relied on for safety in a manner that adequately protects public health and safety and the environment. As appropriate for their authority and responsibility, personnel should have the knowledge and skills necessary to design, operate, and maintain the facility safely.

In addition to the general and specific training requirements for licensing utilization facility operators and senior operators contained in 10 CFR Part 55, the staff of a radioisotope production facility conducting safety related operations with SNM outside of the reactor should be trained and tested in the following additional basic topics:

- Theory and principles of the radioisotope production processes involving SNM
- Theory and principles of radioisotope extraction and purification processes
- Facility design and operating characteristics
- Instrumentation and control systems
- Engineered safety features
- Technical specifications
- Criticality control features and management measures required for each process involving SNM
- Normal and emergency operating procedures
- ANSI/ANS-15.4-2007 may contain additional guidance on training and qualification of personnel applicable to production facilities.

Regulation 10 CFR 50.54(i-1) requires that within 3 months after an operating license is issued, the licensee have in effect an operator requalification program, which at a minimum meets the requirements of 10 CFR 55.59(c). Regulation 10 CFR Part 55 applies specifically to utilization facilities. With regards to Production Facilities, the operators should comply with the same requirements in 10 CFR 50.54(i-1).

Areas of Review

- Conduct of on-the-job training
- Evaluation of training effectiveness

The review of the training and qualification should address the following areas:

- Organization and management of the training function
- Analysis and identification of functional areas requiring training
- Position training requirements
- Development of the basis for training, including objectives
- Organization of instruction and use of lesson plans and other training guides
- Evaluation of trainee learning
- Personnel qualification
- Provisions for continuing quality assurance, including the needs for retraining or reevaluation of qualification

Acceptance Criteria

The reviewer should verify that the operator training and requalification program is acceptable regarding personnel training and qualification based on the following criteria:

- The program should include the following commitments regarding organization and management of training:
  - Line management is responsible for the content and effective conduct of the training.
  - The program clearly defines job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training.
  - The program uses performance-based training as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
  - The program documents and implements procedures to provide reasonable assurance that all phases of training are conducted reliably and consistently.
  - The program ensures that training documents are linked to the configuration management system to provide reasonable assurance that the training reflects design changes and modifications.
  - The program maintains both programmatic and individual training records. These records support management information needs and provide required data on each individual's training and qualification.
- The program should provide formal training for each position or activity that is relied on for safety. Training may be both classroom based and on the job. The application

should state the training that will be conducted and identify the personnel that will be required to complete it. The application should also demonstrate the following:

  – The program ensures that each activity selected for training (initial or continuing) from the facility-specific activities is correlated with supporting procedures and training materials.

  – The program reviews facility-specific activities selected for training and compares training materials on an established schedule, updating them as necessitated by changes in procedures, facility systems and equipment, or job scope. The applicant monitors and evaluates change actions (e.g., procedure changes, equipment changes, facility modifications) for their impact on the development or modification of initial and continuing training and incorporates such change actions in a timely manner.

- The program should contain commitments regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, facility operators, technicians, maintenance personnel, and other staff who perform regulated activities.

- The program should contain commitments regarding minimum qualifications for personnel. Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel as detailed below:

  – Managers should have a bachelor of science (B.S.), bachelor of arts (B.A.), or equivalent degree. Each manager should have either management or technical experience in a facility similar to the facility identified in the application.

  – Supervisors should have at least the qualifications required of personnel being supervised.

  – Technical professional staff whose actions or judgments are critical to satisfying the performance requirements identified in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” should have a B.S., B.A., or equivalent degree in the appropriate technical field.

  – Construction personnel, facility operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant’s training process or have equivalent experience or training.

  – The program should require candidates for process operators to meet the minimum qualifications described in the application. The applicant should require candidates for job functions other than process operators to meet minimum qualifications, but the application need not describe these minimum qualifications.

- The program should include training objectives that state the knowledge, skills, and abilities that the trainee should acquire; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.

- The program should include lesson plans and other training guides that provide guidance to ensure the consistent conduct of training activities based on required learning objectives derived from specific job performance requirements.

- The program should include standards for evaluating acceptable trainee performance. The evaluation of trainee accomplishment is acceptable if the applicant evaluates trainees periodically during training to determine their progress toward full capability to perform the job requirements and at the completion of training to determine their capability to perform the job requirements.

- The program should establish review and approval requirements for all lesson plans or guides and other training materials before their issuance and use.

- The program should describe any on-the-job training used for activities relied on for safety.

- The program should include on-the-job training using well-organized and current training materials. Designated personnel who are competent in the program standards and training methods should conduct the training.

- The program should use actual task performance to complete on-the-job training. When the actual task cannot be performed and is, therefore, "walked down," (simulated or subjected to a dry run) the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

- The program should include provisions for continuing assurance of personnel training and qualification through periodic requalification of personnel by training or testing or both, as necessary, to provide reasonable assurance that personnel continue to understand, recognize the importance of, and be qualified to perform activities that are relied on for safety.

- The program should evaluate training effectiveness, that its relationship to job performance remains acceptable, and that there is reasonable assurance that the training conveys the required skills and knowledge based on the performance of trained personnel in the job setting. The application should also demonstrate the following:

  – Qualified individuals should periodically conduct a comprehensive evaluation of individual training to identify strengths and weaknesses. The applicant should use feedback from trainee performance during training and from former trainees and their supervisors to evaluate and refine the training.

  – The applicant should initiate, evaluate, track, and incorporate improvements and changes to initial and continuing training to correct training deficiencies and performance problems.

Review Procedures

Recognizing that the training objectives and methods and the required personnel qualifications may be graded to correspond to the hazard potential of the facility, the reviewer will perform a

safety evaluation using the acceptance criteria described above. In particular, the reviewer should:

- Evaluate the adequacy of training and qualification on the basis of how well it fulfills the applicant's training objectives, especially when human factors are relied on for safety.

- Determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety.

- Focus on the training and qualification of personnel who will perform activities relied on for safety.

- Become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities correspond to them.

- Determine whether there is reasonable assurance that the applicant's personnel training and qualification efforts will result in only properly trained and qualified personnel performing activities relied on for safety.

Evaluation Findings

A statement similar to the following should be included in this section:

> Based on its review of the license application [insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable], the NRC staff concludes that the applicant has adequately described and assessed its personnel training and qualification in a manner that satisfies the acceptance criteria and is consistent with the guidance in this ISG.
>
> Reasonable assurance exists that implementation of the described training and qualification will result in personnel who are qualified and competent to design, construct, start up, operate, maintain, modify, and decommission the facility safely. The staff concludes that the applicant's plan for personnel training and qualification meets the requirements of 10 CFR Part 50.
>
> Members of the facility operations staff who manipulate the controls of the production facility or who perform other duties to meet the performance requirements of 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d) (or the alternative criteria proposed and justified by the applicant) are fully qualified and licensed, in accordance with the requirements of 10 CFR 50.54(i) and 10 CFR Part 55, "Operator's Licenses," as augmented by this ISG.

As used in this ISG, the term, "performance requirements" is not intended to suggest that 10 CFR Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria by radioisotope production facilities would be found acceptable by NRC staff.

12.11 Startup Plan

The current wording of this section in NUREG-1537 applies to a non-power reactor and radioisotope production facility without change.

12.12 This section has been vacated.

NUREG-1537 Section 12.12, "Environmental Report" is superseded in its entirety by Chapter 19, "Environmental Review." This Interim Staff Guidance has significantly increased the volume of information on environmental matters to reflect requirements in 10 CFR Part 51 which implement the National Environmental Policy Act of 1969 (NEPA), as amended for NRC licensees. As a result, the new Chapter 19 has been created for use in future revisions of NUREG-1537. Section 12.12 is intended to remain permanently vacated, and no new guidance on any topic will be inserted in section 12.12, since applications submitted prior to this change included the environmental information in Section 12.12.

12.13 Material Control and Accounting Plan

The reviewer should ensure that a complete plan is filed in accordance with the requirements of 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material." This section should include the following subsections:

Areas of Review

The reviewer should verify that the application should includes information regarding compliance with Subparts A through E of 10 CFR Part 74, as appropriate, for the class of facility involved. All general and class-specific information should be included as applicable to the following:

- General requirement for all facilities
- Facilities with quantities of low strategic significance
- Facilities with quantities of moderate strategic significance
- Facilities with formula quantities of strategic SNM

Acceptance Criteria

The review shall verify that the material control and accounting plan must contains all of the information prescribed in 10 CFR Part 74 for the specific class of facility contained in the application.

Review Procedures

The reviewer should ascertain that the plan contains a clear, accurate, and thorough account of all inventory, measurement, recordkeeping, and reporting requirements prescribed by the regulations.

Evaluation Findings

The reviewer should be able to conclude the following from the submitted plan:

> The applicant has provided a complete plan that will ensure that all SNM in the facility will be properly accounted for and that will enable the licensee to achieve the specific objectives prescribed in the regulations for the relevant class of material that will be possessed at the facility.

12.14 References

Reference ANSI/ANS 15.1-1990 has been replaced with ANSI/ANS 15.1-2007.

Reference ANSI/ANS 15.4-1988 has been replaced with ANSI/ANS 15.4-2007.

Reference ANSI/ANS 15.8-1976 has been replaced with ANSI/ANS 15.8-2009.

Reference ANSI/ANS 15.11-1993 has been replaced with ANSI/ANS 15.11-2004.

Reference ANSI/ANS 15.16-1978 has been replaced with ANSI/ANS 15.16-2008.

The NRC issued Revision 1 of Regulatory Guide 2.5, “Quality Assurance Program Requirements for Research and Test Reactors,” in June 2010.

13 ACCIDENT ANALYSES

NUREG-1537, Part 2, Chapter 13 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the accident analyses for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 13a1, "Heterogeneous Reactor Accident Analyses"
- 13a2, "Aqueous Homogeneous Reactor Accident Analyses"
- 13b, "Radioisotope Production Facility Accident Analyses"

Guidance for each of these options follows.

13a1 Heterogeneous Reactor Accident Analyses

Chapter 13 of NUREG-1537, Part 2, applies to heterogeneous non-power reactors and can be used without further guidance.

13a2 Aqueous Homogeneous Reactor Accident Analyses

Other chapters of the SAR should contain discussions and analyses of the AHR facility as designed for normal operation. The discussions should include the considerations necessary to ensure safe operation and shutdown of the reactor to avoid undue risk to the health and safety of the public, the workers, and the environment. The analyses should include limits for operating ranges and reactor parameters within which safety can be ensured. The bases for the technical specifications should be developed in those chapters.

In this chapter, the applicant should present a methodology for reviewing the systems and operating characteristics of the reactor facility that could affect its safe operation or shutdown. The methodology should be used to identify limiting accidents, analyze the evolution of the scenarios, and evaluate the consequences. The analyses should start with the assumed initiating event. The effects on designed barriers, protective systems, operator responses, and mitigating features should be examined. The endpoint should be a stable reactor. The potential radiological consequences to the public, the facility staff, and the environment should be analyzed. The information and analyses should show that facility system designs, safety limits, limiting safety system settings, and limiting conditions for operation were selected to ensure that the consequences of analyzed accidents do not exceed acceptable limits.

The applicant should also discuss and analyze a postulated accident scenario whose potential consequences are shown to exceed and bound all credible accidents. For non-power reactors (including AHRs), this accident is called the maximum hypothetical accident (MHA). Because the accident of greatest consequence at a non-power reactor would probably include the release of fission products, the MHA (in most cases) would be expected to contain such a scenario involving fuel or fission products, or both, outside the core and does not need to be

entirely credible. The review and evaluation should concentrate on the evolution of the scenario and analyses of the consequences, rather than on the details of the assumed initiating event.

The MHA is used to demonstrate that the maximum consequences of operating the reactor at a specific site are within acceptable limits. Therefore, a MHA is postulated that results in consequences bounding those of any credible accident likely to occur over the life of the facility. The applicant may perform a sensitivity analysis of the assumptions of the MHA. For example, reactor operating time before accident initiation may be examined to determine the change in MHA outcome if a more realistic assumption is made. Assumptions made in the accident analysis may form the basis for technical specification limits on the operation of the facility. For example, if the accident analysis assumes that the reactor operates for 5 hours a day, 5 days a week, this may become a limiting condition for operation.

The information in this chapter should achieve the objectives stated in this chapter of NUREG-1537, Part 1, by demonstrating that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences. Each postulated accident should be assigned to one of the following categories or grouped consistently according to the type and characteristics of the particular reactor. For AHRs, the following categories are applicable:

- MHA
- Insertion of excess reactivity
- Reduction in cooling
- Mishandling or malfunction of fuel
- Loss of normal electric power
- External events (include natural hazards and manmade events)
- Mishandling or malfunction of equipment
- Large and undamped power oscillations
- Detonation or deflagration of flammable gas mixtures
- Unintended exothermic chemical reactions other than explosion
- Facility system interaction events

The applicant should systematically analyze and evaluate events in each group to identify the limiting event selected for detailed quantitative analysis. The limiting event in each category should have consequences that exceed all others in that group. The discussions could address the likelihood of occurrence, but quantitative analysis of probability is not expected or required. As noted above, the MHA analyzed should bind all credible potential accidents at the facility. The applicant should demonstrate knowledge of the literature available for AHR accident analysis.

Areas of Review

Areas of review should include systematic analysis and discussion of credible accidents for determining the limiting event in each category. The applicant may have to analyze several events in a particular accident category to determine the limiting event. This limiting event should be analyzed quantitatively. NUREG 1537, Part 1, Chapter 13, suggests the steps for the applicant to follow once the limiting event is determined for a category of accidents.

Acceptance Criteria and Dose Limits

The safety analysis must meet the requirements set forth in 10 CFR 50.34, "Contents of application; technical information." In particular, a construction permit application must include a safety analysis report as described in 10 CFR 50.34(a), "Preliminary safety analysis report;" an operating license application must include a safety analysis report as described in 10 CFR 50.34(b), "Final safety analysis report."

The dose limits in 10 CFR Part 20, Subparts C and D apply. Applicants may reference 10 CFR Part 100, as applicable (power and test reactors), for AHR siting criteria. The applicant should discuss why the MHA is not likely to occur during the operating life of the facility.

Review Procedures

Information in the SAR should allow the reviewer to follow the sequence of events in the accident scenario from initiation to a stabilized condition. The reviewer should confirm the following:

- The credible accidents were categorized, and the most limiting accident in each group was chosen for detailed analyses.

- The reactor was assumed to be operating normally under applicable technical specifications before the initiating event. However, the reactor may be in the most limiting technical specification condition at the initiation of the event.

- Instruments, controls, and automatic protective systems were assumed to be operating normally or to be operable before the initiating event. Maximum acceptable non-conservative instrument error may be assumed to exist at accident initiation.

- The single malfunction that initiates the event was identified.

- Credit was taken during the scenario for normally operating reactor systems and protective actions and the initiation of ESFs required to be operable by TSs.

- The sequence of events and the components and systems damaged during the accident scenario were clearly discussed.

- The mathematical models and analytical methods employed, including assumptions, approximations, validation, and uncertainties, were clearly stated.

- The radiation source terms were presented or referenced.

- The potential radiation consequences to the facility staff and the public were presented and compared with acceptable limits.

The reviewer should confirm that the integrity of the primary boundary will be maintained under all credible accidents analyzed. The primary boundary consists of all structures that prevent the release of fuel and fission products in solution and the fission gases generated during operation. Specifically, they include the vessel containing the fuel; the offgas systems and the waste gas holding systems; the cooling coils in the vessel; and the associated pumps, valves, heat exchangers, and piping.

The reviewer should determine whether the applicant has categorized and analyzed all credible accidents, in terms of the limiting phenomena identified below, that could pose a challenge to the integrity of the primary boundary in different locations in the facility. The reviewer should also determine whether the applicant has identified the limiting sources and amounts of radionuclides that could be released within the facility or to the outside environment, thereby exposing the facility staff or the general public to radiation. The limiting phenomena for AHRs are expected to be:

- Thermal-hydraulic safety limits (i.e., change of phase occurs as liquid evaporates into gas)

- Precipitation of fission products

- Precipitation of fuel (uranium)

- Detonation or deflagration of combustible gas mixtures

- Excessively high radiolytic gas release

The limiting phenomena are analogous to phenomena for heterogeneous non-power reactors that set operational and safety limits. For example, departure from nucleate boiling has been identified as a phenomenon that greatly increases the likelihood of cladding failure in light-water reactors and is useful in deriving quantitative operating and safety limits. Additionally, regulatory limits such as cladding oxidation are tied to the phenomenon of loss of cladding ductility. While the specific safety limits will depend on the reactor design, the reviewer should confirm that the applicant has addressed these limiting phenomena in its definitions of operating and safety limits as well as accident analyses.

Reactivity limits and the functional designs of control and safety-related systems should prevent loss of primary boundary integrity during credible accidents involving insertion of some fraction of excess reactivity. The analyses should include applicable reactivity feedback coefficients and automatic protective actions.

The reviewer should confirm that the applicant has analyzed potential power instabilities, including unstable (growing) power oscillations that are large and undamped. These large, undamped power oscillations could result from positive feedback. The reviewer should confirm that the reactor will return to a stable state such that the integrity of the primary boundary is not challenged.

The reviewer should confirm that loss of normal electrical power and consequent reduction in cooling will not lead to a challenge to the primary boundary. A loss of normal electric power should not compromise safe reactor shutdown.

Evaluation Findings

It is essential that all credible accidents at an AHR be considered and evaluated during the design stage. Experience has indicated that facilities can be designed and operated so that the environment and the health and safety of the staff and the public can be protected. Because AHRs are designed to operate with primary coolant temperatures and pressures close to ambient, the margins for safety are usually large, and few, if any, credible accidents can be sufficiently damaging to release radioactive materials to the unrestricted area. For potential accidents and the MHA that could cause a release, the acceptance criteria and review procedures discussed above are sufficiently comprehensive and do not need to be repeated for each postulated accident. However, the potential consequences, detailed analyses, evaluations, and conclusions are facility specific and accident specific. The findings for the eleven major accident categories are presented below. These findings are examples only; the actual wording should be modified for the situation under review.

13a2.1 Accident-Initiating Events and Scenarios

This section of the SAR should contain sufficient information to support the types of conclusions given below. The staff's SER will include those conclusions. The appropriate number for the reactor under evaluation should replace the notation "xx" and "yy." The reviewer should modify these conclusions to conform to the reactor design under consideration.

13a2.1.1 Maximum Hypothetical Accident

The reviewer should determine whether the following finding is applicable:

> The applicant has considered the consequences to the public of all credible accidents at the reactor facility. An MHA, which is an accident that would release fission products from fuel and would have consequences greater than any credible accident, has been analyzed. The MHA scenario is credible but the combination of bounding conditions analyze are, not credible. However, the MHA serves as a bounding accident analysis for a non-power reactor. [The MHA is specific to the reactor design and power. The reviewer may have to evaluate an MHA that differs from the suggested list of MHAs below.]

Possible MHAs for an AHR could be one or a combination of the following events:

- Energetic dispersal of the contents of the primary boundary with bypass of any scrubbing capacity (e.g., a pool surrounding the fuel vessel).

- Detonation of hydrogen in the recombiner resulting in waste gas tank failure and release of some or all of the fuel and fission product contents in aerosolized form.

- Complete loss of fuel inventory (e.g., vessel break).

Possible MHAs for a multi-reactor AHR facility could be one or a combination of the following events:

- A manmade external event that breaches the primary boundary of more than one unit.

- A facility-wide external event that breaches various systems containing radioactive fluids.

The reviewer should modify the following paragraphs, as appropriate:
"The air handling and filtering systems (i.e., confinement or containment) are assumed to function as designed, and radioactive material is held up temporarily in the reactor room and then released from the building. Realistic methods are used to compute external radiation doses and dose commitments resulting from inhalation by the facility staff. Realistic but conservative methods are used to compute potential doses and dose commitments to the public in the unrestricted area. Methods of calculating doses from inhalation or ingestion (or both) and direct shine of gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in Chapter 11 of the SAR. The duration of the accident considered for the calculation of doses for the facility staff is (*xx)* and for the public it is (*yy).*"

The calculated doses for the MHA scenario are the following:

Licensee staff – xx mrem

Maximum exposed member of the public – yy mrem

Nearest residence – xx mrem

These doses and dose commitments are within the acceptable limits [state limits]. Because the assumptions of the scenario are bounding, the doses calculated will likely not be exceeded by any accident considered credible. The applicant has examined more realistic assumptions about operating time and release fractions that decreased the source term by "xx" percent of the one calculated, lowering the maximum doses by that factor (if applicable). Thus even for the MHA, whose consequences bound all credible accidents possible at the facility, the health and safety of the facility staff and the public are protected.

13a2.1.2 Insertion of Excess Reactivity

The reviewer should determine if the following finding is applicable:

> The applicant has considered the following initiators that could insert excess reactivity in AHRs:
>
> - Pressurization of the fuel fluid
>
> - Excessive cool-down via heat sink malfunction
>
> - Moderator injection resulting from cooling system malfunction (e.g., cooling tube rupture)

- Fuel injection
- Realistic, adverse geometry changes (e.g., those caused by “sloshing” of the fuel solution in the vessel)
- Reactivity insertion from moderator lumping effects (e.g., voiding in the cooling coil)
- Inadvertent introduction of other material into the fuel solution (e.g. excessive acid addition)
- Control rod removal or ejection, or system or experiment malfunction

The limiting reactivity insertion event has been identified and analyzed and the consequences of this event are within the dose acceptance limits and bounded by the MHA. The reactor attains a stable condition following the limiting event. Radiation doses to the public and staff are thus within acceptable limits and the safety and health of the staff and public are adequately protected.

13a2.1.3 Reduction in Cooling

The reviewer should determine if the following finding is applicable:

> The applicant has considered postulated events that lead to reduction or loss of cooling. The following initiators have been analyzed:
>
> - Loss of electrical power
> - Failure of active components in the normal heat removal system
> - Cooling coil or heat exchanger tube rupture
> - Flow obstruction in heat exchangers
> - Loss of forced circulation
> - Recombiner burnout

The consequences of reduction in cooling events have been analyzed and shown to be bounded by the MHA. Radiation doses to the public and staff will be within acceptable limits, and the safety and health of the staff and public will be adequately protected.

13a2.1.4 Mishandling or Malfunction of Fuel

The reviewer should determine if the following finding is applicable.

The applicant considered the consequences of fuel solution mishandling events, such as excessive leakage or spillage that could potentially initiate an unintended criticality event in an area or location where it could pose a threat to facility staff. The MHA bounds the accidental

dose consequences of such postulated events. Therefore, doses to the staff and the public will be within acceptable limits, and the health and safety of the staff and public will be adequately protected.

The applicant considered the consequences of fuel malfunction events for an AHR. These events include failure to control pH, temperature, or pressure of the fuel solution, which can impact the physical or chemical form of the fuel or solvent resulting in adverse chemical effects, such as fuel precipitation or excessive corrosion. The MHA bounds the accidental dose consequences of such postulated events. Therefore, doses to the staff and the public will be within acceptable limits, and the health and safety of the staff and public will be adequately protected.

13a2.1.5 Loss of Electrical Power

The reviewer should determine if the following finding is applicable:

The applicant's analysis considered the effects of radiolytic decomposition of the fuel solution and the formation of fission gases, addressed the system response to gas formation, and evaluated the potential for the decomposed gases to react explosively. The applicant's analyses were carried out for a sufficient duration to demonstrate that the reactor reaches a stable state and that the MHA bounds the accidental dose consequences of such postulated events. Therefore, doses to the staff and the public are within acceptable limits and the health and safety of the staff and public are adequately protected.

13a2.1.6 External Events

The reviewer should determine if the following finding is applicable:

Chapters 2 and 3 of the SAR discuss the design of the reactor facility and its ability to withstand external events and the potential associated accidents. The reactor facility is designed to accommodate these events by shutting down, which would not pose undue risk to the health and safety of the public. For events that cause facility damage, the damage is within the bounds discussed for other accidents in this chapter. Therefore, exposure to the staff and the public is within acceptable limits, and external events do not pose an unacceptable risk to the health and safety of the public.

13a2.1.7 Mishandling or Malfunction of Equipment

Initiating events under this heading would require a case-by-case, reactor-specific discussion. If the SAR discusses additional events that fall outside the other categories, the potential consequences should be compared with similar events already analyzed or with the MHA, as applicable.

13a2.1.8 Large Undamped Power Oscillations

Reactivity feedback coupled with plant response could yield conditions that are not inherently stable. For example, positive feedback due to radiolytic gas formation and vessel pressurization under conditions where the recombiner capacity of an AHR is exceeded could result in conditions that are not inherently stable. Conditions where positive feedback is possible should be examined to determine if the reactor remains stable; or, if the reactor becomes unstable and

the power oscillations grow over time, that these unstable power oscillations can be acceptably detected and suppressed.

The reviewer should determine if the following finding is applicable.

The applicant has evaluated potential unstable (growing), large undamped power oscillations and demonstrated that these oscillations are either not possible, or, if they develop, can be readily detected and suppressed so that the reactor reaches a stable state. The applicant considered the potential for positive feedback to arise due to system interaction. Power oscillations should be stable or can be readily detected and suppressed so that the consequences are bounded by the MHA. Therefore, doses to the staff and the public are within acceptable limits and the health and safety of the staff and public are adequately protected.

13a2.1.9 Detonation and Deflagration

The reviewer should determine if the following finding is applicable:

The applicant has evaluated the consequences of potential deflagration or detonation of combustible gases within the primary boundary. The assumptions regarding the impact of potential explosions on primary boundary integrity are valid. The following items have been evaluated: mechanical impact of the explosion in terms of primary barrier integrity; the core response in terms of dynamic fuel response (including potential fuel aerosolization); and reactivity response to any impinging pressure waves. The MHA bounds the consequences of the limiting credible detonation within the primary boundary. Therefore, doses to the staff and public are within acceptable limits, and the health and safety of the staff and public are adequately protected.

13a2.1.10 Unintended Exothermic Chemical Reactions Other Than Explosion

The reviewer should determine if the following finding is applicable:

The applicant has evaluated the consequences of potential unintended exothermic chemical reactions (other than explosions) that could occur within the primary boundary. As a precursor to this event, an excess of gases could accumulate in the primary boundary and subsequently react with oxygen to release heat. The heat could increase pressure within the primary boundary or induce thermal stress on the primary boundary. The applicant identified the types of possible exothermic reactions and assessed the relative consequences.

The MHA bounds the consequences of the limiting unintended exothermic chemical reaction (other than detonations as discussed in Section 13.5.9) within the primary boundary. Therefore, doses to the staff and public are within acceptable limits, and the health and safety of the staff and public are adequately protected.

13a2.1.11 Facility System Interaction Events

Initiating events under this heading would require a case-by-case, reactor-specific discussion. If the SAR discusses additional events that fall outside the other categories, the potential consequences should be compared with similar events already analyzed or with the MHA, as applicable.

For radioisotope production facilities, the reviewer should determine if the following finding is applicable:

The applicant's analysis has considered potential system interactions between the reactor and the isotope production facility. The MHA bounds the accidental dose consequences of these postulated events. Therefore, doses to the staff and the public are within acceptable limits, and the health and safety of the staff and public are adequately protected.

13b Radioisotope Production Facility Accident Analyses

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotopes production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in this section 13b and elsewhere in this ISG, the term "performance requirements" is not intended to suggest that Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria by radioisotope production facilities would be found acceptable by NRC staff. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.

13b.1 Radioisotope Production Facility Accident Analysis Methodology

In this section, the applicant should present a methodology for reviewing the systems and operating characteristics of the facility that could affect safe operation or shutdown. The methodology should be used to identify limiting accidents, analyze the evolution of the scenarios, and evaluate the consequences. The analyses should include the assumed initiating event and the effects on designed barriers, protective systems, and operator responses. The mitigating features should also be examined. The endpoint should be a stable facility. The potential radiological consequences to the public, the facility staff, and the environment should be analyzed. The information and analyses should show that facility system designs, safety limits, limiting control settings, limiting conditions for operation, and surveillance requirements (technical specifications) were selected to ensure that the consequences of analyzed accidents do not exceed acceptable limits.

For a radioisotope production facility, the safety analysis must meet the requirements set forth in 10 CFR 50.34, "Contents of application; technical information." In particular, a construction permit application must include a safety analysis report as described in 10 CFR 50.34(a), "Preliminary safety analysis report;" an operating license application must include a safety analysis report as described in 10 CFR 50.34(b), "Final safety analysis report."

For a radioisotope production facility, the applicant should discuss and analyze an accident scenario with consequences exceeding all credible accidents (i.e., the MHA). The accident analyses of processes involving SNM, radioisotopes, and chemicals outside of the reactor should, as described in 10 CFR Part 70, Subpart H, or alternative methodology proposed and justified by the applicant, and consistent with the guidance found in NUREG-1520, include ISAs for processes involving greater than critical mass (as defined in 10 CFR 70.4) quantities of SNM. The performance criteria in 10 CFR 70.61, "Performance Requirements," categorize accidents according to severity of consequences. Accidents resulting in high consequence, as defined by certain radiological doses or adverse health effects from chemical toxicity, could be considered analogous to an MHA. These performance criteria require that high-consequence accidents to be rendered highly unlikely to occur through the application of in-depth preventive and mitigative measures. Other accidents with less than high consequences, as defined in 10 CFR 70.61, require fewer or less-strict protective measures.

Performance of ISAs of potential accident sequences should identify structures, systems, components, and management measures that will become items relied on for safety (IROFS). The licensee may identify additional protective measures that they become aware of outside of the ISA process that should be designated as IROFS. The license technical specifications should include IROFS and other protective or mitigative measures that meet the criteria for technical specifications, as defined in 10 CFR 50.36, "Technical Specifications."

13b.1.1 Operations Conducted Outside of the Reactor

The information in this section (13b, part 2) should provide the reviewer the assurance that the objectives stated in Part 1 of this section in NUREG-1537, Part 1, have been achieved. All potential accidents at the facility have been considered and their consequences adequately evaluated. At a minimum, the applicant has considered postulated accidents in all of the categories identified below. The information for a particular facility may show that some of the categories do not apply or that certain operations in a facility may warrant the assignment of additional categories.

Processes that are conducted outside of the reactor in a radioisotope production facility and that should be analyzed under accident conditions are divided into three general categories:

(1) Operations with SNM

- Irradiated fuel processed for radioisotope extraction
- Irradiated fuel processed for reuse in the reactor or for waste disposal
- Operations with unirradiated SNM

(2) Radiochemical operations

(3) Operations with hazardous chemicals

13b.1.2 Accident Initiating Events

The ISAs for the above operations and any other planned operations with SNM should include the following initiating events:

- Criticality accident (could be MHA)
- Loss of electrical power
- External events (meteorological, seismic, fire, flood)
- Critical equipment malfunction
- Operator error

The applicant should systematically analyze and evaluate events in each category to identify the limiting event selected for detailed quantitative analysis. The limiting event in each category should have consequences that exceed all others in that category. The discussions may address the likelihood of occurrence, but quantitative analysis of probability is not expected or required. The MHA should bound all credible potential accidents at the facility.

Areas of Review

Areas of review should include a systematic analysis and discussion of credible accidents for determining the limiting event in each category. The applicant may have to analyze several events in a particular accident category to determine the limiting event. This limiting event should be analyzed quantitatively. The steps suggested for performing the analysis of accidents are given in NUREG-1537, Part 1.

The reviewer should determine the following:

- The applicant is fully committed to implementing a safety program, including ISAs (such as those described in 10 CFR 70.62, “Safety Program and Integrated Safety Analysis”) and the management measures prescribed in Section 12.1.6 of this ISG.
- The applicant has addressed all credible accidents involving internal facility and process, abnormal events and process deviations and credible external events that could result in serious adverse consequences to the staff, the facility, the public, and the environment.
- The applicant has identified designated engineered and administrative IROFS necessary to provide preventive or mitigative measures that give reasonable assurance that the facility will operate in a safe manner. One method of demonstrating this would be to demonstrate compliance with the performance requirements of 10 CFR 70.61.

Acceptance Criteria

For a radioisotope production facility, the results of the accident analysis should demonstrate adequate safety by either meeting the performance requirements described in 10 CFR 70.61 or propose and justify alternate performance criteria that the NRC staff determines to demonstrate adequate safety. The staff has determined that while the 10 CFR 70.61 performance criteria

are not a requirement for radioisotope production facility licensed under Part 50, meeting the criteria set forth in 10 CFR 70.61 would likely demonstrate adequate safety.

The applicant should discuss why the MHA is not likely to occur during the operating life of the facility.

NUREG-1520, Section 3.4, provides additional criteria for adherence to the safety program and ISA performance.

Review Procedures

Information in the SAR should allow the reviewer to follow the sequence of events in the accident scenario from initiation to a stabilized condition. The reviewer should confirm the following:

- The credible accidents were categorized, and the most limiting accident in each group was chosen for detailed analyses.

- The process was assumed to be operating normally under applicable technical specifications before the initiating event. However, the process may be in the most limiting technical specification condition at the initiation of the event.

- Instruments, controls, and automatic protective systems were assumed to be operating normally or to be operable before the initiating event. Maximum acceptable non-conservative instrument error may be assumed to exist at accident initiation.

- The single malfunction that initiates the event was identified.

- Credit was taken during the scenario for normally operating process systems. Protective actions were initiated by either the operating staff, control systems, or ESFs.

- The sequence of events and the components and systems damaged during the accident scenario were clearly discussed.

- Validated mathematical models and analytical methods that were employed, including assumptions, approximations, and uncertainties, were clearly stated.

- The radiation source terms were presented or referenced.

- The potential radiation consequences to the facility staff and the public were presented and compared with acceptance criteria (see previous section).

Evaluation Findings

It is essential that all credible accidents at a non-power reactor and radioisotope production facility be considered and evaluated during the design stage. The safety margins should be adequate to prevent the release of radioactive materials, in amounts exceeding regulatory limits, to uncontrolled areas as a result of credible accidents. For potential accidents and the MHA that could cause a release, the acceptance criteria and review procedures discussed above are sufficiently comprehensive. However, the potential consequences, detailed analyses,

evaluations, and conclusions are facility and accident specific. Typical findings for the accident categories are presented below. These findings are examples only. The appropriate number for the facility under evaluation should replace the notation “xx” and “yy.” The reviewer should modify the actual wording of the findings as appropriate to the situation under review.

This section of the SAR should contain sufficient information to support the types of conclusions given below. The staff's SER will include those conclusions.

Evaluation Findings for Specific Accident Scenarios

This section presents examples of some typical accident scenarios that the SER should include. The SER should include other credible accident situations identified by the applicant as they pertain to any other unique processes conducted in the facility and that may have radiological consequences.

Maximum Hypothetical Accident

> The applicant has considered the consequences to the public and the staff of all credible accidents at the radioisotope production facility. A maximum hypothetical accident (MHA), which is an accident that would release fission products from fuel in process (or some other accident with equal or worse consequences) with consequences greater than any credible accident, has been analyzed. The MHA, however, is not considered to be a credible event for this facility.

This section of the SAR (ISA) should contain sufficient information to support the types of conclusions suggested below, which the SER will include. The reviewer should modify conclusions appropriately to conform or relate to the specifics of the accident condition under review.

> The containment-confinement-engineered safety features are assumed to function as designed and radioactive material is held up temporarily in the facility and then released under controlled conditions. Realistic but conservative methods are used to compute potential doses and dose commitments to the public in uncontrolled areas and to compute external radiation doses and dose commitments resulting from inhalation by the facility staff. Methods of calculating doses from inhalation or ingestion (or both) and direct exposure to gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in Chapter 11 of the SAR. The exposure time for the staff is “xx” and for the public it is “yy.”
>
> The calculated maximum effective doses for the MHA scenario are the following:
>
> > “xx” mrem total effective dose equivalent (TEDE) for the staff;
> > “yy” mrem TEDE for the public (maximally exposed individual at the controlled area boundary)
>
> These doses and dose commitments are within the acceptable limits [state limits]. Because the assumptions of the scenario are conservative, the postulated accident would not be likely to occur during the life of the facility. The applicant has examined more realistic assumptions about operating time and

release fractions that decreased the source term by “xx” percent of the one calculated, lowering the maximum doses by that factor [if applicable]. Thus, even in the event of the MHA, whose consequences bound all credible accidents at the facility, the health and safety of the facility staff and the public are protected.

Accidents While Processing Irradiated and Unirradiated Special Nuclear Material

The applicant has discussed initiating events that could accidentally release fission products from irradiated fuel while in process, in storage, or while being transferred within the facility. The applicant has discussed the potential for a criticality incident with unirradiated SNM. The applicant has analyzed the event that would cause the worst radiological consequences. This event is [provide description].

The analysis shows that the consequences of this event are bounded by the incident discussed under the MHA. Therefore, doses to the staff and the public are within acceptable limits.

Accidents While Processing Fission Products or Other RAM

The applicant has discussed the types of processes that could be performed in the separation and purification of radioisotopes under the facility license and technical specifications. The discussions include events that could initiate accidents such as [list events (examples are given below)]:

- Process equipment malfunction
- Operator error
- External events

The analysis shows that the technical specifications that limit the types and amounts of RAM in process and that provide engineered and administrative features and controls give reasonable assurance that the potential consequences of these events would be less severe than those already evaluated in the section on the MHA or in other, more serious, accident scenarios.

Loss of Normal Electrical Power

The applicant has discussed the events (detailing the site-specific responses) that could result from the sudden loss of normal electrical power. All safety-related equipment is either supplied with adequate emergency power or is, by default, returned to a safe condition in a de-energized state. Any requirement for emergency cooling or ventilation functions is provided as intended in the facility design.

The reviewer should modify the following statement to apply to the actual circumstances enumerated in the SAR:

The applicant has demonstrated that the loss of normal electrical power will not result in an unsafe condition for either the facility staff or members of the public in

uncontrolled areas. Chapter 8 of the SAR describes emergency power to the facility. The emergency supply will power the safety-related equipment and systems required to operate after the loss of normal power.

External Events

Chapters 2 and 3 of the SAR discuss the design of the structures, systems, and components to withstand external events and the potential associated accidents. The reactor–radioisotope production facility is designed to withstand the effects of these events. Process operations could continue provided that there would not be undue risk to the health and safety of the staff, the public, and the environment. Consequences of natural external events that cause facility damage (e.g., seismic events that damage the confinement or containment) are within the bounds discussed for other accidents in this chapter. Therefore, exposure to the staff and the public is within acceptable limits, and external events do not pose an unacceptable risk to the health and safety of the public. [An external event could be the MHA if enough damage is done to the facility. The conclusion for the MHA above would apply.]

Mishandling or Malfunction of Equipment

Initiating events under this heading would require a case-by-case, process-specific discussion. If the SAR discusses additional events that fall outside the above-enumerated categories, the potential consequences should be compared with similar events already analyzed or with the MHA, as applicable.

13b.2 Chemical Process Safety for the Radioisotope Processing Facility

The staff's chemical process safety review should focus on chemical safety-related accidents, chemical safety controls, and the corresponding surveillance requirements to ensure that the applicant's equipment and facilities are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material, and chemical risks of plant conditions that affect the safety of licensed material.

The 1988 memorandum of understanding between the NRC and the Occupational Safety and Health Administration directs the NRC to oversee chemical safety issues related to (1) radiation risks of licensed materials, (2) chemical risks of licensed materials, and (3) plant conditions that affect or may affect the safety of licensed materials and thus increase radiation risk to workers, the public, and the environment. The NRC does not oversee plant conditions that do not affect or involve the safety of licensed materials.

Areas of Review

The staff's review should cover the following specifications:

Chemical Process Description

The chemical process descriptions and chemical accidents determined by the applicant are the bases for the chemical process safety evaluation. The reviewer should establish that the applicant's facility design, operations, and safety controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of

licensed material at the facility. The reviewer must verify that the applicant's proposed equipment and facilities are adequate to protect public health and safety and the environment. The reviewer should examine the mechanisms that will allow the applicant to identify and correct potential problems.

Chemical Accident Description

The applicant should describe the potential accidents caused by process deviations or other events internal to the facility and credible external events, including natural phenomena. The reviewer should assess the chemical risks to ensure that the design and the operational plans for the facility reflect the level of safety. In return, to validate the criteria used by the applicant in reporting accidents, the reviewer will make an independent judgment of the comparative risks assigned by the applicant to accidents identified. This judgment is based on risk relative to other sequences of events (competing risks), the complexity of the accidents, facility operating history, and general industry performance. Whenever possible, the applicant should use its own experience to supplement the identification of potential chemical hazards. The reviewer may consider a selected number of lower-risk chemical safety-related accident sequences that were not identified by the applicant and provided in the application.

Chemical Accident Consequences

The reviewer should verify that the proposed quantitative standards used to assess the consequences to an individual and the public from acute chemical exposure are appropriate. Events with high potential consequences should be identified; controls should be used to reduce the likelihood or the consequences of the event. The reviewer should ensure that the select standards are correctly applied to the worker or the member of the public.

Chemical Process Safety Controls

The staff will review the chemical process ESFs or technical specifications, or both, to ensure their adequacy in protecting against all unmitigated accidents identified by the applicant. The reviewer should establish that the applicant's controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility.

Chemical Process Surveillance Requirements

- The application should include a chemical safety element describing the methods, activities, and implementation of the overall safety program. The technical reviewer should verify the applicant's commitment to retaining records for chemical process safety compliance and reporting commitments for chemical releases. In addition, the reviewer should verify the applicant's commitment to refer any unacceptable performance deficiency to those responsible for the facility's corrective action function.

- If the applicant has applied a graded approach to safety, the reviewer should establish that the grading of controls or management measures is appropriate and sufficient to protect against chemical process risks.

Acceptance Criteria

Acceptance criteria are based on meeting the relevant requirements of the following regulations:

- The general contents of an application for chemical process safety information are in 10 CFR 50.34, "Contents of applications; technical information." The section outlines the general information that must be included in the license application.

- The requirements for the approval of the application are in 10 CFR 50.45, "Standards for construction permits, operating licenses, and combined licenses."

Regulatory Acceptance Criteria

The reviewer should find the applicant's chemical process safety information acceptable if there is reasonable assurance that it adequately addresses and satisfies the acceptance criteria presented below.

The applicant should include a description of each process in the facility. The applicant's descriptions of the chemical processes are acceptable if they meet the following conditions:

- Process descriptions are sufficiently detailed to allow an understanding of the chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow the development of potential accidents.

- Process descriptions are sufficiently detailed to allow an understanding of the theory of operation.

Review Procedures

During the safety evaluation, the reviewer determines whether the application comprehensively describes the chemical safety of the licensed activity. For deviations from the specific acceptance criteria, the staff should review the applicant's explanation of how the proposed alternatives to the Standard Review Plan criteria provide an acceptable method of complying with the relevant NRC requirements.

During the license application review, the reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the applicant implemented ESFs or technical specifications, or both, through procedures and operator training.

For an existing facility, the reviewer should consult NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewers should consult with the facility design team to gain a better understanding of the process, its potential hazards, and its safety approaches. The reviewer should coordinate these interactions through the licensing project manager.

The primary reviewer will prepare input to the SER for the licensing project manager in support of the licensing action.

Evaluation Findings

The reviewer's input to the SER should address each topic reviewed and explain why the NRC staff has reasonable assurance that the chemical safety portion of the application is acceptable. The reviewer may propose license conditions to impose requirements for those areas in which the application is deficient. If unable to make a finding of reasonable assurance, the reviewer will prepare input to the SER explaining the deficiencies and the reasons for denying the proposed application. In cases in which the SER is drafted in advance of resolving all outstanding chemical process safety issues, the reviewer should document the review as described below and include a list of open issues that require resolution before the staff can make a finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer should use applicable sections of the acceptance criteria and the SER and note areas that were not reviewed and their chemical process safety significance, if any. On completion of the review, the NRC staff can impose temporary license conditions to authorize short-duration activities. For certain functions and requirements that concern safety or regulatory issues, the NRC can impose a license condition that remains in effect until removed by an amendment or license renewal.

The SER should include a summary statement of what the NRC evaluated and the basis for the reviewer's conclusions. The SER should include statements like the following:

> The NRC staff has evaluated the application using the criteria listed previously. Based on the review of the license application, the NRC staff has concluded that the applicant has adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects. The applicant has constructed a hazard analysis that identified and evaluated those chemical process hazards and potential accidents and established safety controls to provide reasonable assurance of safe facility operation. To ensure that the requirements for acceptability are met, the applicant has provided reasonable assurance that ESFs and technical specifications are available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.
>
> The NRC staff concludes that both the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of the regulations and provide reasonable assurance that the health and safety of the public will be protected.

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14 TECHNICAL SPECIFICATIONS

NUREG-1537, Part 2, Chapter 14 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the technical specifications for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable. Additional sections have been added to this chapter as follows:

- 14a1, "Heterogeneous Reactor Technical Specifications"
- 14a2, "Aqueous Homogeneous Reactor Technical Specifications"
- 14b, "Radioisotope Production Facility Technical Specifications"

Guidance for each of these options follows.

14a1 Heterogeneous Reactor Technical Specifications

The reviewer should follow the current guidance in Part 2 of NUREG-1537.

14a2 Aqueous Homogeneous Reactor Technical Specifications

The reviewer should use the current guidance in Part 2 of NUREG-1537 as it would apply to an AHR. For example, the following change to the evaluation findings would be appropriate:

In the affirmation in the first bullet under *Evaluation Findings*, change the NUREG reference from "NUREG-1537 (Part 1)" to "NUREG-1537 (Part 1) as supplemented by this ISG."

14b Radioisotope Production Facility Technical Specifications

This section provides guidance for reviewing and evaluating the technical specifications submitted for processes involving SNM, radioisotopes, and chemicals outside the reactor. These technical specifications include the IROFS that were identified in the SAR and the ISAs in Chapter 13. The technical specifications (safety limits, limiting control settings, and limiting conditions for operation) for a radioisotope production facility are required as license conditions to comply with 10 CFR 50.36. These technical specifications should also use as a guide the performance requirements in 10 CFR 70.61 using a graded approach, as described in the introduction to Section 13b in Part 1 of this ISG.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety (IROFS), and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotope production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

The technical specifications also include the management measures that are established to ensure that these specified IROFS are designed, implemented, and maintained so that they are available and reliable to perform their functions when needed.

Areas of Review

The reviewer should verify that the ISA Summary provided in accordance with Section 13b, Part 1, of this ISG and the SAR. The staff should review the applicant's method of estimating the consequences of accidents so that all IROFS that should be technical specifications have been identified. The staff should also review the following:

- Safety limits proposed by the applicant for the IROFS that are technical specifications.
- Limiting control settings for active engineered IROFS that are technical specifications.
- Limiting conditions for operation.
- Surveillance requirements.
- Design features that affect the function, availability, or reliability of IROFS that are technical specifications.
- Management measures to ensure that IROFS that are technical specifications will be available when needed.
- Corrective actions proposed to be taken if any technical specifications are exceeded or breached.

Acceptance Criteria

Technical specifications for radioisotope production operations are acceptable if they meet the following criteria:

- The technical specifications include a list of all IROFS for all processes involving SNM, radioisotopes, and hazardous chemicals (associated with operations with SNM) that prevent or mitigate accident consequences.
- The technical specifications comply with the performance requirements of 10 CFR 50.36; NRC recommends they follow 10 CFR 70.61
- The technical specifications are presented in the format prescribed in Appendix 14.1 to NUREG-1537, Part 1, and the guidance of this ISG.
- The technical specification limits for the facility design, construction, and operation provides reasonable assurance that the facility can be operated without endangering the environment and the health and safety of the staff and the public.

These acceptance criteria are explained in greater detail below.

The list describing the IROFS that are technical specifications documents the safety basis of all processes in the facility necessary to comply with 10 CFR 50.36. This list assists in ensuring that the IROFS that are technical specifications are not degraded without a justifying safety review. Thus, the key feature of this list is that it includes all IROFS that are technical specifications. However, sets of hardware or procedures that perform the same safety function may be referred to as a single set of IROFS and do not need to be individually identified.

IROFS that are technical specifications may be hardware with a dedicated safety function or hardware with a property that is relied on to meet 10 CFR 50.36. Thus, IROFS that are technical specifications may be the dimension, shape, capacity, or composition of hardware. The technical specifications need not provide a breakdown of hardware IROFS by component or identify all support systems. However, the technical specifications documentation maintained on site, such as system schematics or descriptive lists, should contain sufficient detail about items within a hardware IROFS such that it is clear to the reviewer and the applicant what structure, system, equipment, or component is included within the hardware IROFS' boundary and would, therefore, be subject to management measures specified in the technical specifications. Some examples of items within hardware IROFS are detectors, sensors, electronics, cables, valves, piping, tanks, and dikes. In addition, ISA documentation should also identify essential utilities and support systems on which the IROFS depends to perform its intended function. Some examples of these are backup batteries, air supply, and steam supply.

The essential features of each IROFS needed to achieve the performance criteria of 10 CFR 70.61, or other alternative criteria proposed and justified by the applicant, and 10 CFR 50.36 must be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that ensures, in principle, that controls of this type will have adequate reliability. The likelihood of failure of items often depends on safety margins; therefore descriptions of the safety parameter controlled by the item, the safety limit on the parameter, and the margin to true failure may be needed. For IROFS that are administrative controls, the nature of the action or prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable. Features of the IROFS that affect its independence from other IROFS, such as reliance on the same power supplies, should be indicated.

The description of each IROFS needed to meet 10 CFR 50.36 should identify its expected function, conditions needed for the IROFS to reliably perform its function, and the effects of its failure. The description of each IROFS within an ISA Summary should identify the management measures, such as maintenance, training, and configuration management that are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information in the ISA Summary. The reliability required for an IROFS is proportionate to the amount of risk reduction it is expected to provide. Thus, the quality of the management measures applied to an IROFS may be graded commensurate with the required reliability. The management measures should ensure that IROFS are designed, implemented, and maintained, as necessary, to be available and reliable to perform their function when needed. The degree of reliability and availability of IROFS ensured by these measures should be consistent with the evaluations of accident likelihoods. In particular, for redundant IROFS, all information necessary to establish the average vulnerable outage time is required in order to maintain acceptable availability. Otherwise, failures must be assumed to persist for the life of the facility. In particular, for IROFS whose availability is to be relied on, the time interval

between surveillance observations or tests of the item should be stated, since restoration of a safe state cannot occur until the failure is discovered.

Review Procedures

The reviewer should compare the proposed technical specifications with ANSI/ANS 15.1, as it could pertain to radioisotope production structures, systems, and components, with previously accepted technical specifications for facilities of similar design and function, and Appendix 14.1 to Part 1 of NUREG-1537 as modified by this ISG.

The reviewer should be able to determine the technical specifications and bases from the analyses in the SAR and the ISAs for all radioisotope production processes. The reviewer should determine that the technical specifications are complete and in the proper format and that each specification is supported by appropriate analyses in the SAR or the ISAs.

The review of the identification of IROFS that are technical specifications should include an acceptance review and evaluation of the ISA Summary that includes an ISA methods review, horizontal review, and vertical slice review.

Evaluation Findings

The current version of this section in NUREG-1537 applies to the radioisotope production facility with the following substitution for the last sentence in the bullet paragraph:

> The staff has reviewed the format and contents of the technical specifications using the guidance of ANSI/ANS 15.1-2007 as it would apply to radioisotope production operations, and NUREG-1537, Part 1, issued February 1996, as modified in this ISG for application to radioisotope production.

15 FINANCIAL QUALIFICATIONS

NUREG-1537, Part 2, Chapter 15 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the financial qualifications for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

Introductory Section

- In paragraph 2, the reference to 10 CFR 2.790 should be replaced with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," for requests for withholding.

- The first sentence of paragraph 3 should be changed as follows:

  Because the review of this information requires specialized knowledge that the non-power reactor technical reviewer usually does not possess, this financial information is submitted to expert financial reviewers (located in the Financial Analysis and International Projects Branch, which is in the Division of Policy and Rulemaking in the Office of Nuclear Reactor Regulation at the time of this writing).

15.1 Financial Ability To Construct a Non-power Reactor

Acceptance Criteria

At the end of the first bullet, add the following:

> The estimate of construction costs should provide, at a minimum, a breakdown of costs into major cost elements, such as material and labor, and include a detailed schedule of construction activity in today's dollars.

Review Procedures

Change the branch name from the "License Renewal and Environmental Review Project Directorate" to the "Financial Analysis and International Projects Branch."

15.2 Financial Ability To Operate a Non-power Reactor

Review Procedures

Change the branch name from the "License Renewal and Environmental Review Project Directorate" to the "Financial Analysis and International Projects Branch."

Evaluation Findings

Replace the text in the bullet with the following:

> The applicant has supplied financial information for the estimates of operating costs and the sources of funds to cover these costs. The NRC staff has reviewed the financial ability of the applicant to operate the proposed facility and concludes that the applicant has demonstrated reasonable assurance of obtaining the necessary funds to cover the estimated facility operation costs. Therefore, the NRC staff concludes that the applicant has met the financial qualifications requirements under 10 CFR 50.33(f) and is financially qualified to engage in the proposed activities regarding the facility. The NRC staff has also reviewed the proposed conduct of commercial activities at the facility and finds that it meets the requirements of [a Class 104 license pursuant to 10 CFR 50.21] or [a Class 103 license pursuant to 10 CFR 50.22.]

15.3 Financial Ability To Decommission the Facility

Areas of Review

Replace the text of the third bullet with the following:

> The means of adjusting the cost estimate and associated funding level periodically over the life of the facility.

Acceptance Criteria

Replace the text of the fourth bullet with the following:

> The applicant should provide a description of the means of adjusting the cost estimate and associated funding level periodically over the life of the facility based on actual changes or changes in cost indices.

Review Procedures

Change the branch name from “License Renewal and Environmental Review Project Directorate” to the “Financial Analysis and International Projects Branch.”

Evaluation Findings

Replace the text of the bullet with the following:

> The applicant has supplied financial information for decommissioning costs of the facility in accordance with 10 CFR 50.75(d). The NRC staff has reviewed the decommissioning cost estimate submitted by the applicant and concludes that the cost estimate is reasonable. The applicant has indicated the method or methods to be used to provide funds for decommissioning and has provided a description of the means of adjusting the cost estimate and associated funding level periodically over the life of the facility. The NRC has reviewed the

applicant's information provided on decommissioning funding assurance and finds that the applicant's financial assurance method to be used to provide funds for decommissioning is acceptable, and the applicant's means of adjusting the cost estimate and associated funding level periodically over the life of the facility is reasonable. The NRC staff notes that any adjustment of the decommissioning cost estimate should incorporate, among other things, changes in costs resulting from the availability of disposal facilities.

15.4 Foreign Ownership, Control, or Domination (FOCD)

Sections 103d and 104d of the AEA provide, in relevant part, that no license may be issued to the following:

> Any person, corporation or other entity if the Commission knows or has reason to believe it is owned, controlled, or dominated by an alien, a foreign corporation or a foreign government. In any event, no license may be issued to any person within the United States if, in the opinion of the Commission, the issue of a license to such person would be inimical to the common defense and security or to the health and safety of the public.

Section 50.38 of 10 CFR implements this statutory prohibition, providing that:

> Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, shall be ineligible to apply for and obtain a license.

The NRC evaluates each application in a manner that is consistent with the guidance provided in the Standard Review Plan, "Foreign Ownership, Control, or Domination of applicants for Reactor Licenses," dated June 1999, (hereafter referred to as the "SRP on FOCD"), to determine whether the applicant is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. (64 FR 52357-52359).

The NRC's position outlined in the SRP on FOCD states that "the foreign control prohibition should be given an orientation toward safeguarding the national defense and security." Further, the SRP on FOCD outlines how the effects of foreign ownership may be mitigated through implementation of a "negation action plan" to ensure that any foreign interest is effectively denied control or domination over the applicant.

The application must include the organizational form of the applicant and provide all of the 10 CFR 50.33(d) information that is applicable to the applicant. The application should also include a statement as to whether the applicant is owned, controlled, or dominated by an alien, foreign corporation, or foreign government. If none of the provisions of 10 CFR 50.33(d) are applicable, the applicant should so state.

Since the Commission has not determined a specific threshold above which it would be conclusive that an applicant is controlled by foreign interests through ownership of a percentage of the applicant's stock, FOCD is determined based on the totality of facts because a foreign entity may exert indirect control through factors other than ownership and voting interests, including, but not limited to, financial interests. The financial analyst will review all of the information submitted by the applicant to determine whether there is foreign ownership, control,

or domination, and if it is determined that there is FOCD, additional action would be necessary to negate FOCD, and the applicant would be advised and requested to submit a negation action plan (SRP on FOCD Section 4.4).

15.5 Nuclear Insurance and Indemnity

The Price-Anderson Act, Section 170 of the Atomic Energy Act (AEA) of 1954, as amended, provides a system to pay funds for claims by members of the public for personal injury and property damage resulting from any nuclear incident. The Price-Anderson Act provides coverage in varying degrees. The implementing regulations regarding the Price-Anderson Act are contained in 10 CFR 140.

Whenever a licensee is required to maintain financial protection in the form of nuclear liability insurance, Price-Anderson requires that the licensee execute and maintain an indemnity agreement with the Commission that extends for the life of the license. The indemnity agreement specifies the obligations of the government with respect to its licensees.

The insurance policies held by licensees as financial protection and provided by American Nuclear Insurers (ANI) are "omnibus" in nature, in that the protection extends to the licensee and to any other person who may be legally liable. The scope of the policy and the provisions of the indemnity agreement includes any incidents in the course of transportation of nuclear fuel to a reactor site; in the storage of fuel at a site; in the operation of a reactor, including discharge of radioactive effluents; in the storage of nuclear fuel and waste; and in the transportation of nuclear fuel and waste.

Prior to issuance of a new license, a licensee will be required to provide satisfactory evidence that it has obtained the appropriate amount of insurance in accordance with the Commission's Price-Anderson Act insurance requirements under Section 170 of the Act and at 10 CFR Part 140, as applicable. In accordance with 10 CFR 140.12(a):

> Each licensee is required to have and maintain financial protection for each nuclear reactor for which the amount of financial protection is not determined in § 140.11, in an amount determined pursuant to the formula and other provisions in this section. . .

Further, pursuant to 10 CFR 140.13, the licensee will be required to have and maintain financial protection of $1,000,000 in insurance prior to fuel being brought on site, and the full financial protection before operation of the reactor. The IFIB staff will request financial documentation from American Nuclear Insurers (ANI) verifying that the licensee is a recorded named insured on the insurance policy provided by ANI. The Commission will execute an indemnity agreement with the licensee and will indemnity the licensee above the amount of financial protection up to $500 million. In addition, the licensee is not required to purchase property insurance under 10 CFR 50.54(w).

With respect to non-profit educational institution applicants, under 10 CFR 140.71, "Scope," a non-profit educational institution licensee is not required to provide nuclear liability insurance. The Commission will indemnify the licensee for any claims arising out of a nuclear incident under the Price-Anderson Act, Section 170 of the Atomic Energy Act, as amended, and in accordance with the provisions of its indemnity agreement pursuant to 10 CFR 140.95, "Appendix E - Form of Indemnity Agreement with Nonprofit Educational Institutions," above

$250,000 up to $500 million. Also, the licensee is not required to purchase property insurance under 10 CFR 50.54(w).

Under 10 CFR 140.51, “Scope,” a Federal Government licensee, is not required to provide nuclear liability insurance. The Commission will indemnity the licensee for any claims arising out of a nuclear incident under the Price-Anderson Act, Section 170 of the Atomic Energy Act, as amended, and in accordance with the provisions under its indemnity agreement pursuant to 10 CFR 140.94, “Appendix D-Form of Indemnity Agreement with Federal Agencies,” up to $500 million. Also, the licensee is not required to purchase property insurance under 10 CFR 50.54(w).

16 OTHER LICENSE CONSIDERATIONS

NUREG-1537, Part 2, Chapter 16 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of other license conditions for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term “reactor” appears, it is understood to mean a “non-power reactor facility,” a “radioisotope production facility,” or both, as applicable.

17 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

NUREG-1537, Part 2, Chapter 17 of the standard review plan and acceptance criteria, as augmented by this ISG, is applicable to reviewing a description of the decommissioning and possession-only license amendments for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

However, most of the current content of this introductory section is outdated. For the purpose of this ISG, this section should read as follows:

> The NRC has developed a systematic approach for licensee and NRC actions to terminate facility licenses. As required by 10 CFR 50.82(b), "Termination of License," an application for termination of a non-power reactor license must be preceded or accompanied by a proposed decommissioning plan (DP). The following guidance is offered to facilitate the composition and review of such decommissioning plans.

17.1 Decommissioning

A new section to NUREG-1537 is added as follows:

> 17.1.0 Decommissioning Report
>
> In accordance with the requirements of 10 CFR 50.33(k)(1), an application for an operating license or a combined license for a production or utilization facility must state, in the form of a report as described in 10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning," how reasonable assurance will be provided that funds will be available to decommission the facility. This report must include a cost estimate, the proposed decommissioning method to be used, and a proposed means of projecting changes to the cost estimate. Chapter 15 of this NUREG provides additional information on funding.

17.1.1 Preliminary Decommissioning Plan

The wording in this section should be changed as follows:

> In accordance with the requirements of 10 CFR 50.75(f)(4), non-power reactor licensees must submit a preliminary decommissioning plan at or about 2 years before the projected end of operation of the facility. The plan shall include an estimate of the cost and an up-to-date assessment of the major technical factors that could affect planning for decommissioning. The factors to be considered include the following:
>
> [The current list of factors in items (i) through (v) apply to a non-power reactor and radioisotope production facility.]

The last paragraph of this section should read as follows:

> The preliminary DP only needs to address the above-listed five factors and may be substantially less detailed than the final DP. The plan should show that the licensee is aware of the technical and administrative complexities of decommissioning. The reviewer should compare the licensee's plan with other plans for similar facilities that have been reviewed.

17.1.2 Decommissioning Plan

The wording of the current NUREG remains unchanged except, in the second paragraph, the references to sections of the regulations should be changed from 10 CFR 50.82(b)(1)(ii) to 10 CFR 50.82(b) and from 10 CFR 50.82(b)(1)(iii) to 10 CFR 50.82(b)(4)(i).

17.1.3 Review of the Decommissioning Plan

The current wording of this section applies to a non-power reactor and radioisotope production facility. A new second paragraph should be inserted to update the regulatory developments and expand the pertinent technical reference material as follows:

> Subsequent to the issuance of this NUREG, the majority of decommissioning oversight responsibility has been shifted to the NRC Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Waste Management and Environmental Protection (DWMEP), Materials Decommissioning Branch. More guidance has been published on decommissioning methods, particularly on the subject of conducting surveys and satisfying acceptance criteria. NUREG-1757, Volume 1, "Consolidated Decommissioning Guidance: Decommissioning Process for Material Licensee," Rev. 2, September 2006; NUREG-1757, Volume 2, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," Rev.1, September 2006; and NUREG-1757, Volume 3, "consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," September 2003, contains this recently developed guidance. Therefore, Appendix 17.1, "The Format and Content of DP for NPRs," may serve as the basic outline for the DP but the content should be augmented by including appropriate parts of NUREG-1757.

Areas of Review

The current wording is applicable, but a final bullet should be added as follows:

- Review Appendix 17.1 to ensure that the DP addressed all of the identified contents of a DP.

Review Procedures

The current wording is applicable. Add a sentence as follows:

> The reviewer should ensure that the applicable sections of the DP include the most current guidance (NUREG-1757).

Evaluation Findings

The current wording is applicable.

17.2 Possession-Only License

The current wording is applicable to a non-power reactor and radioisotope production facility provided the references in the second paragraph are changed from 10 CFR 50.82(a) to 10 CFR 50.82(b)(1) and from 10 CFR 50.82(b)(1)(iii) to 10 CFR 50.82(4)(i).

17.2.1 Review of the Application for Possession-Only License Application

The current wording of this section applies to a non-power reactor and radioisotope production facility.

17.2.1.1 Facility License

The current wording of this section applies to a non-power reactor and radioisotope production facility.

17.2.1.2 Technical Specifications

The current wording of this section applies to a non-power reactor and radioisotope production facility.

17.2.1.3 Emergency, Physical Security, and Operator Requalification Plans

The current wording of this section applies to a non-power reactor or radioisotope production facility.

17.2.1.4 Possession-Only License Amendment Safety Analysis

The current wording of this section applies to a non-power reactor or radioisotope production facility.

17.2.1.5 Changes to Facility without License Amendment

The current wording of this section applies to a non-power reactor or radioisotope production facility.

Appendix 17.1

Format and Content of Decommissioning Plan

For the purpose of this ISG, the content of this appendix has not been reviewed for necessary updates or changes. Regulatory updates and technical guidance have occurred since this NUREG was issued. The reviewer should keep this in mind if any license application reviews are conducted using this guide. In particular, the guidance in NUREG-1757 should be used to supplement the content of applications and reviews.

18 HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSION

NUREG-1537, Part 2, Chapter 18 of the standard review plan and acceptance criteria, is applicable to all non-power reactors fueled with highly enriched uranium. This chapter does not apply to radioisotope production facilities.

19 ENVIRONMENTAL REVIEW

NEPA, as amended, requires Federal agencies to disclose and consider environmental impacts for major federal actions. NRCs environmental protection regulations in 10 CFR Part 51, implement these requirements under NEPA. These regulations describe the type of actions for which NRC must conduct environmental reviews in order to disclose and consider the environmental impacts of a proposed action under NRC regulatory purview.

Environmental reviews for licensing actions fall into one of three categories: those identified as categorical exclusions, those requiring the preparation of an Environmental Assessment (EA), and those requiring the preparation of an Environmental Impact Statement (EIS). 10 CFR 51.20 describes several types of actions that would require an EIS. Construction permits and operating licenses for radioisotope production facilities are not specifically included in 10 CFR 51.20. Such activities may require an EA or an EIS, depending on the action's potential for significant impacts that may affect the quality of the human environment. An EA is used to determine if the impacts from the proposed action may be significant and whether a finding of no significant impact (FONSI) can be made. If an EA concludes that the proposed action could result in significant impacts to the human environment, then an EIS should be prepared. In some cases, the NRC may decide to prepare an EIS, rather than an EA, if there is the potential for significant impacts to the human environment or the proposed action involves a matter that the Commission, in the exercise of their discretion, has determined should be covered by an EIS.

19.1 Introduction of the Environmental Standard Review Plan

This environmental standard review plan (ESRP) consists of a series of instructions developed for NRC staff use in conducting environmental reviews for the construction and operation of radioisotope production facilities. Use of this ESRP helps to ensure the completeness and consistency of the environmental review and analyses conducted for NRC Environmental Assessments (EAs) and Environmental Impact Statements (EISs) related to the construction and operation of radioisotope production facilities.

NRC's Implementation of the National Environmental Policy Act

This ESRP demonstrates how NRC staff meets the provisions in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," to conduct environmental reviews for the construction and operation of radioisotope production facilities. The NRC regulations at 10 CFR Part 51 implement Section 102(2) of NEPA.

Environmental Review Process

The NRC staff has provided guidance in Part 1 of this ISG setting out suggested components of an Environmental Report (ER) for these facilities, including those that are licensed under 10 CFR Part 50 and required of facilities licensed under 10 CFR Part 70, be submitted to facilitate NRC's NEPA analysis.

After receiving an application for a construction permit and operating license for a radioisotope production facility the NRC staff performs an acceptance review of the ER to determine whether the information provided is sufficiently complete to begin the environmental and NEPA review process. After reviewing the information and assessments presented in the applicant's ER, the

NRC staff begins to prepare an EA or EIS. This ESRP guides the NRC staff's environmental review and preparation of the EA or EIS. In the EA or EIS, the NRC staff analyzes the environmental impacts of construction, operations, and decommissioning of the proposed radioisotope production facility (the proposed action) and the alternatives to constructing and operating the proposed facility. The completed EA or EIS presents the staff's recommendation whether the adverse environmental impacts of the proposed action are so great that preserving the option of construction and operation would be unreasonable. The NRC's record of decision (ROD) considers this recommendation, along with the findings from the safety review of the application.

The NRC's NEPA review process consists of the following actions required by 10 CFR Part 51 for an EIS:

- Publish a notice of intent to prepare an EIS in the *Federal Register* (see 10 CFR 51.27, "Notice of Intent") and send copies of the notice to appropriate Federal, state, and local agencies; affected American Indian tribes; state, regional, and metropolitan clearinghouses; and any interested persons upon request. The notice explains the scoping process, states the locations of copies of the ER available for public inspection, and invites public participation in the scoping process.

- Conduct scoping (see 10 CFR 51.28, "Scoping—Participants," and 10 CFR 51.29, "Scoping—Environmental Impact Statement and Supplement to Environmental Impact Statement"). The scoping process includes identifying and inviting appropriate agencies, groups, and persons to participate in the process. Parties may raise issues at the public scoping meeting, which the NRC staff would generally hold near the proposed facility, and in written comments. The scoping process also routinely includes a staff site visit to the facility and communication with local, regional, and state officials and representatives of interested or knowledgeable organizations. As a result of scoping, the staff may request additional information from the applicant.

- Prepare a draft EIS (see 10 CFR 51.70, "Draft Environmental Impact Statement—General," and 10 CFR 51.71, "Draft Environmental Impact Statement—Contents"). In developing the draft EIS, the NRC staff will independently evaluate the information provided by the applicant and others, as well as seek out and collect information from independent sources.

- Distribute the draft EIS for comment (see 10 CFR 51.73, "Request for Comments on Draft Environmental Impact Statement," and 10 CFR 51.74, "Distribution of Draft Environmental Impact Statement and Supplement to Draft Environmental Impact Statement; News Releases"). The NRC will publish a notice of the availability of the EIS in the *Federal Register* and will distribute copies of the draft EIS to the U.S Environmental Protection Agency (EPA); other appropriate federal agencies; affected American Indian tribes; appropriate state, regional, and local agencies; organizations and individuals who have expressed interest in the review; and any other parties requesting a copy.

- Prepare a final EIS (see 10 CFR 51.91, "Final Environmental Impact Statement—Contents"). In developing the final EIS, the NRC staff will consider comments received on the draft, prepare responses, and modify the EIS as warranted. After considering the environmental impacts associated with the proposed action and the alternatives, the staff will determine whether or not the adverse environmental impacts of constructing,

operating, and decommissioning the proposed facility are so great that preserving the option of facility construction and operation would be unreasonable. The NRC will publish a notice of the availability of the final EIS in the *Federal Register* and will distribute copies of the final EIS as specified above for the draft EIS, including to those who participated in the environmental review (see 10 CFR 51.93, "Distribution of Final Environmental Impact Statement and Supplement to Final Environmental Impact Statement; News Releases").

- Provide the ROD (see 10 CFR 51.103, "Record of Decision—General"). The ROD will discuss the alternatives considered in the EIS, the measures taken to minimize environmental harm, and any license conditions adopted in connection with mitigation measures. In making a final decision on the construction permit and operating license, the NRC will determine whether or not the adverse environmental impacts of construction, operations, and decommissioning are so great that preserving the option of facility construction and operation would be unreasonable. The NRC publishes the Commission's final decision on the application in the *Federal Register.*

The environmental review process for an EA is summarized in Office Instruction LIC-203, Revision 2: "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues" (NRC 2009) which is publically available as ADAMS accession number ML080840323.

Roles and Responsibilities

The environmental project manager (EPM) is responsible for the environmental review and preparation of the EA or EIS. The EPM interacts with the applicant's technical and supervisory personnel as well as with NRC management. In addition, the EPM coordinates the efforts of technical staff and contractor personnel during the acceptance review of the applicant's ER and the environmental review conducted for the EA or EIS. With assistance from the technical staff, the EPM develops the overall recommendations for action to be taken by the Director of the Office of Nuclear Reactor Regulation (NRR).

The environmental review is conducted by the environmental technical staff in NRR's Division of License Renewal (DLR) and by the EPM. The responsibilities of the environmental technical staff in carrying out the environmental review, including criteria for ER acceptability, are provided in this ESRP. During the course of the technical staff's environmental review, it may be necessary to request additional information from the applicant. Requests for additional information (RAIs) are transmitted to the applicant by the EPM. RAIs also serve as a public record of the staff's concerns about the applicant's ER during the environmental review.

Guidance for each resource area contained in Chapter 19 of this NUREG (Part 2) provide procedures for the environmental review leading to the preparation of the EA or EIS. The EPM is responsible for reviewing the EA or EIS and ensuring that the technical staff's conclusions meet NRC NEPA requirements and reflect NRC policy.

Standard of Significance

Significance indicates the importance of likely environmental impacts and is determined by considering two variables: context and intensity. Context is the geographic, biophysical, and social context in which the effects will occur. In the case of construction, operations, and decommissioning of radioisotope production facilities, the context is the environment

surrounding the facility. Intensity refers to the severity of the impact, in whatever context it occurs. The NRC developed a three-level standard of significance based upon the Council of Environmental Quality (CEQ) guidelines (40 CFR 1508.27):

- SMALL – environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource. For the purposes of assessing radiological impacts, the Commission has concluded that those impacts that do not exceed permissible levels in the Commission's regulations are considered SMALL.

- MODERATE – environmental effects are sufficient to noticeably alter important attributes of the resource but not to destabilize them.

- LARGE – environmental effects are clearly noticeable and are sufficient to destabilize.

Scope of the Environmental Standard Review Plans

The ESRP for NUREG-1537, Chapter 19, Part 2 guides the review of the environmental impact issues associated with construction, operations, and decommissioning of proposed radioisotope production facilities. Use of the ESRP in the environmental review process would ensure the following:

- Identification of environmental impact issues, data, and other information and analysis

- Consideration of specific environmental issues of concern to federal, state, regional, local, and affected American Indian tribes, as appropriate

- Standardization of review procedures for the analysis of environmental impact issues

- Focused environmental review of potentially significant environmental impacts

NUREG-1537, Part 1, Chapter 19 describes the data needs for each section of the ER. In addition to the applicant's ER, the following sources of information should be considered:

- Applicant's Safety Analysis Report or Updated Final Safety Analysis Report

- NRC Safety Evaluation Reports

- Information and correspondence from other federal, state, local, and regional agencies

- Technical literature

- The internet and other online information

- Public comments

General Instructions

The following instructions, applicable to most of the ESRP, are provided here to avoid repetition in each plan:

- **Project Overview**. As an initial step in each individual environmental review, the reviewer is expected to develop an understanding of the proposed action. The purpose of this instruction is to ensure that reviewers put their individual reviews in perspective with the proposed action and concentrate their efforts on significant issues. This general project review is to be conducted as the first step (acceptance review phase) of the overall environmental review process and is to be completed before developing RAIs.
- **Internal Review Coordination**. The EPM is the central point of contact for all reviewers. Although each section represents a discrete segment of NRC's environmental review, no review can be completed without coordination with related reviews. For example, the technical analysis in Section 19.4 relies on the descriptive Sections (19.1–19.3) for background information. All reviewers are instructed to maintain close communication with other reviewers throughout the review procedure. With few exceptions, the reviews are conducted in parallel; thus, other environmental reviews may not be available to reviewers before their own environmental review is completed.
- **External Review Coordination**. The EPM initiates contact with outside agencies and must be informed of all subsequent contacts made by reviewers. Each reviewer is expected to be aware of any related technical analyses and environmental assessments. Particular attention should be given to analyses and environmental assessments prepared under provisions of memoranda of understanding between the NRC and other federal, state, regional, local, and affected American Indian tribes. Working through the EPM, the reviewer is responsible for resolving any differences of opinion between NRC staff analyses and analyses conducted by other agencies. The reviewer must ensure that all viewpoints are considered or that the specific provisions of the memoranda of understanding are followed.
- **Consultation with Other Agencies**. The environmental reviews may require consultation with other federal, state, regional, local agencies, and affected American Indian tribes. Federal agencies may include, but are not limited to, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) concerning threatened and endangered species and essential fish habitat (EFH); the State Historic Preservation Officer and American Indian tribes concerning historic and cultural resources listed or eligible for listing in the *National Register of Historic Places*; the EPA (or designated state agencies) responsible for compliance with the Clean Water Act (CWA); state agencies responsible for consistency determinations under the Coastal Zone Management Act and State or Federal Implementation Plans under the Clean Air Act. These consultations should be started as soon as possible during the environmental review process and should be coordinated with the EPM.
- **Consultation with the Applicant**. The EPM will coordinate all discussions with the applicant.
- **Site Visit**. Most reviewers benefit from a visit to the site. This visit provides the reviewer with firsthand knowledge of the site and the location and position of facilities. It also allows the reviewer an opportunity to study the environment around the site.
- **Depth of Review**. The reviewer must conduct an environmental impact analysis in sufficient depth to permit verification and validation of the analysis and conclusions.
- **Consideration of Mitigation**. Mitigation measures should be considered in proportion to the level of impact when the staff identifies adverse impacts. Statements should also describe the potential effectiveness of mitigation measures.

- **Best Management Practices**. The reviewer must evaluate the applicant's commitments to use practices that minimize, reduce, or avoid adverse impacts. These practices, often referred to as best management practices (BMPs), are activities that can mitigate potential adverse environmental impacts.
- **Quality Assurance**. Reviewers should identify and evaluate the quality assurance measures taken by the applicant in the collection and analysis of data. Quality assurance measures are also evaluated when the applicant uses computer models to predict environmental impacts.
- **Findings**. Findings should reflect agreement among the reviewers. This requires input from the reviewer, the EPM, and any other NRC reviewers affected by the findings.
- **Documentation**. Each reviewer should maintain documentation, logs, and other records of communication and consultation with outside agencies and organizations, which should be made official agency records, as necessary.

19.1.1 Purpose and Need for the Proposed Action

Areas of Review

This ESRP provides guidance for the preparation of the purpose and need for the proposed action.

Acceptance Criteria

The reviewer should ensure that the introduction is consistent with the following regulations:

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics. The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the environmental impact statement."

- 10 CFR 51, Appendix A to Subpart A of Part 51—Format for Presentation of Material in Environmental Impact Statements

- 10 CFR 51, Appendix A(4), *Purpose of and need for action*.

Technical Rationale

Obtaining a construction permit and operating license from the NRC is just one of the conditions required for safe construction, operations, and decommissioning of a radioisotope production facility. Granting a construction permit and operating license would provide the licensee with the option of constructing and operating a radioisotope production facility, whereas not granting the construction permit and the operating license eliminates this option. Therefore, the purpose and need would be to provide the licensee with the option of constructing and operating a radioisotope production facility. One or more introductory paragraphs should be prepared that define the purpose and need. For example, a description of the purpose and need can be supported by describing how the proposed action would satisfy projected global, national, or regional demands for the isotope products to be produced through implementation of the

proposed action, including, as appropriate, quantifying the benefit in terms of the proposed production volume relative to the projected demand.

Review Procedures

The material to be prepared is informational in nature; no specific analysis of the data is required.

Evaluation Findings

The reviewer should prepare one or more introductory paragraphs for the EA or EIS as described above.

19.2 Proposed Action

Areas of Review

This ESRP provides guidance for the preparation of the discussion of the proposed action. The proposed action may vary depending on the application, but in general, the proposed action is for NRC to grant a construction permit and operating license for the construction and operation of a radioisotope production facility.

The purpose of this section is to (1) provide a statement of the proposed action for the EA or EIS and (2) provide background information related to the regulatory basis for the construction permit and operating license.

Acceptance Criteria

The reviewer should ensure that the introduction prepared under this ESRP is consistent with the following regulations:

- 10 CFR 51, Appendix A to Subpart A of Part 51—Format for Presentation of Material in Environmental Impact Statements

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics. The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the environmental impact statement."

Technical Rationale

The introductory paragraphs prepared under this ESRP should clearly define the action and provide the readers of the EA or EIS with background information related to proposed construction, operations, and eventual decommissioning of a radioisotope production facility.

Review Procedures

The material to be prepared is informational in nature; no specific analysis of the data is required. NUREG-1537, Part 1, Chapter 19 describes data that may be used to describe the

proposed action, including the applicant's schedule for construction, operational, and post-operational activities.

Evaluation Findings

The reviewer for this ESRP should prepare introductory paragraphs for the EA or EIS. The first paragraph should clearly state the nature of the proposed action. The remaining paragraphs should describe the regulatory bases for construction permits and operating licenses and outline the process for applying for construction permits and operating licenses.

19.2.1 General Facility Information

Areas of Review

This ESRP provides guidance for the description of the facility, construction, operations, and post-operational activities. This section includes a description of the layout and appearance of the proposed facility; associated infrastructure and installation of support structures (onsite and offsite); and schedule of the major steps comprising the proposed action, such as start and completion dates of major construction, operational, and decommissioning activities, including the numbers of workers and material and equipment requirements during each major step. It also includes descriptions of (1) the non-power reactor; (2) the radioisotope production facility; (3) the cooling system, auxiliary water system, waste system, and other major systems; and (4) the storage, treatment, and transportation of radioactive and non-radioactive materials, including fuel, waste, radioisotopes, and any other materials.

The scope includes (1) a description of principal structures, site boundaries, exclusion areas, restricted areas, and transportation routes to the site; (2) the type(s) and size(s) of non-power reactors or accelerators and their major performance parameters; (3) a general description of the radioisotope production facility; (4) a general description of all major systems and performance characteristics for these systems; and (5) storage, treatment, and transportation of radioactive and non-radioactive materials, including fuel, waste, radioisotopes, and any other nuclear materials.

Acceptance Criteria

The reviewer should ensure that the introductory and descriptive paragraphs prepared under this ESRP are consistent with the following regulations:

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics…The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement."

Technical Rationale

A description of the overall appearance of the proposed facility and its setting is needed to clarify the physical parameters of the proposed facility and area required for construction, operations, and decommissioning. The description of the external appearance of the facility and facility layout should be in sufficient detail to form an adequate basis for staff analysis of the environmental impacts of construction, operations, and decommissioning.

Review Procedures

The reviewer should ensure that the description of the layout and appearance of the proposed facility and associated structures (onsite and offsite) provides adequate information for the reviews conducted in Sections 19.3 and 19.4. The following review steps are suggested:

(1) Review facility layout and external appearance data;

(2) Review the number of construction, operations, and decommissioning workers; length of time (months/years of construction, operations, and decommissioning); and material requirements during facility construction, operations, and decommissioning;

(3) Determine the relationship of the facility design and layout to the surrounding environment, including any aesthetic features of the site and vicinity; and

(4) Identify maps and drawings that show relevant features of the facility, the site, and the region. The maps and drawings should also identify significant offsite features, if any, in the vicinity (i.e., federal facilities, including national parks, forests, wildlife areas, American Indian and/or Bureau of Indian Affairs lands held in trust for American Indians, and American Indian tribes' lands).

The material to be prepared for this section is informational in nature; no specific analysis of the data is required. Because this material is for descriptive purposes only, ensure that adequate information is available to meet the purpose and scope of this ESRP. As a rule, if the data listed under "Data and Information Needs" in Chapter 19, Part 1 of this NUREG are provided, that objective would be met.

Evaluation Findings

The depth and extent of the input to the EA or EIS should be governed by land use considerations and potential environmental resources that could be affected by the layout of the facility and supporting structures. It should include a summary description of the radioisotope production facility and associated systems, a flow diagram, and a table of design and performance parameters. The reviewer should verify that sufficient information has been provided in accordance with the relevant requirements for analysis of postulated accidents, fuel use and transportation, and waste-disposal issues.

The level of detail of information included in the EA or EIS should include the following information:

- any relevant flow diagrams of the radioisotope production facility and any other relevant production systems
- narrative description of the cooling system, auxiliary system, and waste systems and drawings of these systems
- description of the storage, treatment, and transportation of radioactive and non-radioactive materials, including fuel, waste, radioisotopes, and any other materials.

The reviewer should verify that system component descriptions are consistent, accurate, and given in sufficient detail to serve the needs of other reviewers and members of the public who might read the EA or EIS.

19.3 Description of the Affected Environment

Areas of Review

This ESRP provides guidance for preparing the introduction to sections of the EA or EIS that describe the facility's affected environment based on the reviews conducted under Sections 19.3.1 through 19.3.8. This ESRP also provides material that is applicable to the reviews conducted under Sections 19.3.1 through 19.3.8.

Acceptance Criteria

Reviewers should ensure that Sections 19.3.1 through 19.3.8 are consistent with the following regulations:

- 10 CFR 51.45(d), *Status of compliance*. "The environmental report shall list all federal permits, licenses, approvals and other entitlements which must be obtained in connection with the proposed action and shall describe the status of compliance with these requirements. The environmental report shall also include a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land use regulations, and thermal and other water pollution limitations or requirements which have been imposed by federal, state, regional, and local agencies having responsibility for environmental protection."

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphic. The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement."

- 10 CFR 51, Appendix A(6), *Affected environment*. "The environmental impact statement will succinctly describe the environment to be affected by the proposed action. Data and analyses in the statement will be commensurate with the importance of the impact, with less important material summarized, consolidated, or simply referenced. Effort and attention will be concentrated on important issues; useless bulk will be eliminated."

Technical Rationale

The reviews conducted under Sections 19.3.1 through 19.3.8 lead to preparation of a section describing the affected environment for the EA or EIS that provides background information to be used in evaluating the environmental impacts of construction, operations, and decommissioning.

Review Procedures

The material to be prepared for the introduction is informational and descriptive; no specific analysis of data is required. The introduction should list the information to be presented and describe their relationships to the environmental consequences to be presented in Chapter 4 of the EA or EIS. It should indicate that the objectives of the EA or EIS subsections 3.1 through 3.8 are to provide a general description of the affected environment as background and/or baseline information. Some detailed descriptions may be needed to support the analyses of environmental impacts in Chapter 4.

It may be important to point out specific sections of this chapter that address environmental issues raised by the public in scoping meetings or in correspondence on the construction permit and operating license applications.

Evaluation Findings

The paragraph(s) should introduce the nature of the material to be presented by the reviewers of information covered by Sections 19.3.1 through 19.3.8. The depth and extent of the input to the EA or EIS would be governed, in part, by the extent of the potential impacts of construction, operational, and decommissioning activities.

19.3.1 Land Use and Visual Resources

Areas of Review

This ESRP provides guidance for the review of land use and visual resources of the site, vicinity, and region. The scope should include establishing the nature and extent of present and planned land use and visual impacts within areas that could be affected by construction, operations, and decommissioning.

Acceptance Criteria

Acceptance criteria for the review of onsite and offsite land use are based on the regulations cited in 19.3.

Review Procedures

The reviewer's analysis of land use characteristics should be closely linked with the impact assessment review described in Section 19.4.1 to establish the land use characteristics most likely to be affected by construction, operations, and decommissioning. The following review steps are suggested:

(1) Review the applicant's ER, scoping issues, and any other applicable land use information;

(2) Identify onsite and offsite land use that could be affected by construction, operations, and decommissioning;

(3) Identify land use plans that include the site and vicinity;

(4) Identify any local land use and zoning development plans relevant to population and housing growth and control and changes in land use patterns;

(5) Describe the visual setting prior to construction; and

(6) Prepare a section for the EA or EIS that presents a summary of the land use characteristics and visual setting at the proposed site.

19.3.2 Meteorology, Climatology, and Air Quality

Areas of Review

This ESRP provides guidance for the review of the meteorology, climatology, air quality, and noise environment of the site and surrounding area, and characterization of atmospheric transport. This review should provide background information for inclusion in the EA or EIS and input to other reviewers.

The scope includes descriptions of (1) regional climatology, (2) meteorological characteristics of the site and vicinity using data from the meteorological monitoring program, (3) local and regional atmospheric transport and diffusion characteristics, (4) local and regional air quality, and (5) noise environment of, and in the vicinity of, the site.

Acceptance Criteria

Acceptance criteria for the evaluation of site meteorology and air quality are based on the regulations cited in 19.3 and the following regulations:

- 40 CFR 50, concerning the National Ambient Air Quality Standards
- 40 CFR 51, Subpart W, concerning requirements related to applicable implementation plans
- 40 CFR 51, Appendix W, concerning air quality models
- 40 CFR 81, Subparts C and D, concerning attainment status designations approved by the EPA and identification of mandatory Class I Federal areas
- 40 CFR Part 93, Subpart B, concerning requirements for determining conformity of federal actions to state or federal implementation plans.

Review Procedures

The review of meteorology and air quality should be conducted in stages to permit termination when sufficient analysis has been completed to reach the appropriate conclusions. The following review steps are suggested:

(1) Obtain descriptions of the site meteorological, climatological, and dispersion characteristics, and acoustic (noise) environment from the ER and other relevant environmental documents;

(2) Obtain recent meteorological data for the site and climatological data for the region surrounding the site; and

(3) Obtain the air-quality attainment status and available air-quality data for the region. Specifically,

- Identify the positions of nonattainment and maintenance areas relative to the facility;
- Identify the pollutant or pollutants for which the area is in nonattainment or maintenance, as well as the severity of nonattainment; and
- Describe the meteorological conditions typically associated with poor air quality in each nonattainment and maintenance area, as well as the region.

(4) Determine if there is significant information that would require specialized atmospheric modeling, such as projected emissions above de minimis levels or levels that may go beyond a State Implementation Plan (if the site is located in a non-attainment or maintenance area).

(5) If the atmospheric dispersion calculations would be required to determine the potential impact of workers' vehicles, construction activities, or other activities on air quality in nonattainment or maintenance areas or for dose calculations, or if specialized atmospheric modeling would be required, then continue the review at Step (6). Otherwise, prepare a section for the EA or EIS that presents a summary of the meteorology, climatology, air quality, and noise environment for the facility site and region. The summary should address normal conditions and recent severe weather, including the frequency and severity of severe weather phenomena.

(6) Determine the specific atmospheric models to be used to support reviews being conducted under other sections and the data requirements of those models. Models to support dose calculations are described in Regulatory Guides 1.111, Rev. 1, *Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors* (NRC 1977), and 1.145, Rev. 1, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants* (1983), and models approved by the EPA for air quality calculations are listed in Appendix W of 40 CFR 51.

(7) Prepare the meteorological data for use by the atmospheric models and assist the reviewers of the other sections in making the appropriate model calculations.

(8) Prepare a section for the EA or EIS that presents a summary of the meteorology, climatology, air quality, and noise environment for the facility site and region. The summary should address normal conditions and recent severe weather, including the frequency and severity of severe weather phenomena. The section should describe and summarize the meteorological data used in atmospheric model calculations. The atmospheric models used should be identified in the EA or EIS, but detailed model descriptions should be avoided.

19.3.3 Geology, Soils, and Seismology

Areas of Review

This ESRP provides guidance for the review of the geology, soils, and seismology of the site and surrounding area. This review should provide background information for inclusion in the EA or EIS and input to other reviewers.

The scope includes (1) description of geologic setting, (2) overview of seismicity and seismic history, (3) description of onsite soils and their relationship to site geology, and (4) description of soil erosion potential at the site.

Acceptance Criteria

Acceptance criteria for the evaluation of site soils, geology, and seismology, are based on the regulations cited in 19.3.

Review Procedures

The review of soils, geology, and seismology should be conducted in stages to permit termination when sufficient analysis has been completed to reach the appropriate conclusions. The following review steps are suggested:

(1) Obtain descriptions of regional, local, and site soils, geology, and seismology from the ER and other relevant environmental documents;

(2) Obtain descriptions of seismic potential at the site and seismic history, including a summary of the historical local and regional seismic activity, volcanism, or any information that may indicate a geologic hazard at the site;

(3) Obtain descriptions of any onsite erosion control plans and run-off best management practices (BMPs); and

(4) Prepare a section for the EA or EIS that presents a summary of the geology, seismology, and soils for the facility site and surrounding area.

19.3.4 Water Resources

Areas of Review

This ESRP provides guidance for the review of water use and quality that could be affected by construction, operations, and decommissioning.

The scope includes (1) consideration of water uses such as domestic, municipal, agricultural, industrial, mining, recreation, navigation, and hydroelectric power; (2) identification of their locations; (3) quantification of water diversions, consumption, and returns; and (4) consideration of site specific and regional data on the physical, chemical, and biological characteristics of ground and surface water to provide the basic data for the evaluation of water-quality impacts to water bodies, aquifers, aquatic ecosystems, and water use related to construction, operations, and decommissioning. The review should be limited to present and known future water uses.

Acceptance Criteria

Acceptance criteria for the review of water use are based on the regulations cited in 19.3 and the following regulations:

- 33 CFR 330, Appendix A, concerning conditions, limitations, and restrictions on construction activities;
- 40 CFR 122-133 concerning National Pollutant Discharge Elimination System (NPDES) permit conditions for discharges, including storm water discharges;
- 40 CFR 147 concerning restrictions on waste disposal options;
- 40 CFR 149 concerning possible supplemental restrictions on waste disposal and water use in or above a sole source aquifer;
- 40 CFR 165 concerning the disposal and storage of pesticides and pesticide containers;
- 40 CFR 403 concerning waste effluents;
- 40 CFR 423 concerning effluent limitations on existing and new point sources; and
- Federal, state, regional, local, and American Indian tribal water laws and water rights.

Additional regulatory positions and specific criteria in support of regulations identified above are as follows:

- Compliance with environmental quality standards and requirements of the Clean Water Act (CWA) is not a substitute for and does not negate the requirement for NRC to weigh the environmental impacts of the proposed action, including any degradation of water quality, and to consider alternatives to the proposed action that are available for reducing adverse impacts. If an environmental assessment of impacts is available from the permitting authority, the NRC would consider the assessment in its determination of the magnitude of the environmental impacts in striking an overall cost-benefit balance. When no such assessment of impacts is available from the permitting authority, the NRC (possibly in conjunction with the permitting authority and other agencies having relevant expertise) should establish its own impact determination.
- Because water quality and water supply are interdependent, changes in water quality must be considered simultaneously with changes in water supply.[1]

Review Procedures

The review of surface-water and groundwater use should consider the aspects of water use that are concerned with consumptive use, non-consumptive use, and effluent pathways. The depth of analysis would be related to the importance of water use and proximity of the use to the facility. For water use, information on surface waterbodies or groundwater only needs to be

1 In PUD #1 Jefferson County v. Washington Department of Ecology (511 U.S. 700 (1994)), the United States Supreme Court granted the States additional authority to limit hydrological alterations beyond the State's role in regulating water rights.

provided if the resource could be impacted during construction, operations, or decommissioning. The following review steps are suggested:

(1) Identify the nearest surface water bodies that could be impacted by construction, operations, or decommissioning;

(2) Identify groundwater aquifers that could be impacted by construction, operations, or decommissioning. Describe the direction of flow in those aquifers. If the groundwater discharges to or is recharged by surface water bodies, identify where this occurs;

(3) Identify the nearest wells that could be impacted by the facility; and

(4) Identify consumptive water uses that could affect the water supply of the facility or that may be adversely affected by the facility, including the following important characteristics:

- water source;
- locations of diversions and returns;
- amount and time variation of use; and
- water rights (if applicable).

(5) Identify recreational, navigational, and other non-consumptive water uses. The important characteristics to be quantified are:

- location;
- activity; and
- amount and time variation of use.

(6) Identify the water uses that provide potential pathways for both radiological and non-radiological effluents, including the following important characteristics:

- water sources;
- location of diversions for consumptive uses;
- location of receptors for non-consumptive uses; and
- amount and time variation of use for each.

(7) In addition to information obtained from the applicant's ER, use additional sources of data, such as:

- local water-supply companies or agencies;
- river basin commissions;

- state agencies (e.g., water resources, fish and wildlife); and

- various federal agencies, such as the U.S. Army Corps of Engineers, U.S. Geological Survey, and American Indian tribal agencies when needed to complete the analysis. Local water users may be questioned during the site visit.

(8) Using the above information, summarize water uses by the categories and characteristics described in this section, but limit the analysis to consideration of present and known future water uses. As appropriate, summaries should include the following:

- present and known future groundwater withdrawals on the site and for distances great enough to cover potentially affected groundwater aquifers;

- present and known future surface-water uses that are within the hydrological system in which the facility is located and that may affect or be adversely affected by the facility;

- present and known future recreational, navigational, and other non-consumptive water uses (maps may be useful); and

- references to applicable federal, state, regional, local, and affected American Indian tribal water use laws.

(9) Ensure that water-use data and information are adequate to serve as a basis for assessing the impacts of construction, operations, and decommissioning on water use.

- In evaluating the adequacy of this material, the reviewer should ensure that data are sufficient to predict water-use impacts by the facility as well as water-use characteristics that could be impacted by construction, operations, and decommissioning.

- As appropriate, consult with appropriate federal, state, regional, local, and affected American Indian tribal agencies in making this evaluation.

The reviewer's analysis of water quality should describe the physical, chemical, and biological water-quality parameters that could affect or be affected by construction, operations, and decommissioning. The reviewer should take the following steps:

(a) Identify the location and spatial distribution of the physical, chemical, and biological characteristics, the monthly and annual ranges, and the historical extremes of those water-quality characteristics that could potentially affect or be affected by construction, operations, and decommissioning.

(b) Determine the presence of existing water-quality-related environmental stresses. Consult the quality criteria requirements of other water users, as indicated by the approved water-use classification (such as 303(d) lists) or water resource planning documents for the water body in question.

(c) When applicable, discuss the water-quality conditions, water rights, and agreements as they affect water quality and water resource plans for the site and vicinity with federal,

state, regional, local, and affected American Indian tribal water resource and pollution control and monitoring agencies.

(d) Obtain the information from the applicant's ER and consultation with federal, state, regional, local, and affected American Indian tribal agencies. Use sources of data such as river basin planning organizations and state and federal agencies, such as the EPA, the U.S. Army Corps of Engineers and the U.S. Geological Survey, if additional information or verification is deemed necessary.

(e) Ensure that the

- data are sufficient to provide quantitative information on the physical, chemical, and biological water-quality characteristics potentially affecting or affected by construction, operations, and decommissioning;

- water-quality descriptions are sufficient, concerning relevancy, completeness, reliability, and accuracy for input to the impact assessments of other sections; and

- federal, state, regional, local, and affected American Indian tribal agencies appropriate to the objectives of this review have been consulted.

(f) When evaluating the adequacy of this material,

- Consult the applicable standards and guides for this review and use the site visit and/or consultations with permitting agencies to evaluate the completeness of the water-quality descriptions; and

- Evaluate, when necessary, the collection of additional data, the verification of data, and the substantiation of the methodology used to estimate water-quality parameters.

(g) Include the appropriate depth and extent of the input to the EA or EIS as governed by the water-quality characteristics that could affect or be affected by construction, operations, and decommissioning and by the nature and magnitude of the expected impacts. The following information should be included as input to the EA or EIS:

- Descriptions of site and vicinity surface-water and groundwater quality that could affect or be affected by construction, operations, and decommissioning. The description may consist of statistical summaries of the water-quality characteristics, including mean, mean low and high, and historical low and high values (as available) for the site and vicinity. The data included should be commensurate with the anticipated impacts. Figures may be used to show long-term and seasonal trends, such as variations in dissolved oxygen and nutrient concentrations and pH variations; and

- A description of the water-quality related environmental stresses in the site and vicinity.

19.3.5 Ecological Resources

Areas of Review

This ESRP provides guidance for the review of terrestrial and aquatic ecological resources that could affect or be affected by construction, operations, and decommissioning.

The scope of the terrestrial review should include (1) a description of species composition, spatial and temporal distribution, abundance, and other structural and functional attributes of biotic assemblages that could be affected by construction, operations, and decommissioning; and (2) identification and location of any vulnerable, irreplaceable, or otherwise important terrestrial natural resources, habitats, and wildlife sanctuaries and preserves.

The scope of the aquatic review should include (1) a description of species composition, spatial and temporal distribution, abundance, and other structural and functional attributes of biotic assemblages that could be affected by construction, operations, and decommissioning; and (2) identification and location of any vulnerable, irreplaceable, or otherwise important aquatic natural resources, habitats, sanctuaries and preserves.

Acceptance Criteria

Acceptance criteria for the review of ecological resources are based on the regulations cited in Section 19.3 and the following regulations:

- Bald and Golden Eagle Protection Act (16 USC 668, et seq.) concerning the prohibition of taking, possessing, selling, transporting, importing, or exporting the bald or golden eagle, dead or alive, without a permit

- Endangered Species Act (ESA) of 1973 (16 USC 1531, et seq.) concerning identifying threatened and endangered species, critical habitats, and formal or informal consultation with the FWS and/or NMFS

- Fish and Wildlife Coordination Act of 1958 (16 USC 661, et seq.) concerning consideration of fish and wildlife resources in the planning of development projects that affect water resources

- Migratory Bird Treaty Act (16 USC 703, et seq.) declaring that it is unlawful to take, import, export, possess, buy, sell, purchase, or barter any migratory bird. Feathers, or other parts of nests and eggs, and products made from migratory birds are also covered by the Act. “Take” is defined as pursuing, hunting, shooting, poisoning, wounding, killing, capturing, trapping, or collecting

- Coastal Zone Management Act of 1972 (16 USC 1456(c)(3)(A)) concerning natural resources and land or water use of the coast, including the Great Lakes

- Federal Water Pollution Control Act of 1977 (33 USC 1251, et seq.) concerning restoration and maintenance of the chemical, physical, and biological integrity of water resources

- Marine Mammal Protection Act of 1972 (16 USC 1361, et seq.) concerning the protection of marine mammals

- Marine Protection, Research, and Sanctuaries Act of 1972 (33 USC 1401, et seq.) concerning dumping of dredged material into the ocean

- Rivers and Harbors Appropriations Act of 1899 (33 USC 403, et seq.) concerning the deposition of debris in navigable waters or tributaries to such waters

- The Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 USC 1801, et seq.) concerning establishing the Essential Fish Habitat provisions to identify and protect important habitats of Federally managed marine and anadromous fish species

Review Procedures

The reviewer should ensure that the regional and site-specific terrestrial and aquatic ecological information is adequate to serve as a basis for assessment of the effects of construction, operations, and decommissioning. The following review steps are suggested:

Terrestrial Review:

(1) Describe the terrestrial communities from available information such as present and past studies, federal and state sources, etc., and include representative species of plants, mammals, birds, reptiles, amphibians, and insects. Also describe the types of vegetative communities found within the affected area, especially any delineated wetlands or potential wetland habitat.

(2) Focus on a subset of representative and important species, such as those with the following characteristics: potential or reported susceptibility to the proposed action (e.g. noise, fragmentation, construction activities, development); dominance, commonness, or rarity in numbers or biomass; importance to the structure and function of the ecosystem, such as endemic species, sensitive or indicator species, keystone species, important trophic links, potential for trophic cascade, or habitat formers or modifiers, important recreational wildlife, and ecosystem services.

(3) Describe any protected species or habitats, especially those protected under the ESA and MSA.

(4) Include a description of bird species that nest within the affected area; migratory species and their seasonal use of habitat within the affected area, especially any known migratory bird rookeries; and, if applicable, any nearby flyways and their location in relation to the site.

(5) Include a summary of any available ecological or botanical surveys that have been conducted on or near the site.

(6) Prepare a section for the EA or EIS that presents a summary of the terrestrial resources at the proposed site.

Aquatic Review:

(1) Describe the aquatic communities from available information such as present and past

studies, federal and state sources, etc., and include representative species of aquatic plants, plankton, invertebrates, fish, and mammals, as applicable.

(2) Describe any protected species and habitats, especially those protected under the ESA and MSA.

(3) Focus on a subset of representative and important species, such as those with the following characteristics: potential or reported susceptibility the proposed action (e.g., noise, fragmentation, construction activities, development); dominance, commonness, or rarity in numbers or biomass; importance to the structure and function of the ecosystem, such as endemic species, sensitive or indicator species, keystone species, important trophic links, potential for trophic cascade, or habitat formers or modifiers; indicators of water quality or "ecosystem health;" important recreational or commercial fishing and shellfishing; fish consumption advisories; and ecosystem services.

(4) Include a summary of any available aquatic surveys that have been conducted on or near the site.

(5) Prepare a section for the EA or EIS that presents a summary of the terrestrial resources at the proposed site.

19.3.6 Historic and Cultural Resources

Areas of Review

This ESRP provides guidance for identifying and describing historic and cultural resources that could be affected by construction, operations, and decommissioning. The requirements of the National Historic Preservation Act of 1966 (NHPA) can be integrated into the identification and assessment of impacts on historic and cultural resources required by NEPA per 36 CFR 800.8(c).

The NRC considers historic and cultural resources an all inclusive term that includes prehistoric, historic, and cultural properties such as archaeological sites, historic structures, and traditional cultural properties. To identify historic and cultural resources at a site, the staff should review historic building surveys, archaeological surveys, historical research, surveys of cultural groups who historically used the area in and around the facility site, and consult with the State Historic Preservation Office (SHPO), Tribal Historic Preservation Office (THPO), Office of the State Archaeologist, American Indian tribes, and other knowledgeable groups and agencies. Included in the identification process of historic and cultural resources is an assessment of historic properties, as determined by criteria in the NHPA. The descriptions of the historic and cultural resources should be of sufficient detail to permit subsequent staff assessment and evaluation of specific impacts of the proposed action.

Historic properties means any prehistoric or historic districts, sites, buildings, structures, or objects included in, or eligible for inclusion in, the *National Register of Historic Places* (NRHP) maintained by the Secretary of the Interior (see 36 CFR 60). This term includes properties of traditional religious and cultural importance to an American Indian tribe or Native Hawaiian organization and that meet the National Register criteria. The term also includes archaeological resources, such as artifacts, records, and remains, that are related to and located within such prehistoric or historic districts, sites, buildings, or structures.

The area(s) where historic and cultural resources should be identified is referred to as the area of potential effect (APE), defined in 36 CFR 800.16(d) as the geographic area or areas within which an undertaking may directly or indirectly cause alterations in the character or use of important cultural resources, if any such resources exist. For NRC reviews, the APE is often defined as the area that may be impacted by construction, operational, or decommissioning activities associated with the proposed action. The APE typically encompasses the facility site and its immediate environs, including the viewshed. The APE may extend beyond the facility site if these activities may affect historic properties. This determination is made irrespective of land ownership or control. The APE is influenced by the scale and nature of an undertaking and may be different for different kinds of effects caused by the undertaking (36 CFR 800.16(d)). The APE may extend beyond the immediate environs in those instances where land-disturbing activities specifically related to the construction permit or operating license may potentially have an effect on known or proposed historic sites. When reviewing cultural and historic resources, the visual APE should also be considered.

The scope should include a description of the historic and cultural resources within the APE in sufficient detail to allow the reviewer to predict the potential for impacts from construction, operations, and decommissioning on these resources.

Acceptance Criteria

Acceptance criteria for the review of historic and cultural resources are based on the regulations cited in 19.3 and the relevant requirements of the following:

- 36 CFR 800 defines the process by which a federal agency meets the requirements under Sections 106 and 110 of the NHPA to ensure that agency assisted or licensed undertakings consider the effects of the undertaking on historic properties included in or eligible for the NRHP. Under this regulation, the NRC is required to identify and evaluate all historic properties in the project area and take measures to mitigate adverse effects. As allowed under 36 CFR 800.8(c), Section 106 reviews may be integrated with NEPA reviews.

- 36 CFR 63 contains guidance by which historic properties are evaluated and determined eligible for listing on the NRHP.

Review Procedures

The description of historic and cultural resources should form the basis for the impact assessment review described in Section 19.4.6 to establish the historical, cultural, and archaeological characteristics that are most likely to be affected by construction, operations, and decommissioning. The following review steps are suggested:

(1) Review the historic and cultural resource identification and impact assessment prepared by the applicant in the ER;

(2) Coordinate with the EPM to identify consulting parties (i.e., SHPO/THPO, Advisory Council on Historic Preservation (ACHP), appropriate American Indian tribes, and any other group or organization that has been identified; as the review progresses, additional letters could be sent to other interested groups);

(3) Review comments received during the scoping process to identify any issues associated with historic and cultural resources;

(4) Collect additional information during the site audit. Review cultural resource assessments prepared by the applicant and any prepared previously in the vicinity. Tour the APE to see locations where construction activities and other ground disturbing activities would occur; visit any known sites within the APE;

(5) Contact the SHPO and arrange for a meeting during the site audit to explain the proposed action, the NRC's approach to conducting the cultural resource assessment (Section 106 integration with NEPA), explain the opportunities for the SHPO to comment, and capture any issues, concerns, and expectations. Invite the SHPO to attend the site audit. If the SHPO has comments or information that add to or amplify that which was provided by the applicant, request that the SHPO forward, by letter to the staff, these additional comments. The SHPO can alert the staff to relevant state and local laws, orders, ordinances, or regulations aimed at the preservation of cultural resources applicable to the proposed action. Be sure to discuss the following:

- the APE

- the data necessary to accomplish the impact assessment

- additional organizations or individuals that might be able to assist in identifying and locating historic and cultural resources

- guidance on consulting with the appropriate American Indian tribes

(6) Review the files for any recorded sites or buildings in and adjacent to the APE, and information concerning the cultural resource surveys that have been conducted. In many cases, the site files and surveys are located at the SHPO's office. Contact the State Archaeological Site Files Office and the State Historic Buildings Survey Office if unable to locate the necessary files at the SHPO. The sites and buildings identified should match the findings presented in the ER;

(7) Compare the areas of the site potentially affected by construction activities and other ground disturbing activities with known cultural resource surveys to determine if the area has been surveyed before and whether there is potential for important cultural resources to be located there. Factors to consider include whether the area has been heavily disturbed in the past, availability of water or other critical resources, and other environmental characteristics such as slope;

(8) Compare the information provided by the applicant with that obtained from the SHPO and the NRHP and resolve any differences in identification and location of historic and cultural resources within the APE; and

(9) Prepare a section for the EA or EIS that presents a summary of the historic and cultural resources at the proposed site. Ensure that any sensitive archaeological reports are withheld from public disclosure per Section 304 of the NHPA or have been redacted. All redactions must be approved by the SHPO.

19.3.7 Socioeconomics

Areas of Review

This ESRP guides the review and consideration of socioeconomic factors that could be affected by construction, operations, and decommissioning. A radioisotope production facility and the people and communities surrounding it can be described as a dynamic socioeconomic system. The facility requires people, goods, and services from local communities to operate the facility; and the communities, in turn, provide the people, goods, and services to run the facility. Facility employees residing in the community receive income from the facility in the form of wages, salaries, and benefits, and spend this income on goods and services within the community thereby creating additional opportunities for employment and income. People and businesses in the community also receive income for the goods and services sold to the facility. Payments for these goods and services create additional employment and income opportunities in the community. The measure of a communities' ability to support the operational demands of a facility depends on the ability of the community to respond to changing socioeconomic conditions.

The socioeconomic region of influence (ROI) is defined by the areas where facility employees and their families reside, spend their income, and use their benefits, thereby affecting the economic conditions of the region. The scope should include the description of the current socioeconomic factors within the socioeconomic ROI that might be impacted or modified as a result of construction, operations, and decommissioning.

Acceptance Criteria

Acceptance criteria for evaluating socioeconomics are based on meeting the regulations cited in Section 19.3.

Review Procedures

The reviewer's description of socioeconomic conditions should be closely linked with the impact-assessment review described in Section 19.4.7 to establish the socioeconomic factors most likely to be affected by construction, operations, and decommissioning. The following review steps are suggested:

(1) Review socioeconomic data to determine the background condition. Suggested sources include the following:

- The applicant's ER
- Records of public scoping meetings and correspondence related to the application
- Data from the U.S. Census Bureau, Bureau of Economic Analysis, Bureau of Labor Statistics and other federal, state, or local agencies

(2) Determine the socioeconomic ROI:

- Identify the counties where workers are predicted to reside during construction, operations, and decommissioning. Also note the nearest sizeable

urban/metropolitan areas, cities, and towns.

- Describe the proposed site including any existing infrastructure, site access, and aesthetic conditions.

(3) Describe the socioeconomic characteristics of each of the counties within the socioeconomic ROI (the extent and detail of the descriptions should be in proportion to the magnitude of the impacts anticipated, and only those terms necessary for subsequent impact evaluation should be used):

- Population demographics, including race and ethnicity
- Housing infrastructure
- Civilian labor force and unemployment
- Median household and per-capita income and poverty
- Public services (i.e., water, schools, and recreation areas)
- Transportation infrastructure
- Property tax payment requirements in the county where the proposed facility would be located

(4) Prepare a section for the EA or EIS that presents a summary of the socioeconomic factors near the proposed site. The reviewer should ensure that the socioeconomic information presented in this section provides a basis for an assessment of impacts in the EA or EIS.

19.3.8 Human Health

Areas of Review

This ESRP provides guidance for the discussion of public and occupational health impacts of a radioisotope production facility. The scope includes descriptions of the radioactive and nonradioactive hazardous liquid, gaseous, and solid waste management programs and effluent control systems.

Acceptance Criteria

The reviewer should ensure that the introductory and descriptive paragraphs prepared under this ESRP are consistent the regulations cited in Section 19.3.

Review Procedures

The EA or EIS section to be prepared on the human health impacts is informational in nature. No specific analysis is required in this section. The following review steps are suggested:

(1) Obtain information on effluent release points and expected radioactive and nonradioactive effluent releases and exposures from construction, operational, and decommissioning activities.

(2) Obtain information on the radiological and non-radiological environmental monitoring programs.

(3) Obtain historic information on releases of radioactive and nonradioactive materials from nearby facilities, if any.

(4) Prepare a section describing the radiological and non-radiological programs and systems for the EA or EIS. The use of tables may assist data organization in the EA or EIS. This section should include summary descriptions of the applicant's proposed radiological and non-radiological environmental monitoring programs, or current radiological and non-radiological environmental monitoring program if the facility is to be collocated with operating nuclear facilities.

19.3.9 References

Areas of Review

This ESRP provides guidance for the listing of references cited in the EA or EIS chapter on the affected environment.

Review Procedures

The EPM should contact reviewers for Sections 19.3.1 through 19.3.8 and compile a list of references cited in the EA or EIS sections that the reviewers have prepared. The EPM should check the reference listing for completeness and consistency and prepare them for inclusion in the EA or EIS.

19.4 Impacts of Proposed Construction, Operations, and Decommissioning

Areas of Review

This ESRP provides guidance for preparing the introduction to the sections of the EA or EIS that evaluate the environmental impacts of construction, operations, and decommissioning. This ESRP also provides material that is applicable to the reviews conducted under Sections 19.4.1 through 19.4.14.

Acceptance Criteria

The reviewer should ensure that ER Sections 19.4.1 through 19.4.14 are consistent with the following regulations:

- 10 CFR 51.45(c), *Analysis*. "The environmental report must include an analysis that considers and balances the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects."

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics. The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement."

- 10 CFR 51.71(d), *Analysis*. "The draft environmental impact statement will include a preliminary analysis that considers and weighs the environmental effects of the proposed action; the environmental impacts of alternatives to the proposed action; and alternatives available for reducing or avoiding adverse environmental effects."

Technical Rationale

The reviews conducted under Sections 19.4.1 through 19.4.14 lead to the preparation of an EA or EIS section that evaluates the environmental impacts of construction, operations, and decommissioning.

Review Procedures

The material to be prepared in the introduction is informational in nature; no specific analysis of data is required.

Evaluation Findings

The EPM should prepare the introductory paragraphs for the EA or EIS. The paragraph(s) should introduce the issues to be covered by Sections 4.1 through 4.13 in the EA or EIS. The introduction should summarize how staff collected and analyzed the environmental data.

19.4.1 Land Use and Visual Resources

Areas of Review

This ESRP provides guidance for the review of potential land use and visual impacts of construction, operations, and decommissioning. The scope includes evaluating the impacts to land use and visual resources and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of land use impacts are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential land use and visual impacts from the proposed action, including:

    - The applicant's ER

- Records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application

- Land use requirements affecting the land use of the facility

(2) Evaluate the significance of the information with respect to land use changes as a result of construction, operations, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted,

- describes the impacts from construction operation, and decommissioning, including the significance level of the environmental impacts,

- describes the basis for the conclusions, and

- describes measures to mitigate adverse impacts.

19.4.2 Meteorology, Climatology, and Air Quality

Areas of Review

This ESRP provides guidance for the review of air quality and noise impacts from construction, operations, and decommissioning. The scope includes evaluating the impacts to air quality and the acoustic environment and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of air quality and noise impacts are based on the regulations cited in Section 19.4 and the following regulations:

- 40 CFR 50, concerning the National Ambient Air Quality Standards

- 40 CFR 51, Subpart W, concerning requirements related to applicable implementation plans

- 40 CFR 51, Appendix W, concerning air quality models

- 40 CFR 81, Subparts C and D, concerning attainment status designations approved by the EPA and identification of mandatory Class I federal areas

- 40 CFR Part 93, Subpart B, concerning requirements for determining conformity of federal actions to state or federal implementation plans.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential air quality and noise impacts from the proposed action, including:

- The applicant's ER
- Records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- Air quality and noise standards and regulations

(2) Evaluate the significance of the information with respect to air quality degradation and increased noise as a result of construction, operations, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- describes the analysis of construction, operations, and decommissioning-related stationary and mobile-source emissions, including fugitive dust, and whether changes in emissions would cause or contribute to exceeding threshold emission (*de minimis*) levels
- describes the normalized concentration and/or relative deposition of emissions at points of potential maximum concentration outside the site boundary, at points of maximum individual exposure, and at points within a reasonable area that could be impacted
- describes visibility impacts (e.g., any emission plume)
- identifies greenhouse gas emissions, including both direct emissions from construction, operations, and decommissioning of the proposed facilities and indirect emissions from activities such as commuting, vehicle deliveries, etc.
- describes the predicted noise levels or change in noise levels in decibel A-weighted (dBA) scale from construction, operations, and decommissioning activities as compared to appropriate standards or guidelines
- identifies noise impacts to sensitive receptors (i.e., hospitals, schools, residences, wildlife)
- describes measures to mitigate adverse impacts
- provides the significance level of the environmental impacts and the basis for these conclusions.

19.4.3 Geology, Soils, and Seismology

Areas of Review

This ESRP provides guidance for the review of potential impacts of construction, operations, and decommissioning associated with geology and soils. The scope includes evaluating the impacts to geology and soils, including assessing implications to the proposed facility from identified geologic hazards, and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of geology and soil impacts are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential impacts to the geologic environment from the proposed action, including:

- The applicant's ER
- Records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- Available soil surveys, geologic maps, and seismic investigations

(2) Evaluate the significance of the information with respect to soil erosion and land stability as a result of construction, operations, and decommissioning activities.

(3) Prepare a section for the EA or EIS describing the search for environmental data, summarizing the data found, presenting results of evaluation of significance, and summarizing the conclusion with sufficient supportive information.

19.4.4 Water Resources

Areas of Review

This ESRP provides guidance for the analysis of surface water and groundwater impacts from construction, operations, and decommissioning. The scope includes evaluating the impacts to surface water and groundwater and preparing input to the EA or EIS.

Acceptance Review

Acceptance criteria for the evaluation of surface water and groundwater impacts are based on the regulations cited in Section 19.4 and the following regulations:

- 40 CFR 6, Appendix A, concerning procedures on floodplain and wetlands protection
- 40 CFR 149 concerning possible supplemental restrictions on water use in or above a sole source aquifer
- Federal, state, regional, local, and affected American Indian tribal agencies' water laws and water rights
- 40 CFR 122 concerning the NPDES permit conditions for discharges including storm-water discharges

- 40 CFR 124 concerning the NPDES process
- 40 CFR 125 concerning water-quality standards
- 40 CFR 133 concerning treated effluents
- 40 CFR 149 concerning possible supplemental restrictions on waste disposal and water use in or above a sole source aquifer
- 40 CFR 165 concerning the disposal and storage of pesticides
- 40 CFR 403 concerning waste effluents
- 40 CFR 423 concerning effluent limitations on existing and new point sources

Additional regulatory positions and specific criteria in support of regulations identified above are as follows:

- Compliance with environmental quality standards and requirements of the Federal Water Pollution Control Act (FWPCA), commonly referred to as the CWA, is not a substitute for and does not negate the requirement for NRC to weigh the environmental impacts of the proposed action, including any degradation of water quality, and to consider alternatives to the proposed action that are available for reducing the adverse impacts. If an environmental assessment of aquatic impacts is available from the permitting authority, the NRC should consider the assessment in its determination of the magnitude of the environmental impacts in striking an overall benefit-cost balance. When no such assessment of aquatic impacts is available from the permitting authority, the NRC (to the degree possible in conjunction with the permitting authority and other agencies having relevant expertise) should establish its own impact determination.
- In PUD #1 Jefferson County v. Washington Department of Ecology (511 U.S. 700, (1994)), the U.S. Supreme Court granted the States additional authority to limit hydrological alterations beyond the States' role in regulating water rights. As a result of this ruling, the States may regulate the quantity of water as a part of the definition of water quality.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential impacts to water resources from the proposed action, including:

- The applicant's ER
- Records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application. Document any communications with regulatory agencies (e.g., EPA or other water quality permitting agencies) that are relevant to assessing the impacts and are not documented elsewhere in the ER. If relevant communications are documented elsewhere, refer the reader to the appropriate sections.

- A copy of the current NPDES permit issued under the CWA, or the application for a NPDES permit

- Other studies and monitoring programs: briefly summarize any studies or monitoring programs that provide site-specific data and can assist with understanding the environmental impacts. Include the location, dates, objectives, methods, and results applicable to this application, and what data or data summaries might be available for NRC review.

  If data are more than 5 years old, explain why the studies would or would not be relevant for assessing the effects of construction, operations, and decommissioning. For example, show that both the potentially affected resources and the effect of the facility on them have remained and can be expected to remain unchanged over the term of the construction permit and operating license.

(2) Evaluate the significance of the information with respect to water use and degradation of water quality as a result of construction, operation, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- Describes analysis of impacts from construction, operations, and decommissioning, including any potential spills or other releases of chemicals or radionuclides

- Summarizes statutory and other legal restrictions relating to water use or specific water-body restrictions on water use imposed by state or federal regulations

- Describes federal, state, regional, local, and affected American Indian tribal standards and regulations applicable to water quality and water use; determine if there are any state policies regarding hydraulic continuity

- Summarize any means proposed by the applicant to ensure compliance with water-quality and water-use standards and regulations

- Describes any currently employed or proposed practices and measures to control or limit operational water-use and water quality impact (BMPs)

- Describes the facility's groundwater and surface water protection program(s)

- Describes measures to mitigate adverse impacts

- Provides the significance level of the environmental impacts.

(4) If groundwater or surface water resources could be affected by construction, operation, or decommissioning activities:

- Determine whether the river or water body used for the water supply is over subscribed (i.e., the demand for water exceeds supply) during any season. Water-use permits often include specific restrictions on withdrawals during

certain low-flow conditions. If the basin is over subscribed, characterize low-flow water availability impacts and describe the source of alternate supplies of water that might be needed and the impact of using that water.

- Determine whether the river or other water bodies hydraulically connected to the aquifer will be supplying the facility with groundwater. Describe the impact of groundwater use on surface water availability. If surface water is used as a source of water, describe the impact on groundwater availability.

- If groundwater is used as a source of water either directly or indirectly though surface water bodies, determine the magnitude of the impact on groundwater availability, water quality, and on water levels in nearby wells. Describe the impact of construction (e.g., erosion), operations (e.g., potential leaks of chemicals and fluids), and decommissioning (e.g., erosion) on the water quality of surface water bodies and groundwater aquifers.

19.4.5 Ecological Resources

Areas of Review

This ESRP provides guidance for the review of ecological resource impacts from construction, operations, and decommissioning. The scope includes evaluating the impacts to ecological resources and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of ecological resource impacts are based on the regulations cited in Section 19.4 and the following regulations:

- 40 CFR 122 concerning NPDES permit conditions specified in the CWA

- 40 CFR 423 concerning effluent guidelines and thermal standards

- Coastal Zone Management Act of 1972 concerning natural resources and land or water use of the coastal zone

- Endangered Species Act of 1973 (ESA), as amended, concerning identifying threatened and endangered species, critical habitats, and initiating formal or informal consultation with FWS or NMFS or both

- CWA (as amended) concerning restoration and maintenance of the chemical, physical, and biological integrity of water resources

- Fish and Wildlife Coordination Act of 1958 concerning consideration of fish and wildlife resources in the planning of development projects that affect water resources

- The Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 USC 1801, et seq.) concerning establishing the Essential Fish Habitat provisions to identify and protect important habitats of Federally managed marine and anadromous fish species

Review Procedures

For all ecological issues, the same general approach can identify the environmental consequences of construction, operations, and decommissioning of a radioisotope production facility and its alternatives. This approach generally follows the framework for ecological risk assessment (EPA 1998).

The following review steps are suggested:

(1) Review sources of information on potential ecological impacts from the proposed action, including:

- The applicant's ER

- Records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application. Document any communications with regulatory agencies (e.g., EPA or other water quality permitting agencies) and resource agencies (e.g., NMFS, FWS, state fish and wildlife agencies) that are relevant to assessing impact and are not documented elsewhere in the ER. If relevant communications are documented elsewhere, refer the reader to the appropriate sections.

  Discuss the major points of view concerning environmental impacts of construction, operations, and decommissioning and an analysis of significant problems and objections raised by other federal, state, and local agencies; affected American Indian tribes; and other interested persons.

- A copy of the current NPDES permit issued under the CWA or the application for a NPDES permit

- Other studies and monitoring programs: Briefly summarize any that provide site-specific data and can help understand environmental impacts. Include the location, dates, objectives, the biological entities or attributes chosen for study, methods, and results applicable to the construction permit and operating license application, and what data or data summaries might be available for NRC review.

  If data are more than 5 years old, explain why the studies would or would not be relevant for assessing the effects of construction, operations, and decommissioning. For example, show that both the potentially affected resources and the effect of the facility on them have remained and can be expected to remain unchanged over the term of construction permit and operating license.

(2) Identify specific biological resources and their attributes used for assessing impact. Because biological systems are complicated, only a subset of resources can be addressed.

- <u>Identify potentially affected resource entities:</u> Describe the potentially affected resources in terms of representative species, functional group of species (e.g., insectivores), communities, an ecosystem (e.g., oak-hickory forest), a specific valued habitat (e.g., wet meadows), a unique place, or other entity of concern.

Additional guidance on identifying important species to be evaluated can be found in "U.S. Fish and Wildlife Service Mitigation Policy; Notice of Final Policy."[2] Contact federal, state, local, and regional government agencies with jurisdiction over biological resources to assist with the identification of important species and habitats.

- Identify attributes of those resources potentially at risk: Identify the attributes of the resources of concern that are important to protect and potentially at risk (U.S. EPA 1998). If the reviewer identifies potentially adverse effects on a species, habitat, or other terrestrial resource, the resource should be assessed concerning local, regional, and national social, economic, and ecological value. Biodiversity, which comprises the variation between and among biological entities and includes components of genetic, species, habitat, local ecosystem, and regional ecosystem diversity, is an important biological attribute to consider (CEQ 1993).

(3) Assess and characterize impact. For each ecological issue, multiple natural populations or entities may be affected, and each population may have multiple measurable and susceptible attributes. The effects of construction, operations, and decommissioning on any ecological attribute may be direct or indirect, and the assessment approach can be prospective or retrospective. With such complexity, examining a single line of evidence may not be sufficient to assess impact. In such cases, the reviewer should examine several lines of evidence involving several populations when data allow.

Present in the EA or EIS a narrative explanation of the conceptual model for the analysis that includes the justification for selection of representative entities or their attributes, the hypothetical mechanism through which construction or operation may act upon them, the approaches used to assess impact, and possible outcomes. If using multiple lines of evidence, explain in narrative the qualitative or quantitative method for combining them to make an overall assessment of impact. A typical approach for accomplishing this in ecological risk assessment is to consider weight of evidence (e.g., Menzie et al. 1996, EPA 1998).

(4) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

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[2] The notice (46 FR 7644, January 23, 1981) establishes final policy guidance for Fish and Wildlife Service personnel involved in making recommendations to protect or conserve fish and wildlife resources. Guidance is provided on the definition and identification of "evaluation species," evaluation of direct and indirect effects of a project on the evaluation species, on the levels of mitigation and on the various methods for accomplishing mitigation when adverse effects are identified. The types of species that should be considered are discussed in the notice at pages 7662 and 7663. In this regulatory guide, the terms "important species" and "evaluation species" are used interchangeably.

For terrestrial ecology, also provide the following:

- Describe any activities associated with construction, operations, and decommissioning that would involve disturbing any terrestrial habitat, including during transport and delivery of equipment, structures, components, or radioisotopes. For each areas to be disturbed, describe (1) the amount of land to be disturbed, (2) ecological characteristics of the habitat, (3) species of plants and animals found in the area, and (4) the extent to which the habitat is unusual. Note that the information and analysis for this issue overlap the information and analysis for assessing impacts on threatened and endangered species. If any temporary or permanent structures would be built, provide a map of the site that includes the proposed location of these structures. If any road or bridge construction or modifications would occur, describe potential effects to the terrestrial environment.

For aquatic ecology, also provide the following:

- Describe any thermal, chemical, or other discharges to waterbodies. The CWA requires that discharge system operation must ensure the protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife in and on the receiving water body. Responsibility for making this determination rests with the EPA or with its designees.

  Discharge system impacts on aquatic biota may result from the effects of thermal, chemical, or other alterations to the receiving water body. Major alterations are usually confined to a limited discharge area (the mixing zone), whereas lesser alterations may extend over a larger portion of the receiving water body. Adverse effects on biota that are transported through, migrate through, or are attracted to the mixing zone may be acute or chronic, and impacts may be reflected as changes in the populations of important species and in the structure and function of the ecosystem.

- Additional information may also be needed on the specific nature of the thermal or chemical stress, such as:

  - maximum sustained temperatures for each season that are consistent with maintaining local ecological systems

  - temperature effects data for local species or their surrogates

  - thermal requirements of downstream aquatic life where upstream warming would adversely affect downstream temperature requirements

  - areal extent of the plume

  - physical factors that might concentrate biota in the plume

19.4.5.1 Protected Species and Habitats

Areas of Review

This ESRP provides guidance for the review of construction, operations, and decommissioning impacts to protected species and habitats listed under the ESA and designated EFH under the MSA. The scope includes evaluating the impacts to listed species and EFH and preparing input to the EA or EIS.

The ESA and MSA require federal agencies, such as the NRC, to evaluate the potential impacts of actions on species and habitats protected under the acts. Section 3.5 in the EA or EIS should discuss the ESA and MSA and provides a description of the species and habitats protected under those acts. This section focuses on treatment of environmental consequences and impacts under those acts.

Endangered Species Act

The FWS and NMFS (collectively, The Services) jointly administer the ESA. The FWS manages the protection of and recovery effort for listed terrestrial and freshwater species, while the NMFS manages the protection of and recovery effort for listed marine and anadromous species. Section 7(a)(2) of the ESA states that each federal agency shall, in consultation with the Secretary (Secretary of the Interior or Secretary of Commerce), ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Guidance for conducting Section 7 consultations can be found in the *Endangered Species Act Consultation Handbook: Procedures for Conducting Section 7 Consultations and Conferences (FWS 1998).*

While the analyses of environmental impacts under NEPA and NRC's regulations in the EA or EIS would include an assignment of NRC impact levels of SMALL, MODERATE, or LARGE for each issue, the assessment of protected species and habitats under the ESA should conclude one of the conclusions specified in Section IIIa of the ESA, "Review Procedures for Species and Habitats Protected Under the ESA."

Magnuson-Stevens Act

The MSA includes provisions for protected EFH. The EFH consultation process is similar to the section 7 consultation process for species and designated critical habitat under the ESA. Guidance for conducting EFH consultations with NMFS can be found in "Essential Fish Habitat Consultation Guidance, Version 1.1" (NMFS 2004).

Similar to conclusions regarding species and habitats protected under the ESA, the conclusions regarding EFH should include a determination specific to the MSA. For designated EFH, the assessment should conclude one of the conclusions specified in Section IIIb of the MSA, "Review Procedures for Designated EFH Under the MSA."

Biological Assessments and EFH Assesssments

Designated EFH may overlap with the habitat of listed species or designated critical habitat. In such cases, one assessment can be prepared that integrates the biological assessment under ESA and the EFH Assessment under the MSA. In addition, an integrated consultation process can be conducted with NMFS. However, the reviewer should coordinate such an integrated

consultation in advance because an integrated assessment may involve the review of the FWS and multiple offices of the NMFS.

Discussion of Protected Species and Habitats in EAs and EISs

As part of the Fish and Wildlife Coordination Act, NRC should also consult with state agencies regarding state-listed species. State-listed species should also be discussed in the EA or EIS.

Information about protected species and habitats should be included in three parts of the EA or EIS:

1. Chapter 3 should summarize the life history(ies) of protected species and habitat in a level of detail that is appropriate for the level of analysis in Chapter 4.

2. Chapter 4 should assess the potential impacts to protected species and habitats.

3. Finally, an appendix to the EA or EIS should include communications with the Services and state resource agencies regarding protected species and habitats. If the geographic range of either listed species or EFH includes the facility site, then a biological assessment or EFH Assessment should also be included in the appendix.

Acceptance Criteria

Acceptance criteria for the evaluation of protected species and habitats are addressed in ESRP Section 19.4.5, Ecological Resources.

Review Procedures

Suggested steps for the protected species and habitats review process are as follows:

Review Procedures for Species and Habitats Protected Under the ESA

(1) Follow the general approach for information and analysis content for all ecology issues, described in Section 19.4.5, Ecological Resources, with the following additions:

- Identify potential environmental effects from construction, operations, and decommissioning that might specifically impact listed species or designated critical habitat.

(2) Determine whether the NRC should initiate section 7 consultation with the FWS or NMFS:

- If the proposed action will have **no effect** on listed species or designated critical habitat, then the reviewer should document this in the EA or EIS. No section 7 consultation with the FWS or NMFS is necessary in this case.

- If the proposed action **is not likely to adversely affect** a listed species or designated critical habitat, the NRC should initiate informal section 7 consultation with the FWS or NMFS, as appropriate. Informal consultation may include the preparation of a biological assessment, or it may be more appropriate to include a brief assessment in the EA or EIS. The process for conducting informal

consultation is described at 50 CFR 402.13 and in the *Endangered Species Act Consultation Handbook: Procedures for Conducting Section 7 Consultations and Conferences* (FWS 1998).

- If the proposed action: (a) **is likely to adversely affect listed species**, (b) **is likely to jeopardize listed species**, or (c) **is likely to adversely modify designated critical habitat**, the NRC should prepare a biological assessment and initiate formal section 7 consultation with the FWS or NMFS, as appropriate. The contents of biological assessments are specified at 50 CFR 402.12. The process for conducting formal consultation is described at 50 CFR 402.14 and in the *Endangered Species Act Consultation Handbook: Procedures for Conducting Section 7 Consultations and Conferences* (FWS 1998).

(3) Prepare a section for the EA or EIS that:

- summarizes the information that has been reviewed and the analyses that have been conducted, and the basis for the opinion rendered by the FWS, NMFS, and state resource agencies;
- summarizes the NRC's conclusions in the biological assessment, if applicable;
- includes the FWS, NMFS's, or state resource agency conclusions and the basis for those conclusions;
- summarizes the FWS or NMFS's biological opinion, if applicable. The summary should highlight any reasonable and prudent alternatives suggested by FWS or NMFS, reasonable and prudent measures to mitigate impacts, any incidental take statement, and any terms and conditions;
- include a discussion of any additional mitigation or best management practices; and
- provides the significance level of the environmental impacts.

Review Procedures for Designated EFH Under the MSA

The review of EFH can be integrated into the review process for species and habitats protected under the ESA when both apply to a particular project.

(1) Follow the general approach for information and analysis content for all ecology issues, described in Section 19.4.5, Ecological Resources, with the following additions:

- Identify potential environmental effects from construction, operations, and decommissioning that might specifically impact designated EFH.

(2) Determine whether the NRC should initiate EFH consultation with the NMFS:

- If the proposed action will **not adversely affect** EFH, then the reviewer should document this in the EA or EIS. No consultation with the NMFS is necessary in this case.

- If the proposed action **may adversely affect** the EFH, the NRC should prepare an EFH Assessment per 50 CFR 600.905(e). The NRC must submit its EFH Assessment to NMFS as soon as practicable, but at least 60 days prior to a final decision on the action (50 CFR 600.905(h)(4)). With the submittal of the EFH Assessment, the NRC should request either abbreviated or expanded EFH consultation.

    - If the proposed action is **not likely to adversely affect** EFH, the NRC should request abbreviated consultation per 50 CFR 600.905(h).

    - If the proposed action would result in **substantial adverse effects** to EFH, the NRC should request expanded consultation per 50 CFR 600.905(i).

- Once the NRC receives NMFS's EFH Conservation Recommendations in response to the EFH Assessment, the NRC must reply in writing to the NMFS within 30 days of receipt of the recommendations and at least 10 days prior to the final approval of the action. The response should include a description of measures proposed by the agency for avoiding, mitigating, or offsetting the impact of the activity on EFH. In the case of a response that is inconsistent with NMFS's EFH Conservation Recommendations, the NRC must explain its reasons for not following the recommendations, including the scientific justification for any disagreements with NMFS over the anticipated effects of the action and the measures needed to avoid, minimize, mitigate, or offset such effects (50 CFR 600.905(k)).

(3) Prepare a section for the EA or EIS that:

- summarizes the information that has been reviewed, the analyses that have been conducted, and the basis for the opinion rendered by the NMFS;

- summarizes the NRC's conclusions in the EFH Assessment, if applicable;

- includes the NMFS's conclusions and the basis for those conclusions and EFH Conservation Recommendations, if applicable;

- summarizes any mitigative measures or BMPs that would be undertaken to minimize the adverse impacts to EFH; and

- provides the significance level of the environmental impacts.

Review Procedures for State-listed Species

(1) Follow the general approach for information and analysis content for all ecology issues, described in Section 19.4.5, Ecological Resources, with the following additions:

- Identify potential environmental effects from construction, operations, and decommissioning that might specifically impact state-listed species.

(2) Prepare a section for the EA or EIS that:

- summarizes the information that has been reviewed, the analyses that have been conducted, and the basis for the opinion rendered by the state resource agencies;
- summarizes the NRC's conclusions; and
- includes the state resource agency conclusions and the basis for those conclusions.

19.4.6 Historic and Cultural Resources

Areas of Review

This ESRP provides guidance for the review of potential impacts on historic and cultural resources during construction, operations, and decommissioning. The scope includes evaluating the impacts to historical and cultural resources and preparing input to the EA or EIS.

Section 106 of the NHPA requires that federal agencies take into account the effects of the agency's undertaking on historic properties included in or eligible for the *National Register of Historic Places* (NRHP) and, prior to approval of an undertaking, afford the ACHP a reasonable opportunity to comment on the undertaking. The issuance of a construction permit and operating license for a radioisotope production facility is an undertaking that could possibly affect either known or currently undiscovered historic properties.

In accordance with 36 CFR 800.8(c) "*Use of the NEPA process for section 106 purposes*", the NRC coordinates its Section 106 responsibilities under the NEPA process for construction permit and operating license reviews. The NRC may use the NEPA process to comply with Section 106 in lieu of the procedures set forth in §§ 800.3 through 800.6 provided all consulting parties (ACHP, SHPO, THPO, American Indian tribes, the public, and other interested stakeholders) have been notified in advance. The NRC will consult with the appropriate SHPO/THPO for each facility-specific review. Early coordination is necessary to identify all areas of concern.

The purpose of the historic and cultural resources assessment is to ensure that historic properties considered eligible for inclusion in the NRHP are not adversely affected by proposed activities related to the construction permit and operating license. Historic and cultural resources may include, but are not limited to, prehistoric or historic archaeological sites; historic structures, districts, and landscapes; and traditional cultural properties that may have significance to a particular community such as an American Indian tribe.

Acceptance Criteria

Acceptance criteria for the review of historic and cultural resources impacts are based on the regulations cited in Section 19.4 and on the relevant requirements of the following:

- National Historic Preservation Act of 1966, as amended (16 U.S.C. 470 et seq)
- 36 CFR 800, "Protection of Historic Properties," specifically, 36 CFR 800.8(c), Section 106 integration with NEPA reviews

- 36 CFR 63 contains guidance by which historic properties are evaluated and determined eligible for listing in the NRHP

Review Procedures

To analyze the impact of construction, operations, and decommissioning on historic and cultural resources, complete the following steps:

(1) Analyze the historic and cultural resources impacts associated with construction, operations, and decommissioning, as follows:

- Determine the direct and indirect impacts that could result from construction, operational, and decommissioning activities (e.g., building new facilities, parking areas, or access roads);
- Review any issues related to historic and cultural resources identified during the public scoping period;
- Identify historic and cultural resources through consultation with the SHPO/THPO and by reviewing any archaeological investigations or surveys conducted within the APE (typically the facility site) and the immediate environs;
- Review the site disturbance map (developed by a qualified archaeologist) that indicates areas of heavy disturbance and areas of high potential for undiscovered historic and cultural resources;
- Review any correspondence from the SHPO, any American Indian tribes, or local preservation officials regarding any archaeological investigations or building surveys conducted on the applicant's site;
- If significant resources are located within the APE, review any procedures or integrated cultural resources management plans proposed or instituted by the applicant to protect the historic and cultural resources identified on the site or within associated infrastructure. Identify the applicant's procedures for inadvertent discovery of historic and cultural resources. Also, verify that the applicant has developed these procedures and plans in consultation with the appropriate SHPO, local preservation official, or American Indian tribes;
- Confirm the eligibility of known historic properties within the APE. Also, apply criteria for NRHP eligibility to historic properties within the APE that have not been previously evaluated; and
- Through consultation with appropriate parties, identify any traditional cultural properties.

(2) Evaluate the effects of construction, operations, and decommissioning to historic and cultural resources. If historic properties are found to be in or near the APE, the assessment of effects can be conducted using criteria for effect and adverse effect contained in 36 CFR 800.5 *Assessment of adverse effects*. Assessments of effect should involve consultation with the SHPO, local historic preservation officials, and

American Indian tribal members, as necessary, to ensure that all potential values are identified for specific resources. The assessment would result in one of the following conclusions:

- No effect: the proposed construction and operational activities would not affect any known significant historic properties.
- No adverse effect: the activities would affect one or more historic properties, but the effect would not significantly alter the historic character of the resource(s).
- Adverse effect: the proposed activities would result in harm to the qualities that make one or more historic property significant.

(3) If an adverse effect would result from construction or operations, the applicant, in consultation with the NRC, SHPO, American Indian tribes, and other interested parties should identify strategies to avoid, minimize, or mitigate the impacts to significant historic properties.

(4) Review the applicant's ER, including:

- the applicant's process for identifying historic and cultural resources
- all correspondence initiated by the applicant to the SHPO, American Indian tribes, or local preservation officials
- a map that identifies the APE and facility property boundary
- cultural resource protection procedures or cultural resource management plans
- previous cultural resources investigations that have identified historic and cultural resources, along with site-specific locations for those resources that are either located in or near the APE, information related to past evaluations for eligibility for the NRHP (36 CFR 60), and associated consultations with the SHPO, local preservation officials, or American Indian tribal officials

(5) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.7 Socioeconomics

Areas of Review

This ESRP guides the assessment of socioeconomic impacts from the construction, operations, and decommissioning of the proposed facility. The scope includes evaluating the socioeconomic impacts and preparing input to the EA or EIS.

The potential impacts of construction, operations, and decommissioning may include the following:

- Population and housing
- Public services and education
- Employment and income (including recreation and tourism)
- Aesthetics
- Transportation
- Tax revenues

Acceptance Criteria

Acceptance criteria for the evaluation of the socioeconomic impacts are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of socioeconomic information, including:

- the applicant's ER
- records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- Environmental quality standards and regulations

(2) Evaluate the significance of the socioeconomic information with respect to construction, operation, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;

- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.8 Human Health

Areas of Review

This ESRP provides guidance for the analysis and assessment of the human-health impacts from construction, operations, and decommissioning. The scope includes evaluating the human health impacts and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of human-health impacts are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential human-health impacts from the proposed action, including:

- the applicant's ER
- records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- 10 CFR Part 20 standards and regulations (Does the applicant provide sufficient information to show how the human health effects from the proposed action would be within the applicable standards and regulations?)

(2) Evaluate the significance of the information with respect to human health as a result of construction, operation, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- compares the proposed action to the requirements in 10 CFR Part 20;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.9 Waste Management

Areas of Review

This ESRP provides guidance for the review of waste management activities during construction, operations, and decommissioning. The scope includes reviewing and evaluating the waste management programs and preparing input to the EA or EIS.

Acceptance Criteria

Acceptance criteria for the evaluation of waste management activities are based on the regulations cited in 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential waste management impacts from the proposed action, including:

- the applicant's ER
- records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- environmental quality standards and regulations

(2) Evaluate the significance of the information with respect to waste management as a result of construction, operation, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.10 Transportation

Areas of Review

This ESRP provides guidance for the review of environmental impacts of transportation of radioactive and non-radioactive materials. The scope includes identification and evaluation of information related to transportation of nuclear materials and preparation of input to the EA or EIS.

Acceptance Criteria

Acceptance criteria are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential impacts to transportation from the proposed action, including:

- the applicant's ER
- records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- environmental standards and regulations

(2) Evaluate the significance of the information with respect to transportation as a result of construction, operations, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.11 Postulated Accidents

Areas of Review

This ESRP provides guidance for the review of environmental impacts of postulated accidents. The scope includes identification and evaluation of information related to environmental impacts of postulated accidents and preparation of input to the EA or EIS.

Acceptance Review

Acceptance criteria are based on the regulations cited in Section 19.4.

Review Procedures

The following review steps are suggested:

(1) Review sources of information on potential impacts from accidents from the proposed action, including:

- The applicant's ER
- The applicant's SAR
- records of public scoping meetings and correspondence with the public and local, state, and federal agencies related to the application
- environmental standards and regulations

(2) Evaluate the significance of the information with respect to accidents as a result of construction, operations, and decommissioning activities.

(3) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning, including the significance level of the environmental impacts;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.12 Environmental Justice

On February 11, 1994, the President signed Executive Order 12898 "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (59 FR 7629) which directs all federal agencies to develop strategies for considering environmental justice in their programs, policies, and activities. Environmental justice is described in the Executive Order as "identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." On December 10, 1997, the CEQ issued, *Environmental Justice Guidance Under the National Environmental Policy Act* (CEQ 1997). The Council developed this guidance to, "further assist federal agencies with their NEPA procedures."

On August 24, 2004, the Commission issued a *Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions* (69 FR 52040), which states, "the Commission is committed to the general goals set forth in E.O. 12898, and strives to meet those goals as part of its NEPA review process." The following guidance is consistent with this policy statement.

Areas of Review

This ESRP provides guidance on conducting environmental justice reviews for proposed actions requiring an EIS as part of NRC's compliance with NEPA. For EAs, environmental justice determinations are described in Appendix C to NRR Office Instruction LIC-203, *Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues* (NRC 2009).

The scope of this ESRP includes the review and evaluation of the impacts to minority and low-income populations and preparation of input to the EIS. The review and evaluation should include an analysis of impacts on minority and low-income populations and the location and significance of any environmental impacts from the construction, operations, and decommissioning of the proposed facility. The descriptions to be provided by this review should be of sufficient detail to permit subsequent staff assessment and evaluation of specific impacts, in particular whether these impacts are likely to be disproportionately high and adverse to minority and low-income populations.

NRC staff should consider the demographic composition of the affected area to determine the location of minority and low-income populations and whether they may be affected by the proposed action. The staff then needs to determine if human health or environmental impacts would have a disproportionately high and adverse effect on minority or low-income populations.

Acceptance Criteria

The acceptance criteria for environmental justice impacts are based on the regulations cited in Section 19.4 and on the relevant requirements of the following:

- Executive Order 12898, which provides guidance concerning federal actions to address environmental justice in minority and low-income populations.

Additional regulatory positions and specific criteria in support of the acceptance criteria identified above are as follows:

- CEQ guidance for addressing environmental justice, *Environmental Justice: Guidance under the National Environmental Policy Act*, December 10, 1997 (CEQ 1997).

- Guidelines for specific information requirements for environmental justice determinations are described in Appendix C to NRR Office Instruction LIC-203, *Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues*. NRR Office Instruction LIC-203 is revised periodically. Obtain a copy of the latest revision for current guidance.

Review Procedures

The review procedure should be as follows:

(1) Review the discussion of potential environmental justice impacts from construction, operations, and decommissioning in the ER.

(2) Identify minority and low-income populations within a 5-mi (8-km) radius of the site. All minority and low-income populations with percentages higher than the geographic area should be identified on 5-mi (8-km) radius maps.

(3) Identify environmental justice issues during the scoping process.

- Determine geographic distribution by race, ethnicity, and poverty, as well as delineation of tribal lands.

In calculating the minority populations, individual(s) who are members of the following population groups listed in the most current Census data are considered minority individuals.

Race: (Not Hispanic or Latino)

Black or African American

American Indian or Alaska Native

Asian

Native Hawaiian and Other Pacific Islander

Some other race

Two or more races

Ethnicity:

Hispanic, Latino, or Spanish origin (may be of any race)

Low-income population is defined as individuals or families living below the poverty level.

Sources of information for determining geographic distribution and location of minority and low-income populations:

- Geographic information software—Missouri Census Data Center, Circular Area Profiling System (CAPS). Version 10C. Using Data from Summary File 1, most current Census Summary of Census Tracts in a 5-mi (8-km) radius around the proposed facility site for race and ethnicity.
- U.S. Census Bureau, Summary File 1, most current Census, for poverty information by county
- Local governments
- State agencies
- Local universities

(4) Determine whether there are human health and environmental impacts to minority or low-income populations or environmental justice concerns.

- Potential human health and environmental impacts are determined through the normal NEPA process
  - Impacts that could potentially affect or cause concern to minority and low-income populations should be summarized in the environmental justice section of the EIS or EA

- In considering human health and environmental impacts to minority and low-income populations, different patterns of consumption of natural resources should also be considered (i.e., differences in rates and/or pattern of fish, vegetable, water, and/or wildlife consumption among groups defined by demographic factors such as socioeconomic status, race, ethnicity, and/or cultural attributes) (see Section 4-4 of Executive Order 12898, Subsistence Consumption of Fish and Wildlife)

- Consider whether there are any means for minority or low-income populations to be disproportionately affected by examining potential impacts to American Indian, Hispanic, and other traditional lifestyle-special pathway receptors. For example, special pathway impacts take into account levels of contaminants in native vegetation, crops, soils and sediments, surface water, fish, and game animals on or near nuclear sites

- Potential sources of information include:

    1. Environmental Monitoring Program (radiological and non-radiological), annual environmental operating reports (radiological and non-radiological) if the site is near an operating nuclear facility

    2. State environmental monitoring programs (radiological and non-radiological)

(5) Determine whether there are disproportionately high and adverse human health or environmental effects on minority and low-income populations.

- Take into account different patterns of living and consumption of natural resources, such as subsistence consumption. Also consider the following questions:

    - Would the impact(s) be greater for minority and low-income populations than the general population?

    - Are there any unique effects experienced by minority and low-income populations that would not be experienced by the general population?

- After identifying human health and environmental impacts that could disproportionately affect minority and low-income populations, it is necessary to determine if the effect(s) would be high and adverse. Another way of stating this:

    - Would the effect(s) on minority and low-income populations be significant, unacceptable, or above generally accepted norms such as regulatory limits or State and local statutes and ordinances? Each human health and environmental impact, and where appropriate, the cumulative and multiple effects of the impact(s), should be reviewed for significance.

- To the extent practicable, mitigation measures should reflect the needs and preferences of the affected minority and low-income populations and communities.

(6) Make a determination regarding impacts to minority and low-income populations.

(7) Prepare a section for the EA or EIS that:

- summarizes the information reviewed and the analyses conducted;
- describes the impacts from construction, operations, and decommissioning;
- describes the basis for the conclusions; and
- describes measures to mitigate adverse impacts.

19.4.13 Cumulative Impacts

Areas of Review

This ESRP provides guidance for the analysis and assessment of cumulative impacts. The scope for each individual section includes analysis and evaluation of the cumulative impacts and preparation of input to the EA or EIS.

Acceptance Criteria

Cumulative impact is defined by CEQ in 40 CFR 1508.7. Actions to be considered in cumulative impact analyses include new and continuing activities that could have overlapping impacts with the proposed action. An action should be considered regardless of whether it is proposed or operated by a federal or non-federal entity. The cumulative impacts analysis takes into account all actions, however minor, because impacts from individually minor actions may be significant when considered collectively over time. The goal of the analysis is to identify potentially significant impacts to improve decisions and move toward more sustainable development (CEQ 1997; EPA 1999).

Review Procedures

The following review steps are suggested:

(1) The analysis of cumulative impacts should focus on the resources that could be affected by the incremental impacts of construction, operations, and decommissioning. These resource areas include:

1. Land Use and Visual Resources
2. Air Quality and Noise
3. Geologic Environment
4. Water Resources
5. Ecological Resources
6. Historic and Cultural Resources

7. Socioeconomics

8. Human Health

9. Waste Management

10. Transportation

11. Environmental Justice

(2) For each resource area, establish the following:

- The geographic scope (i.e., regions of influence). The regions of influence encompass the areas of affect and the distances at which impacts associated with construction, operations, and decommissioning may occur. Geographic boundaries may vary by the resource area being evaluated and the distances over which an impact may occur (e.g., the evaluation of impacts on air quality may have a greater regional extent than that of impacts on cultural resources).

- The time frame for the analysis. The time frame incorporates the sum of the effects of construction, operations, and decommissioning in combination with past, present, and future actions, since impacts may accumulate or develop over time. One reasonably foreseeable time frame for future actions evaluated would be the end of the operating license period and decommissioning activities.

(3) Identify other actions (including related and nonrelated federal and non-federal actions) that could contribute to cumulative impacts. The cumulative impacts of activities associated with the proposed action should be evaluated for each resource area.

(4) Identify resource areas, or categories within resource areas, wherein the contributions of ongoing actions within a region on cumulative impacts are regulated and monitored through a permitting process (e.g., NPDES) under state or federal authority. In these cases, it may be assumed that cumulative impacts are managed as long as these actions (facilities) are in compliance with their respective permits.

(5) Prepare the section for the EA or EIS describing the search for information, summarizing information found, presenting results of evaluation of significance, and summarizing the conclusion with sufficient supportive information.

19.4.14 References

Areas of Review

This ESRP provides guidance for the listing of references cited in the EA or EIS chapter on environmental consequences.

Review Procedures

The EPM should contact reviewers for Sections 19.4.1 through 19.4.13 and compile a list of references cited in the EA or EIS sections that the reviewers have prepared. The EPM should

check the reference listings for completeness and consistency and prepare the listing for inclusion in the EA or EIS.

19.5 Alternatives

Areas of Review

This ESRP provides guidance for the preparation of introductory paragraphs for the portion of the EA or EIS that describes the environmental impacts of reasonable alternatives to the proposed action. The scope introduces the material from the reviews conducted under Sections 19.5.1 through 19.5.3, including a description of the reasonable alternatives to the proposed action, identification of alternatives eliminated from detailed study, and how the applicant identified and selected alternatives to the proposed action. This ESRP also provides material that is applicable to the reviews conducted under Sections 19.5.1 through 19.5.3.

Acceptance Criteria

The reviewer should ensure that guidance in Section 19.5 are consistent with the intent of the following regulations:

- 10 CFR 51.45(b)(3), Alternatives to the proposed action. "The discussion of alternatives shall be sufficiently complete to aid the Commission in developing and exploring, pursuant to section 102(2)(E) of NEPA, "appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." To the extent practicable, the environmental impacts of the proposal and the alternatives should be presented in comparative form."

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics. The format provided in section 1(a) of appendix A of this subpart should be used. The NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement."

- 10 CFR 51.71 (d), *Analysis. "*The draft environmental impact statement will include a preliminary analysis that considers and weighs the environmental effects of the proposed action; the environmental impacts of alternatives to the proposed action; and alternatives available for reducing or avoiding adverse environmental effects."

- 10 CFR 51.103(2). "Identify all alternatives considered by the Commission in reaching the decision, state that these alternatives were included in the range of alternatives discussed in the environmental impact statement, and specify the alternative or alternatives which were considered to be environmentally preferable."

- 10 CFR 51, Appendix A to Subpart A of Part 51—Format for Presentation of Material in Environmental Impact Statements.

- 10 CFR 51, Appendix A(5), *Alternatives including the proposed action*. "Environmental impacts of the proposed action and the alternatives should be

presented in comparative form. Where important to the comparative evaluation of alternatives, appropriate mitigating measures of the alternatives will be discussed. All reasonable alternatives will be identified. The range of alternatives discussed will encompass those proposed to be considered by the ultimate decision maker. An otherwise reasonable alternative will not be excluded from discussion solely on the ground that it is not within the jurisdiction of the NRC."

- 10 CFR 51, Appendix A(7), *Environmental consequences and mitigating actions.* "Alternatives eliminated from detailed study will be identified and a discussion of those alternatives will be confined to a brief statement of the reasons why the alternatives were eliminated. The level of information for each alternative considered in detail will reflect the depth of analysis required for sound decision making."

Technical Rationale

Section 12.5 examines the potential environmental impacts associated with alternatives, including not granting the construction permit and operating license (i.e., the no-action alternative). 10 CFR 51, Appendix A to Subpart A of Part 51— 4, "Purpose of and need for action," explicitly requires an analysis of the no-action alternative. If the construction permit and operating license are not granted, then the facility would not be built and operated, and other sources would presumably be pursued to obtain radioisotopes.

The no-action alternative does not involve the determination of whether radioisotopes are needed or should be generated. The decision to produce radioisotopes is at the discretion of applicants.

Review Procedures

Examine the applicant's ER and consider the range of reasonable alternatives. Alternatives considered may include, but are not limited to, alternative sites, alternative siting within a proposed site, modification of existing facilities versus construction of an entirely new facility, alternative technology(s), and/or alternative transportation methods. The reviewer should identify the criteria used in evaluating the reasonableness of the alternatives and explain which alternatives would not be considered for detailed analysis and why. The reviewer should identify the alternatives that would be carried forward for comparison with the proposed action.

Evaluation Findings

The reviewer of information covered by this ESRP should prepare introductory paragraphs for the EA or EIS. The paragraph(s) should introduce the nature of the material to be presented by the reviewers of information covered by Sections 19.5.1 through 19.5.3

19.5.1 No-Action Alternative

Areas of Review

This ESRP provides guidance for the analysis and assessment of potential impacts of the no-action alternative. The scope of the review includes identification and evaluation of information

related to potential impacts of the no-action alternative and preparation of input to the EA or EIS.

Acceptance Criteria

Acceptance criteria are based on the relevant requirements stated in Section 19.5.

Review Procedures

To analyze the environmental impacts of the no-action alternative, the reviewer should complete the following steps:

(1) Review information related to the potential environmental impacts of the no-action alternative. The following sources of information should be considered:

- the applicant's ER
- records of public scoping meetings and correspondence with federal, state, and local agencies related to the application

(2) Determine, from the scope of environmental impacts of the no-action alternative, those that are minor and those that are likely to be sufficiently important to require detailed analysis.

If, based on this analysis, the reviewer determines that there would be more than minor impacts, proceed to Step (3). Otherwise, if the reviewer determines that there would be no environmental impacts or that the impacts would be minor, develop a statement to this effect.

(3) Analyze the environmental impacts associated with the no-action alternative, as follows:

- Identify the likely environmental impacts of the no-action alternative.
- Analyze the direct, indirect, and cumulative impacts for each source area.

(4) Consider and evaluate potential mitigation measures or alternatives that might reduce or eliminate the adverse impacts or the disproportionate distribution of the impacts in those cases where the impacts are MODERATE or LARGE. The applicant may have considered this in its ER.

(5) Based on the results of the assessments listed above, prepare the following for the EA or EIS:

- A summary statement (qualitative or quantitative, as appropriate) about the degree to which environmental resources are expected to be impacted by the no-action alternative, together with the significance of the impacts
- A discussion of the rationale or basis for conclusions supporting the degree of impact

- A discussion of any mitigative measures that would or could reduce adverse environmental impacts

19.5.2 Environmental Consequences of Alternatives

Areas of Review

This ESRP provides guidance for the review of the environmental impacts of alternatives. The scope includes identification and evaluation of information related to potential impacts of alternatives and preparation of input to the EA or EIS.

Acceptance Review

Acceptance criteria are based on the relevant requirements stated in Section 19.5.

Review Procedures

To analyze the environmental impact of alternatives, the reviewer should complete the following steps:

(1) Obtain and review information on the potential environmental impacts of alternatives. The following sources of information should be included in the search for information:

- The applicant's ER
- Records of public meetings and correspondence with other federal, state, and local agencies related to the application

(2) Determine, from the scope of environmental impacts of alternatives, those that are minor and those that are likely to be sufficiently important to require detailed analysis.

If, based on this analysis, the reviewer determines that there would be more than minor impacts, proceed to Step (3). Otherwise, if the reviewer determines that there would be no environmental impacts or that the impacts would be minor, develop a statement to this effect.

(3) Analyze the environmental impacts associated with alternatives, as follows:

- Describe the impacts in sufficient detail so that reviewers may compare the adverse and beneficial impacts of the alternatives with those of the proposed action. Impact analyses should consider resource areas described in Sections 19.3 and 19.4. The impact analyses should include direct, indirect, and cumulative impacts. For each alternative, the analysis should identify and, to the extent possible, quantify, unavoidable adverse impacts, irreversible and irretrievable resource commitments, and tradeoffs between short-term use and long-term productivity of the environment. To the extent possible, each alternative should be analyzed on a site- or region-specific basis. Each impact should be analyzed in proportion to its significance.
- The significance or potential significance of such environmental impacts

- Any mitigative measures for which credit is being taken to reduce environmental concerns

(4) Consider and evaluate potential mitigation measures or alternatives that might reduce or eliminate the adverse impacts or the disproportionate distribution of the impacts in those cases where the impacts are MODERATE or LARGE. These may have been considered in the applicant's ER.

(5) Based on the results of the assessments listed above, prepare the following for the EA or EIS:

- A summary statement (qualitative or quantitative, as appropriate) about the degree to which environmental resources are expected to be impacted by the alternatives, together with the significance of the impacts

- A discussion of the rationale or basis for conclusions supporting the degree of impact

- A discussion of any mitigative measures that would or could reduce adverse environmental concerns

19.5.3 Cost-Benefit Analysis

Areas of Review

This ESRP provides guidance for the review of the cost-benefit analysis. The scope includes identification and evaluation of information related to the cost-benefit analysis and preparation of input to the EA or EIS.

Acceptance Criteria

Acceptance criteria are based on the relevant requirements stated in Section 19.5.

Review Procedures

To analyze the costs and benefits of the alternatives and the proposed action, the reviewer should complete the following steps:

(1) Obtain and review information on the potential costs and benefits of the alternatives and the proposed action. The following sources of information should be included in the search for information:

- The applicant's ER

- Records of public meetings and correspondence with other federal, state, and local agencies related to the application

- Related sections of the EA or EIS

(2) Prepare the following for the EA or EIS:

- For each alternative and the proposed action, describe the costs, such as (1) environmental degradation (e.g., impacts to air and water quality, biotic resources, and aesthetics, as well as socioeconomic impacts such as noise, traffic congestion, increased demand for public services, and land use changes) and effects on public health and safety; and (2) other costs (e.g., lost tax revenue, decreased recreational value, transportation, as appropriate).

- For each alternative and the proposed action, describe the environmental benefits such as (1) the average annual production of commercial products; (2) expected increase (if any) of tax payments to state and local tax jurisdictions during construction, operations, and decommissioning; (3) creation and improvement of transportation infrastructure and other facilities; and (4) other benefits, such as any other environmental benefits.

- After considering the cost-benefit aspects of the project, balance the benefits of the proposed project against the total environmental costs and reach a final conclusion as to the overall benefit-cost balance of the proposed project and alternatives.

19.6 Conclusions

Areas of Review

This ESRP provides guidance on preparing the chapter of the EA or EIS that summarizes the conclusions of the proposed action and the alternatives. The chapter should conclude whether the adverse environmental impacts of the proposed action are so great that preserving the option of facility construction and operation would be unreasonable.

The scope includes (1) review of the impact analyses prepared for the EA or EIS, (2) evaluation of the cumulative impacts associated with the proposed action, (3) review of the discussions of the environmental impacts of alternatives, (4) comparison of the environmental impacts of the proposed action with the environmental impacts of the alternatives, and (5) preparation of input to the EA or EIS.

The EA or EIS input should (1) identify adverse environmental impacts that are unavoidable, (2) identify commitments of resources that are irreversible and irretrievable, and (3) discuss the trade-off between the proposed project's short-term uses of the environment and the effects of these uses on long-term environmental productivity. The review should also include an evaluation of the extent to which the proposed project's use of the environment will preclude any options for other future use of the environment.

Acceptance Criteria

Acceptance criteria for the preparation of the summary and conclusions are based on the relevant requirements of the following regulations:

- 10 CFR 51.70(b). "The draft environmental impact statement will be concise, clear and analytic, and written in plain language with appropriate graphics. The format provided in section 1(a) of appendix A of this subpart should be used.

The NRC staff will independently evaluate and be responsible for the reliability of all information used in the draft environmental impact statement."

- 10 CFR 51.71(d). *Analysis*. "The draft environmental impact statement will include a preliminary analysis that considers and weighs the environmental effects of the proposed action; the environmental impacts of alternatives to the proposed action; and alternatives available for reducing or avoiding adverse environmental effects and consideration of the economic, technical, and other benefits and costs of the proposed action and alternatives and indicate what other interests and considerations of federal policy, including factors not related to environmental quality if applicable, are relevant to the consideration of environmental effects of the proposed action."

Technical Rationale

The EA or EIS should include NRC staff recommendations regarding the environmental acceptability of the proposed action. This ESRP summarizes the environmental impacts of the proposed action, comparison of the environmental impacts of the proposed action with the impact of the alternatives, and the staff recommendations.

Review Procedures

The EPM is responsible for the preparation of the EA or EIS summary and conclusions section. The summary and conclusions section should be sufficiently complete that a person reading this section would understand:

- The purpose and need for the proposed action
- The NEPA process and NRC's environmental review process including preparation of the EA or EIS
- The environmental impacts of construction, operations, and decommissioning
- The environmental impacts of alternatives to the proposed action
- Staff conclusions and recommendations

Suggested steps for the preparation of the summary and conclusions chapter of the EA and EIS are as follows:

(1) Prepare introductory paragraphs for the Summary and Conclusions chapter.

(2) Prepare a table that summarizes the findings of the environmental impacts presented in the EA or EIS. The summary and conclusions table should list the environmental impacts of the proposed action and the alternatives (including the no-action alternative) and state the level of significance of each impact. This table should be organized by environmental resource area.

(3) The EPM should create a list of unavoidable adverse impacts and irreversible and irretrievable resource commitments, based on input from the SMEs. Additionally, the EPM, in coordination with the SMEs, should draw conclusions related to the trade-off of

the short-term use of the environment from the proposed project compared to the long-term productivity of the environment. The lists of unavoidable adverse impacts and irreversible and irretrievable resource commitments, and a discussion of the effects of short-term use on the long-term productivity of the environment, should also be included in the EA or EIS.

(4) Prepare input to the EA or EIS summary and conclusions chapter.

Evaluation Findings

The EPM prepares the EA or EIS section that presents (1) the overall summary of the environmental impacts of the proposed action and alternatives and (2) the staff recommendations regarding the environmental impacts associated with the construction permit and operating license.

19.7 References

10 CFR 51, *Code of Federal Regulations*, Title 10, *Energy,* Part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.

33 CFR 330, *Code of Federal Regulations*, Title 33, *Navigation and Navigable Waters,* Part 330, "Nationwide Permit Program."

36 CFR 60, *Code of Federal Regulations* , Title 36, *Parks, Forests, and Public Property*, Part 60, "National Register of Historic Places."

36 CFR 63, *Code of Federal Regulations* , Title 36, *Parks, Forests, and Public Property*, Part 63, "Determinations of Eligibility for Inclusion in the National Register Of Historic Places."

36 CFR 800, *Code of Federal Regulations* , Title 36, *Parks, Forests, and Public Property*, Part 800, "Protection of Historic Properties."

40 CFR 6, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 6, "Procedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions."

40 CFR 50, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 50, "National Primary and Secondary Ambient Air Quality Standards."

40 CFR 51, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 51, "Requirements for Preparation, Adoption, and Submittal of Implementation Plans."

40 CFR 81, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 81, "Designation of Areas for Air Quality Planning Purposes."

40 CFR 93, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 93, "Determining Conformity of Federal Actions to State or Federal Implementation Plans."

40 CFR 122, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 122, "EPA Administered Permit Programs: The National Pollutant Discharge Elimination System."

40 CFR 124, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 124, "Procedures for Decisionmaking."

40 CFR 125, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 125, "Criteria and Standards for the National Pollutant Discharge Elimination System."

40 CFR 133, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 133, "Secondary Treatment Regulation."

40 CFR 147, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 147, "State, Tribal, and EPA-Administered Underground Injection Control Programs."

40 CFR 149, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 149, "Protection of Environment, Sole Source Aquifers."

40 CFR 165, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 165, "Pesticide Management and Disposal."

40 CFR 403, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 403, "General Pretreatment Regulations for Existing and New Sources of Pollution."

40 CFR 423, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 423, "Steam Electric Power Generating Point Source Category."

40 CFR 1508, *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 1508, "Terminology and Index."

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Executive Order 11990, Protection of Wetlands.

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