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

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
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
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
LCO	limiting condition for operation
LEU	low-enriched uranium
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
NOx	nitrogen oxide
NRC	U.S. Nuclear Regulatory Commission
NRCS	Natural Resources Conservation Service (U.S. Dept. of Agriculture)
NRHP	National Register of Historic Places
NRU	National Research Universal
PSAR	preliminary safety analysis report
OSHA	U.S. Occupational Safety and Health Administration
RAM	remote area monitor
Rev	Revision
RG	regulatory guide
SAR	safety analysis report
SGI	safeguards information
SHPO	State Historic Preservation Office
SL	safety limit
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 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," 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.

Since NUREG-1537 was published in 1996 two significant changes occurred that call for additions to the "General Requirements" section of the Introduction of that document. First, regulations have changed to address advances in text processing and the electronic submittal of information. Second, the guidance needed in 1996 was a standardized format and content of a safety analysis for the renewal of licensed non-power reactors; the guidance currently needed is for new, uniquely designed utilization and production facilities. To address this new environment the following material augments the existing "General Requirements" of NUREG-1537.

The application must be prepared and submitted in accordance with the following regulations:

- 10 CFR 2.101, Filing of Application
- 10 CFR 50.4, Written Communication

The content of an application must be in accordance with the following regulations:

- 10 CFR 50.33, Contents of applications; general information
- 10 CFR 50.34, Contents of applications; technical information
- 10 CFR 50.34(a), Preliminary safety analysis report
- 10 CFR 50.34(b), Final safety analysis report
- 10 CFR 50.34(c), Physical security plan
- 10 CFR 50.34(d), Safeguards contingency plan
- 10 CFR 50.34(e), Protection against unauthorized disclosure

Per the regulations cited above, each application for a construction permit must contain a preliminary safety analysis report (PSAR) and each application for an operating license must contain the final safety analysis report (FSAR), physical security plan, safeguards contingency plan, and plan for protection against unauthorized disclosure. Applicants should segregate documents that are subject to frequent change with forethought to the ease of maintaining

updated documents. For example, the quality assurance program description required in the PSAR may be identified by reference in the PSAR as an appendix or as an independent part of the application. The same may be done with the FSAR requirements for an emergency plan, technical specifications, and the operator requalification program.

NUREG-1537 and this ISG provide general guidance for the format and content of a complete FSAR. The applicant should use the same format and chapter headings for the PSAR. However, the PSAR content pursuant to 10 CFR 50.34(a) is less detailed and sub-chapter headings should be modified as appropriate to match its focus on the criteria and standards used for the design and analysis rather than that of a detailed description and safety analysis of the completed operational facility.

It is recognized that the guidance addresses topics that may not apply to all applications and therefore those topics need not be discussed. Some technologies and applications may involve terminology that is not defined and used in the guidance documents, in which case the more appropriate terminology should be defined and used.

The section titled, "Physical Specifications of the Application," of the "Introduction" of NUREG-1537, Part 1, is being modified to include information on electronic submission of licensing applications to the NRC. The last bullet of the subsection titled, "Style and Composition," is modified to read:

- Submit the application in accordance with 10 CFR 50.30, 10 CFR 50.4, and other applicable regulations. The regulations in 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," contains information on licensing and amendment fees.

A new bullet is added to the end of the subsection that reads:

- When submitting the application electronically, use the electronic submission guidance for new reactor-related application submittals. This guidance is found in the electronic submission guidance referenced in 10 CFR 50.4(a) and available on the NRC public website at http://www.nrc.gov/site-help/e-submittals/guide-electronic-sub.pdf.

The section titled, "References," is modified to remove the reference "Generic Letter 84-14," and replace it with the following reference:

> U.S. Nuclear Regulatory Commission, "Guidance for Electronic Submissions to the NRC," Revision 6.1, May 2011

1 THE FACILITY

NUREG-1537, Part 1, Chapter 1 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the 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

The inherent or passive safety features and any unique design features of the radioisotope production facility should be described.

1.2 Summary and Conclusions on Principal Safety Considerations

The first bullet should read: "consequences from the operation and use of the non-power reactor and radioisotope production facility, and the methods used to ensure the safety of the facility."

The last line in the second bullet should read: "…the type of building housing the facility and any special factors."

1.3 General Description of the Facility

The description of the reactor facility required by NUREG-1537, Part 1, should be expanded to include the radioisotope production facility.

1.4–1.8

The standard format and content of these sections is applicable if, wherever the term "reactor" appears, it is understood to encompass either or both "non-power reactor" and "radioisotope production facility," as applicable. The discussion should be expanded to include the radioisotope production facility, as applicable.

2 SITE CHARACTERISTICS

NUREG-1537, Part 1, Chapter 2 of Part 1 of the format and content guide, as augmented by this ISG, is applicable to providing 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.

2.1.1.2 Boundary and Zone Area Maps

The fifth and sixth bullets call for the inclusion of rural and urban zones in the area maps. Only test reactor SARs need to include this information.

In this section, the controlled area prescribed by 10 CFR 20.1003, "Definitions," and further specified by 10 CFR 70.61(f), is comparable to or is satisfied by one or more of the areas defined in this section. If it is not, the controlled area should be defined in this section.

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 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 1, Chapter 3 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the design of structures, systems, and components 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 following paragraph should be added immediately following the first paragraph of the introduction in this chapter:

> As stated above, facility and system design must be based on defense-in-depth practices. Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of accident analysis can then be used to supplement the final design by focusing attention on the prevention and mitigation of the higher risk potential accidents.

The design must incorporate both of the following, to the extent practicable:

(1) preference for the selection of engineered controls over administrative controls to increase overall system reliability

(2) features that enhance safety by reducing challenges to items relied on for safety (IROFS)

3.1–3.4

The standard format and content of these sections are applicable if, wherever the term "reactor" appears, it should be understood to mean a "non-power reactor," a "radioisotope production facility" or both, as appropriate.

3.5 Systems and Components

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 facility.

The baseline design criteria for facilities that process SNM, and hazardous chemicals that are coincident with or result from operations with SNM, are prescribed in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." 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. The NRC staff has determined that addressing the baseline design criteria and defense in depth practices in 10 CFR 70.64 is an acceptable way of demonstrating adequate safety of structures, systems, and components in the design of a radioisotope production facility. The term "Requirements for New Facilities or New Processes at Existing Facilities" is not intended to mean 10 CFR 70.64 is required for a radioisotope production facility license, only that their use as baseline design criteria may be found acceptable by NRC staff. Applicants may propose alternate design criteria that provide protection against the uncontrolled release of radioactive material.

3.6 Bibliography

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

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

4 REACTOR AND ISOTOPE PRODUCTION FACILITY DESCRIPTION

NUREG-1537, Chapter 4, Part 1 of the format and content guide, as augmented by this ISG, is applicable to providing 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"

4a1 Heterogeneous Reactor Description

NUREG-1537, Part 1, Chapter 4, should be used for guidance in preparing this chapter.

4a2 Aqueous Homogeneous Reactor Description

NUREG-1537, Part 1, Chapter 4, should be replaced in its entirety with the following guidance:

In this chapter of the SAR, the applicant should describe and discuss 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.

While considering the guidance in this chapter for the AHR, it should be noted that the fuel solution performs the function of the fuel and moderator. If the reactor is intended to be used for the production of radioisotopes, the core can also be the radioisotope production target. However, in the following subsections, any direct reference to a moderator or a target is also intended to apply 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 primary fission-product barrier performed by the cladding does not apply to an AHR and a radioisotope production facility. The primary fission-product barrier in an AHR is 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.

A glossary of terms often used when discussing an AHR is found below:

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: 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.

Primary System Boundary: The 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, and pumps, valves, and piping.

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

Reactor Core: The 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 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 gas.

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

Recombiner: Device that recombines hydrogen and oxygen.

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

4a2.1 Summary Description

In this section, the applicant should briefly summarize the design and functional characteristics of the reactor. The applicant should present the principal safety considerations of the reactor, as well as the design principles for the components and systems that address those considerations. This section should contain summary tables of important reactor parameters and sufficient drawings and schematic diagrams to explain and illustrate the main reactor design features.

The applicant should briefly address the following features of the reactor:

- thermal power level
- fuel type and enrichment
- use of gas-tight vessel
- forced and/or natural convection cooling
- type of coolant, solid moderator (if any), and reflector materials
- principal features for experimental programs or commercial isotope production programs or both as applicable
- pulsing or steady power

- novel concepts requiring substantial new development

- gas management system

4a2.2 Reactor Core

In this section, the applicant should present all design information and analyses necessary to demonstrate that the core can be safely operated. The major core components to be described are fuel, solid neutron moderator (if any), neutron reflector, control elements, neutron startup source, in-core cooling components, and any in-core experimental facilities. The source or basis of the information presented should be given.

4a2.2.1 Reactor Fuel

In this section, the applicant should describe the reactor fuel system. Design features selected to ensure that the fuel (including fission products) barrier can withstand all credible environmental and irradiation conditions during its life cycle at the reactor site should be included. The discussions should address the in-core fuel operating conditions. Chapter 9, "Auxiliary Systems," of the SAR should discuss handling, transport, and storage of fuel. Drawings and tables of design specifications and operating characteristics of the fuel should be presented.

In AHRs, radiolysis and fission-product gases build up within the reactor vessel above the liquid fuel. Hydrogen and oxygen from the radiolysis of water could lead to the development of an explosive gas mixture. In addition, where applicable, nitrate-based aqueous fuel will generate acidic nitrogen gases (NOx) by radiolysis. Gases generated during fission will also collect in the cover gas space. Therefore, information relevant to the headspace and the gas handling systems should be provided. See References 1 and 2 at the end of this chapter.

All information should be current; supported by referenced tests, measurements, and operating experience and compared with additional applicant experience where applicable. For AHRs, the information should include the following:

- Chemical composition, enrichment, uranium loading, and chemistry of the fuel. Information should be provided for fresh and reloaded fuel composition; solvent type and molarity; uranium loading and enrichment; expected fissile density in solution at operating pressure, temperature, and pH; uranium solubility; buildup of fission products and related decay daughters in solution, precipitates, and sweep gas system.
- Information on radiolytic gas formation and impact on reactor core chemistry, homogeneity, and reactivity. Implications of void formation and condensate return to the core for reactor performance should be discussed.
- Short-term changes in the chemistry of the fuel. Changes in the pH, temperature fluctuations, fission gas release, and changes in concentration because of radiolytic water and acid destruction would be expected during an operation cycle. The range of these fluctuations and their effects on reactor operation and control should be described.
- Long-term changes in the chemistry of the fuel. In particular, the buildup of fission products, activation products, and corrosion products would be of interest. Any plans and approaches for stabilizing or adjusting the fuel characteristics or composition should be included. Any plans regarding periodic reconstitution or purification of the fuel should

also be included. Any scheduled periodic analysis plans for the fuel should be described. Finally, a description of the fuel at its end of life should be given.

- Description of the volume occupied by the fuel solution, including the height and diameter and the portion of the volume occupied by solids. Separate descriptions should be given for conditions with and without significant power and gas generation (i.e., the gas evolved during irradiation should be included in the description of the fuel). Special features, such as reflectors, external geometrical designs to enhance cooling capability, and inherent safety or feedback provisions, should be discussed.
- Physical properties significant to safety that are important for the thermal-hydraulic analyses, such as solution density, power density and distribution, temperature, pH, pressure, heat capacity, gas evolution or diffusion (including fission-product gas), changes in void fraction, precipitation of fuel or fission-product complexes, and sweep gas.
- Material and structural information for the core vessel and coolant coils that relate to the integrity of the primary barrier, such as dimensions, fabrication methods, compatibility of materials, and specifications with tolerances.
- All types of fuel solution chemical constituents used should be described, as well as the fuel preparation method and location.
- Information on material parameters that could affect the integrity of the core vessel, the coolant components, control rod channels, and fuel transport piping, such as melting, softening, or blistering temperatures; corrosion; erosion; and mechanical factors, such as swelling, bending, twisting, compression, and shearing.
- A brief history of the fuel type, with references to the fuel development program, including summaries of performance tests, qualification, and operating history.
- Hydraulic forces, thermal changes and temperature gradients, internal pressures including that from fission products and gas evolution (including removal to gas treatment), pH control, pressure, precipitation, frothing, malfunctions of the gas treatment system, and radiation effects on the solution chemistry. Extended and more detailed discussion of these characteristics and effects may be included in Section 4a2.7, “Gas Management System” (addressed below).
- Adequate mixing of the fuel solution based on convection and gas evolution.

Information and analyses should support the limits on operating conditions for the fuel. These limits are specified to ensure that the integrity of the fuel barrier will not be impaired by solution pH, radiolytic gas evolution, solution boiling, power oscillations, precipitation from solution, temperature and pressure extremes or distributions, and materials compatibility. They should form the design bases for this and other chapters of the SAR, for the reactor safety limits, and for other fuel-related TS.

4a2.2.2 Control Rods

In this section, the applicant should give information on the control rods, including all rods or control elements that are designed to change reactivity during reactor operation. The physical, kinetic, and electromechanical features demonstrating that the rods can fulfill their control and safety functions should be described. Results of computing control-rod reactivity worths may be presented in this section, but details of the calculation of reactivity effects should appear in

Section 4.5, “Nuclear Design,” of the SAR. The information in this section should include the following:

- The number and types of rods (e.g., shim, safety, regulating, transient), their designed locations in the core, and their designed reactivity worth. Provide the considerations and bases for redundancy and diversity and discuss the limits on core configuration.
- The structural and geometric description, including the shape, size, materials, cladding, fabrication methods, and specifications with tolerances for the rods. This should include the type and concentration of neutron absorber, or emitter, if applicable. Also, provide calculations of changes in reactivity worth due to burnup and assessment of radiation damage, heating effects, and chemical compatibility with the coolant and other core components. If the control rods have followers, the design, composition, and reactivity effects of the follower should be discussed.
- The structural and mechanical design relative to the core vessel penetrations provided for them. Are the penetrations closed or open-ended thimbles or tubes? Will the rods require cooling during operation at power? How does the thermal-hydraulic design keep the reactor within the specified operational and safety limits? Cooling calculations may be included in Chapter 5, “Cooling Systems.”
- The design of mechanical supports for the active component, the method of indicating and ensuring reproducible positioning in the core, and the drive mechanism of each type of rod. This information should include the source of motive power, usually electrical, and the systems ensuring scram capability.
- The kinetic behavior of the rods, showing either the positive or negative rate of reactivity changes, in the normal drive and scram modes of operation. This information should be supplied for all rods, including transient rods in a reactor designed for pulsing.
- The applicant should show that the control rod design conforms to the shutdown margin requirements.
- The scram logic and circuitry, interlocks and inhibits on rod withdrawal, trip release and insertion times, and trip or scram initiation systems should be summarized here and described in detail in Chapter 7, “Instrumentation and Control Systems.”
- Special features of the control rods, their core locations, power sources, drive or release mechanisms designed to ensure operability and capability to provide safe reactor operation and shutdown under all conditions during which operation is required in the safety analysis if there is a single failure or malfunction in the control system itself. Such features may include mechanisms to limit the speed of rod movement.
- TS requirements for the control rods and their justification. These are the limiting conditions for operation (LCO’s), surveillance requirements (SR’s), and design features as discussed in Chapter 14, “Technical Specifications,” of this standard format and content guide.

4a2.2.3 Neutron Moderator and Reflector

In this section, the applicant should discuss any additional materials and systems designed to moderate the neutrons within the fuel region (e.g., solid moderator, if any) and reflect leakage neutrons back into the fuel region. The information should include the materials, geometries, designs for changes or replacement, provisions for cooling, radiation damage considerations,

and provisions for experimental facilities or special uses. Multiple-use systems and features such as moderator coolant, fuel moderator, and reflector shields should be described. If solid moderators or reflectors are encapsulated to prevent contact with coolant, the effect of failure of the encapsulation should be analyzed. It should be possible to operate the reactor safely until failed encapsulations are repaired or replaced. If reactor operations cannot be safely continued, the reactor should be placed and maintained in a safe condition until encapsulations are repaired or replaced. TS requirements should be proposed and justified for the moderator and reflector in accordance with the guidance in Chapter 14 of this format and content guide. The nuclear design of the moderator and reflector should be discussed in Section 4.5 of the SAR.

4a2.2.4 Neutron Startup Source

In this section, the applicant should present design information about the neutron startup source and its holder. The applicant should show that the source will produce the necessary neutrons to allow a monitored startup with the reactor instrumentation. The information should include the neutron strength and spectrum, source type and materials, its burnup and decay lifetime, and its regeneration characteristics. Other necessary information includes the material and geometry of the holder, the method of positioning the source in the core, and the core locations in which the source is designed to be used. Utilization information and such limitations as radiation heating or damage and chemical compatibility with coolant and other core components should be discussed. Any TS limits on the source should be proposed and justified in this section of the SAR in accordance with the guidance in Chapter 14 of this format and content guide. Examples include the maximum power level at which the reactor can be operated with the source in place (for plutonium-beryllium sources and other source types that can act as fuel) or SRs that ensure source integrity.

4a2.2.5 Reactor Internals Support Structure

In this section, the applicant should present design information about the mechanical structures that support and position the core and its components. The information should include the following:

- Since the reactor core is an aqueous solution, the AHR core support structure is the reactor vessel. Therefore, this section should discuss the vessel and reflector vertical and lateral support structure, as well as the support for the reactor control and cooling components and any other components connected to the reactor vessel. The fuel positioning function of a heterogeneous reactor core support structure is not applicable to an AHR.
- The materials of construction, including considerations for radiation damage, corrosion, erosion, chemical compatibility with coolant and fuel solution and core components, potential effects on reactivity, induced radioactivity, and maintenance.
- Design features of the support structures that accommodate other systems and components such as radiation shields, reflectors, coolant coils and piping (including accommodation for buoyant and dynamic loads such as vibration), control rod drive thimbles, coolant plenums or deflectors, gas treatment systems, and nuclear detectors. Piping for fuel transfer to and from the core should be specifically addressed.
- TS that control important design features, LCO's, and SR's, as discussed in Chapter 14 of this format and content guide. The applicant should justify these TS in this section of the SAR.

4a2.3 Reactor Vessel and Pool

The core of the AHR is an aqueous solution within a gas-tight vessel. This vessel may rest in a pool, which acts as a shield and removes some small amount of heat from the reactor. In this section, the applicant should present all information about the vessel and pool necessary to demonstrate their integrity. The information should include the following:

- Design considerations to ensure that no hydrodynamic, hydrostatic, mechanical, chemical, and radiation forces or stresses could cause failure or loss of integrity of the vessel and pool during its projected lifetime over the range of design characteristics.
- Design and dimensions to ensure sufficient shielding water to protect personnel and components, as well as sufficient depth to ensure necessary coolant flow and pressures. (Also see Sections 4.4 and 4.6 and Chapter 11, "Radiation Protection Program and Waste Management," of this format and content guide).
- Design and description of materials, including dimensions, supporting structures, chemical compatibility with the coolant and other reactor system components, radiation fields and any consequences of radiation damage, protection from corrosion in inaccessible regions, and capability to replace components.
- Locations of penetrations and attachment methods for other components and pipes. The relationships of these penetrations to core and water surface elevations should be discussed. Safety-related features that mitigate loss of coolant should be discussed and related to Sections 4.4 and 4.6 and to the reduction-in-cooling scenarios analyzed in Chapter 13, "Accident Analyses," as applicable.
- If the inner surface of the vessel is coated to alleviate the impact of contact with the fuel, the effect of failure of the coating should be analyzed.
- Planned methods for assessing radiation damage, chemical damage, erosion, pressure pulses, or deterioration during the projected lifetime. In this section the applicant should assess the possibility of uncontrolled leakage of fuel solution into the coolant or the pool and should discuss preventive and protective features.
- TS that control important design features, LCO's, and SR's as discussed in Chapter 14 of this standard format and content guide. The applicant should justify these TS in this section of the SAR.

4a2.4 Biological Shield

In this section, the applicant should present information about the principal biological shielding designed for the reactor. The information should include the following:

- The design bases for the radiation shields (e.g., water, concrete, or lead), including the projected reactor power levels and related source terms and the criteria for determining the required protection factors for all applicable nuclear radiation activity. Chapter 11 should present information about conformance with the regulations for radiation exposure and the facility ALARA (as low as reasonably achievable) program. The design bases should include the designed reactor power levels, the associated radiation source terms, and other radiation sources within the pool or tank that require shielding.

- The design details and the methods used to achieve the design bases. The applicant should discuss the protection of personnel and equipment functions. The information should specify the general size and shape of the shields and the methods used to ensure structural strength, rigidity, and functional integrity. The applicant should discuss the distribution of shielding factors between liquid (e.g., water) and solid (e.g., concrete, lead) materials. If loss of shield integrity could cause a reduction in cooling, the features to prevent the loss of integrity should be described.
- The materials used and their shielding coefficients and factors, including a detailed list of constituents and their nuclear and shielding properties. The applicant should discuss radiation damage and heating or material dissociation during the projected lifetime of the reactor; induced radioactivity in structural components; potential radiation leakage or streaming at penetrations, interfaces, and other voids; shielding at experimental facilities; and shielding for facilities that store fuel and other radioactive materials within the reactor pool or tank.
- The assumptions and methods used to calculate the shielding factors, including references to and justification of the methods. Detailed results of the shielding calculations should give both neutron and gamma-ray dose rates at all locations that could be occupied. The applicant should calculate shield penetrations and voids, such as beam ports, thermal columns, and irradiation rooms or vaults, as well as the shielding of piping and other components that could contain radioactive materials or allow radiation streaming.
- Methods used to prevent neutron irradiation and activation of ground water or soils surrounding the reactor shield that could enter the unrestricted environment. The applicant should estimate the maximum activity should such activation occur and describe remedial actions.
- TS that control important design features, LCO's, and SR's as discussed in Chapter 14 of this standard format and content guide. The applicant should justify these TS in this section of the SAR.

Regulatory Guide 2.1, "Shield Test Program for Evaluation of Installed Biological Shielding in Research and Training Reactors," has been replaced by Regulatory Guide 1.69, "Concrete Radiation Shields and Generic Shield Testing for Nuclear Power Plants," issued May 2009.

4a2.5 Nuclear Design

In this section, the applicant should give information on the nuclear parameters and characteristics of the reactor core and should analyze the behavior of the reactor for steady-state and transient operation throughout its life cycle of allowed cores and burnup, as discussed in the safety analysis. The descriptions, analyses, and results should address all safety issues in the design and operation of the reactor and should support the conclusion that the reactor can be built and operated without unacceptable risk to the health and safety of the public. A detailed description of the analytical methods used in the nuclear design should be given. Computer codes that are used should be described in detail as to the name and type of code, the way it is used, and its validity on the basis of experiments or confirmed predictions of similar operating non-power reactors. Code descriptions should include methods of obtaining parameters such as cross sections. Estimates of the accuracy of the analytical methods should be included. Tables and figures should be used as necessary to present information clearly.

4a2.5.1 Normal Operating Conditions

In this section, the applicant should present information on the core geometry and configurations. The limiting core configurations for a reactor are the core conditions that would yield the highest power density, the highest excess reactivity, and other possible limiting parameters that are of safety interest using the fuel specified for the reactor. All other core configurations should be demonstrated to be encompassed by the safety analysis of the limiting core configuration. Sections 4a2.5.3 and 4a2.6 should give further information on power density limitations. The information in the SAR should include the following:

- Discussion and analyses to reflect the impact of the gas management system that is contained within the fission-product barrier on the core physics. The discussion should include holdup times and subsequent release of fission-product gases and NOx. Sweep gas operation and discharge limits, recombiner operations, and reactivity impacts associated with these operations will need to be included in this section and in Section 4a2.7.
- Discussions and analyses of the reactor operating characteristics. The applicant should describe in detail the effects of changes in configuration and fuel chemistry, including effects related to pH, pressure, temperature, radiolytic gas recombination capacity, reactivity and power oscillation, and the control philosophy and methodology for each parameter. If applicable, the applicant should analyze safety-related considerations for all requested operating modes.
- Changes in core reactivity with fuel burnup, plutonium buildup, and poisons, both fission products and those added by design. 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 also be discussed.
- Analyses of the reactor kinetic behavior and the design requirements and dynamic features of the control rods that allow controlled operation for all possible reactor conditions. This includes the expected effects of radiolysis on power oscillations resulting from formation and movement of voids, effects of malfunctions in the recombiner and the possible resulting pressure pulses causing fuel solution density changes, and the effects of temperature changes or gradients in the solution.
- Analyses of the basic reactor criticality physics, including the interacting effects of fuel, solid neutron moderators (if any) and neutron reflectors, control rods, and in-core or in-reflector components such as those used for radioisotope production. This also includes discussion of the subcritical storage and handling of the full core mass outside the reactor vessel and during transport from and to the core, the reactivity swing of the processed core material after selected fission-product removal, and any compensatory measures (such as fissile addition or dilution) to achieve or maintain criticality after reinsertion into the reactor vessel.
- Discussion of the safety considerations for different core configurations, including a limiting core configuration that would yield the highest power densities and fuel temperatures achievable with the planned fuel. This includes the power stability effects of uneven, stochastic surface frothing, and other phenomena such as hot transfer that may affect stability.

- The calculated core reactivities for all core configurations, including the limiting configuration that would yield the highest possible power density.

- Discussion of the administrative and physical constraints to prevent inadvertent addition of positive reactivity.

- TS that control important design features, LCO's, and SR's as discussed in Chapter 14 of this standard format and content guide. The applicant should justify these TS in this section of the SAR.

4a2.5.2 Reactor Core Physics Parameters

In this section, the applicant should discuss the core physics parameters and show the methods and analyses used to determine them. The information should include the following:

- Analysis methods and values for neutron lifetime and effective delayed neutron fraction. The applicant should describe the effects of reactor operating characteristics and fuel burnup, along with a method for calculating and verifying burnup.
- Analysis methods, values, and signs for coefficients of reactivity (e.g., fuel temperature, solid moderator temperature, void, and power). The applicant should describe the effects of reactor operating characteristics and fuel burnup. This analysis, along with the analysis in Chapter 13, should show that reactivity coefficients are sufficiently negative to prevent or mitigate damaging reactor transients.
- The axial and radial distributions of neutron flux densities, justifications for the methods used, and comparisons with applicable measurements. The applicant should describe changes in flux densities with power level, fuel burnup, core configurations, and control rod positions. The information on neutron flux density should include peak-to-average values for thermal-hydraulic analyses. Consideration should be given to hot spots as dictated by peak-to-average values for power density, tempature, distribution, and void profile. The applicant should validate these calculations by comparing them with experimental measurements and other validated calculations.
- The analysis methods used to address the dynamic behavior of changes in void fraction because of radiolytic gas formation and the agglomeration and transport of bubbles to the fuel solution surface. The neutronic impacts of these phenomena should be discussed to demonstrate that they have no adverse effect on safe reactor operations.
- TS that control important design features, LCO's, and SR's as discussed in Chapter 14 of this standard format and content guide. The applicant should justify these TS in this section of the SAR.

4a2.5.3 Operating Limits

The applicant should present the following information on reactor operating limits:

- Reactivity conditions, excess reactivity, and negative reactivity for combinations of control rods inserted that are analyzed for the limiting core and operating cores during the life of the reactor. The applicant should discuss operational and safety considerations for excess reactivity.
- The excess reactivity based on the worth of reactor temperature coefficients, poisons, applicable experiments, and the worth associated with the radiolytic gas formation and

changes in void fraction. The applicant should justify the upper limit on excess reactivity to ensure safe reactor operation and shutdown.

- The amount of negative reactivity that must be available by control rod action to ensure that the reactor can be shut down safely from any operating condition and maintained in a safe-shutdown state. The analyses should assume that the most reactive control rod is fully withdrawn (one stuck rod), nonscramable control rods are at their most reactive position, and normal electrical power is unavailable to the reactor. The applicant should discuss how the shutdown margin will be verified. The analyses should include all relevant uncertainties and error limits.
- The limiting core configuration that is possible with the planned fuel in this reactor. The limit should be imposed by the maximum neutron flux density and thermal power density compatible with coolant availability and maintaining operational stability (for the AHR, the limiting power density has been associated with the propensity for the core to become unstable with increasing power density). Consequently, the operating power density must be quantified and substantiated, including any margins specified. The safety limits and limiting safety system settings for the reactor should be derived from this core configuration. The detailed analyses should be included in Section 4a2.6. Normal operating conditions and credible events, such as a stuck control rod, should be considered.
- A transient analysis assuming 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 is not damaged and fuel integrity is not lost.
- The redundancy and diversity of control rods necessary to ensure reactor control for the considerations noted above.
- Stability should be defined with criteria for acceptable performance. The applicant should describe protection solutions to maintain power oscillations within operational or safety limits and may include operational limits on parameters such as power density.
- TS for safety limits (SL's), limited safety system settings (LSSS's), LCO's, and SR's as discussed in Chapter 14 of this standard format and content guide. The applicant should justify these TS in this section of the SAR.

4a2.6 Thermal-Hydraulic Design

In this section, the applicant should present the information and analyses necessary to show that sufficient cooling capacity exists to prevent fuel overheating and loss of fuel barrier for all anticipated reactor operating conditions, including pulsing, if applicable. The applicant should address the coolant flow conditions for which the reactor is designed and licensed, forced or natural convection flow, or both. A detailed description of the analytical methods used in the thermal-hydraulic design should be provided. Computer codes that are used should be described in detail as to the name and type of code, the way it is used, and its validity on the basis of experiments or confirmed predictions of similar operating non-power reactors. Estimates of the accuracy of the analytical methods should be included. The information should include the following:

- The various systems and approaches for removing heat from the core should be identified (e.g., cooling coils, pool heat removal, and gas management (heat removal) system including recombiner and reflux chiller condenser). The expected fraction of

heat removed by each approach should be discussed. The ability of the combined systems and approaches to accommodate the varying power, from gas formation, changes in void fraction, and transport, during normal and transient operation should also be discussed.

- The coolant hydraulic characteristics of the core, including cooling coil number and arrangement and coupling between coils; individual coil and total system flow rates; fuel solution and coolant pressures; pressure changes at channel exits and entrances; material compatibility and heat transfer between fuel solution and coolant coils, to include plating or precipitation of material on the surface of the coil; natural circulation within the fuel solution; temperature profile along a coil from entrance to exit; and frictional and buoyant forces. The applicant should address individual coils, as well as the core as a whole, for all flow conditions in the primary coolant system, including temperature variations and wave propagation caused by vibration and chemistry changes resulting from breached coils. The transition from forced to natural convection flow in the cooling coils should be calculated, and the applicant should prepare calculations for an event during which normal electrical power is lost and the core decay heat must be removed. The discussion should also describe the above-core gas removal and overall pool cooling systems and the effect of the loss of these systems on core coolability and decay heat removal.
- The thermal power density distribution in the fuel and heat fluxes into the coolant of each coil and along the coil, derived from the fuel loading and neutron flux characteristics discussed above.
- Calculations and the thermal-hydraulic methodology for the transfer of heat to the coolant. The applicant should consider uncertainties in thermal-hydraulic and nuclear parameters and such engineering factors as coil thickness and the buildup of any layers both in the coil and on the outside of the coil. The calculations should be based on fuel measurements and procurement specifications, as well as operating history and conditions. The calculational methodology should be applicable to the thermal-hydraulic operating conditions, and the applicant should justify its use.
- The calculations and experimental measurements to determine the coolant conditions ensuring that fuel solution tempature and pressure limits are not exceeded. The applicant should calculate at least the limiting core configuration. The discussion should also examine the positive reactivity feedback characteristics of overcooling. Operating conditions should include steady fission power, shutdown decay heat, planned pulses, and transients analyzed in Chapter 13. The applicant should consider operational and fuel characteristics from the beginning to the end of fuel life.
- For the core geometry and the coolant thermal-hydraulic characteristics, a discussion to establish the fuel conditions that ensure vessel integrity and prevent solution boiling, such as fuel pressure, temperature, pH, solubility of fuel and fission products, radiolytic gas recombiner capacity, and temperature distributions. The discussion should show correlations among these factors and justify their use in deriving SL's and LSSS's for the TS.
- The design bases for the primary coolant system, emergency core cooling system, gas treatment system cooling and pool cooling, and other systems designed to maintain vessel and primary fuel barrier integrity and prevent solution boiling, which should also be discussed in Chapter 5, "Reactor Coolant Systems." The analyses here and in Chapter 13 should describe reduction-in-cooling scenarios for forced-flow reactors.

Natural convection cooling that removes decay heat to ensure thermal stability should also be discussed. Flow blockages should be analyzed in Chapter 13.

- In the case of the AHR, the coolant flows through coils immersed in the fuel solution; thus, the breach of a coolant coil should be analyzed in Chapter 13, as should the effects of localized moderation in the vicinity of the coil.

- Boiling has been identified as a limiting phenomenon that could compromise primary barrier integrity. The applicant should identify operational limits and/or engineered safety features to preclude the onset of bulk boiling of the solution. One key concern is the influence of bulk boiling on the transport of radioactive material through the plant systems. In instances where the applicant does not preclude solution boiling during transient or accident conditions, the effect of bulk boiling should be analyzed.

4a2.7 Gas Management System

In this section, the applicant should describe the design of the system for removing radiolysis and fission-product gases from the core and cover gas of the AHR. The gas management system may also provide some reactor cooling; Section 4a2.6 and Chapter 5 of the SAR should describe this aspect of its function. The applicant should describe the major components of the gas management system, which may include the following:

- particulate trap
- radiolytic gas recombiner
- recombiner cooling system
- reflux condenser
- gas chiller/condenser
- condensate return
- chemical makeup
- compressor
- gas storage tanks
- pressure-relief valves

The essential functions of a gas management system are to remove the radiolytic hydrogen and oxygen, and subsequently recombine them, to prevent a hydrogen deflagration or detonation hazard, contain hazardous chemicals (e.g., radiolytic NOx gases) and volatile fission products (e.g., krypton, xenon, iodine) until ultimate discharge, and provide venting of any pressure transients that could result in damage to the reactor vessel or primary cooling system and result in loss of containment of the reactor fuel. The applicant should describe the gas management system features that perform these duties in sufficient detail to demonstrate that the reactor core can be operated safely and in accordance with applicable environmental release criteria. This information should include the geometric dimensions of the major components and piping (including whether it is favorable geometry), the materials of construction (including chemical compatibility with evolved gases), the composition of any trap media/filters, the pressure the equipment is designed to withstand, surge capacity for fission-product storage, and any additional passive or active devices, such as alarms and pressure-relief devices, needed to perform the system's intended function.

The recombiner may need its own cooling system because the catalyzed recombination of hydrogen and oxygen is an exothermic reaction. If this is not part of the primary cooling system of the reactor, but rather an auxiliary system, it should be discussed in Chapter 9.

The proper function of the gas management system, which is part of the primary fission-product barrier, is essential. Malfunction or failure of components in this system could cause excessive pressure that could have positive reactivity feedback to the fuel solution and operating instability. Excess hydrogen production, beyond the capacity of the recombiner, could lead to an explosive mixture in the system. Failure of any inert cover gas supply that may be part of the system could also result in an explosive hydrogen concentration. Instability or loss of cooling to the recombiner or condenser could cause containment failure due to overheating or thermal stress. All of the process variables controlling the gas management system must be analyzed and appropriate limits assigned in the TS to avoid such consequences.

The technical rationale for this section is that the specific components in the gas management system may vary from one applicant to another; this system is designed to be general in nature. A component for recombining hydrogen and oxygen will be essential. A system for condensing water and acid and allowing it (and hopefully entrained uranium) back into the reactor core is desirable and would probably be part of any gas management system. A system for trapping entrained uranium and holding fission products until they can be safely disposed of is essential. There would be essentially five classes of hazards to be considered: 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. The means of preventing these events must be described. Two of these hazards, deflagration/detonation and pressure increase, could potentially increase the density of the core and affect the power density. These potential events should be discussed in terms of reactor control.

4a2.8 References

1. International Atomic Energy Agency, “Homogeneous Aqueous Solution Reactors for the Production of Mo-99 and Other Short Lived Radioisotopes,” IAEA–TECDOC-1601, September 2008.

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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.

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4b Radioisotope Production Facility Description

The following guidance should be used for the standard format and content of applications for radioisotope production facility licenses.

4b.1 Facility and Process Description

In this section, the applicant should provide a summary description of the process and processing facilities. The description should include the principal safety considerations factored into the design. The design bases and functions of the structures, systems, and components should be presented in sufficient detail to allow a clear understanding and assurance 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 understanding of physical facility features and of the processes involved.

The summary description should include an analysis of the anticipated maximum radioactive inventory that will be in process at any particular time. The analysis should include a breakdown by radionuclide of the material in process. It should include the physical and chemical forms, volumes of solutions, and any anticipated airborne contaminants that will be present during routine operations.

4b.2 Processing Facility Biological Shield

The application should include a detailed description of the design and construction of the biological shield in which radiochemical processes will be conducted. The general layout of the processing facility relative to the reactor and other parts of the facility should be presented. The applicant should provide the shielding design basis, including any calculations that were used to prescribe the required form and substance of the shield.

The application should describe the functional design of the biological shield showing entry and exit facilities for product, process equipment and operating staff; number and location of windows, manipulators, optics, and any other accessory operating equipment. It should also describe any other penetrations into the shield that facilitate passing processing material or utilities into, out of, or among segments of the shield.

The application should also include a detailed description of the ventilation system for the biological shield structure, including the design basis and function. The description should include the design and location of vent ducting, filters, and fans. The description should include details on vent system operating limits under both normal and emergency operating conditions. The description should include 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, “Standards for Protection against Radiation,” for the protection of the staff and the public, should be evaluated and included in the proposed engineered safety feature (ESF) in Chapter 6 and TS in Chapter 14 as applicable.

4b.3 Radioisotope Extraction System

The initial step in the fission-product radioisotope production process is the extraction of specific radioactive elements from the fission-product mixture contained in the irradiated SNM. This section of the application should describe this part of the production process in enough detail to provide assurance that the process can be performed within the regulatory limits of 10 CFR 20.1201, “Occupational Dose Limits for Adults,” and 10 CFR 20.1301, “Dose Limits for Individual Members of the Public.”

The application should explain the theory underlying the process design. In the case of an AHR facility, the radioisotope(s) will most likely be extracted from the reactor fuel. In the case where targets containing SNM in solid form are used in the production process, the initial step will be to prepare the target material so that specific fission-product radioisotopes may be separated from the SNM. To the extent necessary to understand the safety of the process, the application should provide processing details such as the following:

- The general method to be used for separating specific fission products from the fuel (e.g., ion-exchange, precipitation or liquid/liquid extraction from SNM in solution, or sublimation from SNM in solid form).

- The SNM in terms of physical and chemical form, volume or amount in process, and radioactive inventory in process.

- The sequence of radioisotope(s) extraction and the time increments involved.

- The processing apparatus including any piping, separation columns, reagent or reaction vessels, heating or cooling apparatus, local shielding of storage or transfer vessels, and any other apparatus involved in the process. These descriptions should include information such as materials of construction, physical size and arrangement, equipment operating characteristics, process monitoring or control equipment, and associated instrumentation (if extensive remote control instrumentation is involved details should be provided in Chapter 7).

- Auxiliary equipment that will be used, such as pumps, siphons, vents, filters, spill pans, heat exchangers, or ventilation or gas management apparatus.

- Criticality control features that may be provided by the physical design parameters of components, materials of construction, and any other measures derived according to the guidance in Chapter 6, "Engineered Safety Features," Section 6b.3, "Nuclear Criticality Safety in the Radioisotope Production Facility."

Drawings and diagrams should provide the necessary details of the radioisotope production facility.

The license TS in Chapter 14 of the SAR should include those engineered features or administrative measures in the radioisotope extraction process that are safety related and that are required to prevent the uncontrolled release of SNM or fission products that would result in exceeding the exposure limits to individuals or exceeding the limits on effluents as prescribed by 10 CFR Part 20 , Subparts C and D, and Appendix B, respectively.

4b.4 Special Nuclear Material Processing and Storage

Possession and use of SNM are generally licensed under the regulations of 10 CFR Part 70. It is anticipated that most radioisotope production facilities will be licensed under 10 CFR Part 50. The basic licensing safety premise of 10 CFR Part 50 and 10 CFR Part 70, relating to utilization and SNM facilities, respectively, differs in that the utilization facility allows the SNM to be safely made supercritical and maintained critical, while in the SNM facility criticality is not allowed. The guidance for license applications under 10 CFR Part 50 (found in NUREG-1537) covers safety issues with SNM in the form of fuel as it is used in a reactor, but it does not specifically address processes using SNM (except when it is in small, laboratory-scale batches) that are carried on outside of the reactor context. Such operations are usually proposed and reviewed under the guidance of NUREG-1520, which pertains to all of the regulatory requirements of 10 CFR Part 70. To provide thorough guidance for composing and reviewing applications for the unique features of a radioisotope production facility, the staff has combined NUREG-1537 and NUREG-1520 in such a way that the standard format and content of NUREG-1537 have been maintained and those unique, nonduplicative parts of NUREG-1520 that are not

addressed in NUREG-1537 are included in this ISG. This section dealing with SNM operations outside of the reactor containment primarily uses NUREG-1520 guidance with regard to criticality and chemical safety. The contents of this chapter deal with processing components and procedures. Other chapters (e.g., 6, 11, 12, 13, and 14) address accident analyses and the consequent requirements for accident prevention and mitigation.

4b.4.1 Processing of Irradiated Special Nuclear Material

The postextraction part of the radioisotope separation process involves either returning the fuel solution to the reactor core vessel or performing subsequent procedures to prepare it for further use as fuel or for disposal as waste. This section of the application should describe this part of the production process in enough detail to provide assurance that the process can be performed within regulatory limits.

The application should explain the technical basis underlying the process design. To the extent necessary for understanding the safety of the process, the application should provide processing details such as the following:

- Description of the SNM in terms of physical and chemical form, SNM concentration, volume or amount in process, and radioactive inventory in process.

- Description of the sequence of sampling, analyzing, and conditioning or reconditioning (including the form and amount of chemical reagents used) the fuel solution as is necessary or appropriate for its intended further use, as well as the time increments involved.

- Description of the processing apparatus including any piping, separation columns, reagent or reaction vessels, and transfer or storage vessels. The information should include dimensions, materials of construction, equipment arrangement, equipment operating characteristics, and process monitoring or control equipment (if extensive remote control instrumentation is involved details should be provided in Chapter 7).

- Description of auxiliary equipment that will be used, such as pumps, siphons, vents, filters, spill pans, heating and cooling apparatus, and ventilation and gas management systems including filters or other gas (radiolytic or fission-product) isolation features.

- Description of criticality control features that may be provided by the physical design parameters of components, materials of construction, and any other measures derived per the guidance in Section 6b.3.

Drawings and diagrams should provide the necessary details of the SNM processing facilities and procedures.

The proposed license TS in Chapter 14 of the SAR should include those engineered features or administrative measures involved in irradiated SNM processing that are safety related and that are required to prevent the uncontrolled release of SNM or fission products that would result in exceeding the exposure limits to individuals or exceeding the limits on effluents as prescribed by 10 CFR Part 20.

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. To the extent necessary for understanding the safety of the process, the application should provide details such as the following:

- Criticality accident prevention measures that are derived according to the guidance in Section 6b.3.
- The chemical and physical form of the fuel in each phase of the operations before it is used in the reactor core.
- Areas in the facility where this material will be processed and stored.
- Any processing equipment and procedures used while storing or preparing the fuel for use in the core.
- Chemical accident prevention measures as appropriate.

The license TS in Chapter 14 of the SAR should include those engineered features or administrative measures involved in unirradiated SNM processing that are safety related and that are required to prevent criticality or the uncontrolled release of SNM or fission products that would result in exceeding the exposure limits to individuals or exceeding the limits on effluents as prescribed by 10 CFR Part 20.

Appendix 4.1

Regulatory Guide 2.1, "Shield Test Program for Evaluation of Installed Biological Shielding in Research and Training Reactors," has been replaced by Regulatory Guide 1.69, "Concrete Radiation Shields and Generic Shield Testing for Nuclear Power Plants," issued May 2009.

5 COOLANT SYSTEMS

NUREG-1537, Part 1, Chapter 5 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the coolant 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. The coolant system for an AHR is significantly different than a traditional reactor coolant system. The reactor may or may not function as a radioisotope production facility. This chapter may consist of multiple parts depending on the function of the facility. If the application is for a combined reactor and radioisotope production facility, it should contain two parts, each for the appropriate type of facility involved. Additional sections have been added to this chapter as follows:

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

Guidance for each of the reactor options follows.

5a1 Heterogeneous Reactor Coolant Systems

NUREG-1537, Chapter 5, Part 1, provides guidance for preparing this chapter.

5a2 Aqueous Homogeneous Reactor Cooling System

Replace NUREG-1537, Chapter 5, Part 1, in its entirety with the following guidance.

In this chapter of the SAR, the applicant should give the design bases, descriptions, and functional analyses of the AHR cooling systems. The principal purpose of the cooling systems is to safely remove the fission and decay heat from the reactor and dissipate it to the environment. The discussions should include all significant heat sources in the reactor and should show how the heat is safely removed and transferred to the environment.

The 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 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 gas. It is expected that during normal operation most, if not all, of the heat generation will occur in the core. Decay heat, however, can be produced by two separate sources within the reactor vessel: by soluble and insoluble decay products that remain in the core, and by gaseous decay products and any other decay products entrained by those gases into the gas space above the core. It may be necessary to provide separate systems to remove the decay heat from each of these regions.

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. Heat from an AHR core is expected to be removed through one or more cooling coils immersed in the core, and this system is expected to remove most of the heat produced in the core. This guidance does not pertain to cooling systems in which the fuel solution is transported outside the vessel in an external loop. Supplemental cooling systems may be necessary to remove heat from the fission gases above the core and heat produced in the recombiners. If the AHR is designed to operate at such low power levels that no significant temperature

increases will occur during normal operation, an engineered primary cooling system is not required. For such a design, the applicant should, in Chapter 4, "Reactor Description," of the SAR, discuss the disposition of the heat produced, estimate potential temperature increases during operation, and justify why an engineered primary cooling system for heat removal is not required. In this chapter, the applicant should summarize those considerations and conclusions.

The applicant should also describe and discuss systems to remove and dispose of the waste heat in this chapter. The design bases of the reactor cooling systems for the full range of normal operation should be based on ensuring acceptable reactor conditions established in Chapter 4 of the SAR. 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." In this chapter, the applicant should discuss and reference the TS where analyses are used as the basis for a requirement.

The "secondary cooling systems" for an AHR are those systems and components that transfer heat from the primary cooling systems to the environment or heat sink(s). These secondary cooling systems may involve additional heat exchangers and pumps to circulate the coolant. In this chapter, the applicant should identify and discuss reactor cooling systems, including auxiliary and reactor core subsystems that remove heat from the reactor. The description should include, for example, information on core cooling coils (which are the primary cooling system) and the partition of heat removal by additional reactor cooling systems that remove heat directly, such as the gas management system, or passively through the reactor vessel walls. These additional reactor cooling systems should be summarized in Section 5a2.1 and discussed in detail in Chapter 4, if reactor core systems, such as a gas management system, are involved. Details of auxiliary systems using coolant other than the primary cooling system, such as passive core cooling by the pool surrounding the vessel, should be discussed in Chapter 9, "Auxiliary Systems."

In this chapter, the applicant should describe all auxiliary and subsystems that use and contribute to the heat load of either the primary or secondary cooling systems. Any auxiliary systems using coolant from other sources should be discussed in Chapter 9.

5a2.1 Summary Description

In this section the applicant should briefly describe the primary cooling systems and supplementary core heat removal pathways and summarizing the principal features. Information should include the following:

- type of coolant: liquid, gas, or solid (e.g., conduction to surrounding structures).
- type of cooling system.
- type of coolant flow in the primary cooling system: forced convection, natural convection, or both.
- type(s) of secondary cooling system(s), if present, and the method of heat disposal to the environment.

- description of capability to provide sufficient heat removal to support continuous operation at full licensed power.

- special or facility-unique features.

For an AHR, the applicant should provide additional information in this section on the reactor cooling systems unique to the principal features of AHRs, including supplementary core heat removal pathways. If the primary cooling system is not the sole means of heat removal and the core heat removal is partitioned between supplementing pathways, these additional pathways should be mentioned. The energy partitioning should be given. These other means of heat transport from the core should be summarized, including the corresponding amount of heat transported from the core and fraction of total core heat removed.

5a2.2 Primary Cooling System

The basic requirements and design bases of the primary cooling system are to maintain reactor facility conditions within the range of design conditions and accident analyses assumptions derived from other chapters of the SAR, especially Chapters 4 and 13. The applicant should show the interrelationships among all SAR chapters and the way the designed primary cooling system provides all necessary functions. The following information should be included:

- Design bases and functional requirements of the primary cooling system.

- Schematic and flow diagrams of the system, showing such essential components as the heat source (i.e., reactor core), heat sink (i.e., heat exchanger), pumps, piping, valves, control and safety instrumentation, interlocks, and other related subsystems.

- Tables of allowable ranges of important design and operating parameters and specifications for the primary cooling system and its components, including the following:

  – coolant material

  – coolant flow rates

  – inlet and outlet temperatures and pressure throughout the system

  – elevation of components and water levels relative to the reactor core

  – construction materials of components

  – fabrication specifications of safety-related components

  – coolant quality requirements for operation and shutdown conditions, including pH and conductivity at a minimum

- Discussions and analyses keyed to drawings showing how the system provides the necessary cooling for all heat loads and all potential reactor conditions analyzed in the thermal-hydraulics section of SAR Chapters 4 and 13, including the following:

  - Removal of heat from the fuel and waste gases by all modes of heat transfer that apply. Discussion and analyses of the effect of the size, shape, and structural features of the primary vessel or surrounding pool on cooling characteristics; the function of the pool as a heat reservoir; and the effect of water depth on natural thermal convection cooling.

  - Transfer of heat from the primary coolant to a secondary coolant system for all reactor conditions. This discussion should include any heat exchanger design and operating conditions. Some AHRs may have only a primary cooling system that functions as a heat reservoir. For such systems, the analyses should include any factors that limit continuous operation, such as pool water temperature, and the proposed TS that ensure operation within the analyzed limits.

  - Safe reactor shutdown, including passive removal of decay heat from the fuel. This discussion should include the methods of removal of decay heat in the event of loss of offsite electrical power.

  - Locations, designs, and functions of essential components such as primary cooling coils. 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. In addition, locations, designs, and functions of such essential components as drains, siphon-breaks, pumps, isolation valves, and check valves should be identified. Radiological effects of potential coolant releases should primarily be analyzed in Chapter 11, "Radiological Protection Program and Waste Management."

- Discussion of the control and safety instrumentation, including location and functions of sensors and readout devices. The scram or interlock functions that prevent safety limits from being exceeded should be shown and discussed, including those related TS.

- Description and function of any special features of the primary cooling system.

- Brief description and functions of special features or components of the primary coolant system that affect or limit personnel radiation exposures from such radionuclides as nitrogen-16 and argon-41 and from radioactive contaminants.

- Description of radiation monitors or detectors incorporated into the primary cooling system and discussion of their functions.

- Brief discussion and references to detailed discussions in later sections of auxiliary systems using primary cooling, such as coolant cleanup, makeup water, emergency core cooling, cooling of experiments or targets, and biological shield cooling. The direct effect of these auxiliary systems on the design and functioning of the primary cooling system should be discussed.

- Discussion of leak detection and allowable leakage limits, if any.

- Discussion of normal primary coolant radiation concentration limits, including sampling frequency, isotopes of interest, and actions to be taken if limits are exceeded.

- For reactors that have closed systems, a discussion of allowable hydrogen limits in air spaces that are in contact with the primary coolant.

- Discussion of TS requirements for parameters of the primary cooling system, including the bases and surveillance requirements.

5a2.3 Secondary Cooling System

In this section, the applicant should give information about those AHRs that include a secondary cooling system. For other AHRs, the applicant should state that a secondary cooling system is not needed and should justify that conclusion. The applicant should provide the following information:

- The design bases and functional requirements of the secondary cooling system, including whether the system is designed for continuous full-power reactor operation and whether it is shared with other reactors within the facility.

- Schematic and flow diagrams of the secondary cooling system, showing such essentials as how the heat exchanger connects the primary cooling system (i.e., the heat source) to the secondary cooling system, pumps, piping, valves, control and safety instrumentation, interlocks, and interface with the environment for ultimate release of the heat.

- Tables of the range of important design and operating parameters and specifications of the secondary cooling system, including the following:

  - coolant material and its source

  - coolant flow rates

  - type of heat dissipation system, such as cooling tower, refrigerator, radiator, or body of water

  - location of heat dissipation system in relation to the reactor and the heat exchanger

  - construction materials and fabrication specifications of components

  - heat dissipation specifications related to environmental factors (e.g., temperature and humidity)

  - specifications and limitations on coolant quality and corrosion of the secondary cooling system components, including the environmental effects of the use of secondary cooling chemicals

- Discussion and functional analyses keyed to the drawings showing how the system provides the necessary cooling for all potential reactor conditions. These discussions should address the following:

  - Inlet and outlet temperatures and pressures throughout the system, including the pressure differential between the primary and secondary cooling systems in the heat exchanger. The applicant should discuss how the pressure in the secondary cooling system is maintained above that in the primary cooling system for all operating conditions, or analyze the radiological effect of leakage of contaminated primary coolant into the secondary cooling system. Isolation of the heat exchanger during shutdown periods is an acceptable method to control potential primary-to-secondary system leakage if secondary cooling system pressure is lower than primary cooling system pressure only during periods of system shutdown. The applicant does not need to analyze primary-to-secondary-system leakage if secondary cooling system pressure is lower than primary cooling system pressure for only short periods for system testing or repair. If the transfer of primary coolant into the secondary cooling system is caused by an abrupt event, such as a tube rupture in the heat exchanger, the analysis should be given in Chapter 13 of the SAR and summarized here.

  - Control of heat removal from the secondary cooling system necessary to maintain temperatures in the core and primary cooling system within the limits derived in the thermal-hydraulics analyses in Chapters 4 and 13 of the SAR.

  - Removal of heat from the heat exchanger and release to the environment when the primary cooling system operates in all anticipated and licensed modes, as applicable.

  - Safe reactor shutdown and removal and dissipation of decay heat.

  - Secondary cooling system response to the loss of primary coolant.

  - Locations, designs, and functions of such essential components as drains, sumps, pumps, makeup water, and check valves that ensure contaminated primary coolant is not inadvertently transferred to the secondary coolant system and released to the environment.

- Discussion of control and safety instrumentation, including locations and functions of sensors and readout devices and interlocks or safety capabilities.

- Descriptions of functions of any radiation monitors or detectors incorporated into the secondary cooling system. Discussion of surveillance methods to measure secondary coolant radioactivity including frequency, action levels, and action to be taken.

- Brief comments and reference to detailed discussion in other sections of auxiliary cooling systems that transfer heat to the secondary coolant system.

- Discussion of TS requirements, as appropriate, for the secondary cooling system, including the bases and SRs.

5a2.4 Primary Coolant Cleanup System

In the AHR, the primary coolant is separated from the fuel solution by a material barrier, such as a cooling tube wall, which isolates the mobile fission products from the coolant system components. For an AHR, the inner wall surface of an immersed cooling coil (e.g., a tube) is the primary coolant boundary, analogous to defining the outer surface of fuel cladding surrounding solid fuel as a primary coolant boundary. Experience has shown that integrity of cladding and presumably of other metal boundaries is improved if corrosion is reduced by maintaining high chemical purity of the coolant. Thus, purity of the primary coolant should be maintained as high as reasonably possible for the following reasons:

- to limit the chemical corrosion of primary coolant barrier, 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 could be made radioactive by neutron irradiation.

The applicant should include the following information:

- The design bases and functional requirements of the primary coolant cleanup system. Experience at non-power reactors has shown that with a well-planned water cleanup system and good housekeeping practices, primary coolant quality can be maintained within the following ranges:

  - electrical conductivity <5 μmho/cm
  - pH between 5.5 and 7.5

  The design bases should be consistent with the discussions in Chapter 4 of the SAR.

- Schematic drawings and flow diagrams of the primary coolant cleanup loop.

- Table of specifications for the cleanup system demonstrating that it is designed for the volume and throughput of the primary cooling system.

- Locations and functions of control and monitoring instrumentation, including sensors, recorders, and meters. The discussion of monitors should include methods for continuously assessing coolant quality and effectiveness of the cleanup system.

- Locations and functional designs of cleanup system components such as branch points, pumps, valves, filters, and demineralizers.

- Discussion of schedules and methods for replacing or regenerating resins and filters and disposing of resultant radioactivity to ensure that radiation exposures do not exceed the limits discussed in Chapter 11 of the SAR.

- Summary of methods for predicting, monitoring, and shielding radioactivity deposited in filters and demineralizers from routine operations. The detailed discussion should be in Chapter 11 of the SAR.

- Summary of methods for predicting and limiting exposures of personnel in the event of inadvertent release of excess radioactivity in the primary cooling system and deposition in filters and demineralizers. The detailed discussion should be in Chapter 13 of the SAR.

- Provisions in the design and operation of the cleanup system to avoid malfunctions that could lead to significant loss of primary coolant or release of contaminated coolant, which could cause radiological exposure of personnel or release to the unrestricted environment to exceed the requirements in 10 CFR Part 20 and the guidelines of the facility's ALARA program.

- Discussion of TS requirements for the primary coolant cleanup system, including the bases and SRs.

5a2.5 Primary Coolant Makeup Water System

During operations at non-power reactors with a water-based primary cooling system, primary coolant must be replaced or replenished. Coolant may be lost as a result of radiolysis, designed leakage as from pump seals, or other operational activities. The AHR should include a system or a procedure that meets the projected needs for coolant. The makeup water system need not be designed to provide a rapid, total replacement of the primary coolant inventory, but should be able to maintain the minimum acceptable water quantity and quality for reactor operation.

The applicant should provide the following information:

- The design bases for the primary coolant makeup water system that account for all activities that could cause a decrease in the primary coolant. A large loss-of-coolant event should be analyzed in Chapter 13 of the SAR. Although a required emergency core cooling system need not be a part of the makeup water system, if it exists, it should be discussed in Chapter 6 of the SAR.

- Schematic diagrams and functional discussions that show the source of water, the methods of addition to the primary cooling system, and the requirements for pretreatment before addition.

- Locations and functions of control instrumentation, including sensors, readout displays, and interlocks. Methods should be discussed for tracking additions of makeup water to detect significant changes that might indicate leaks or other malfunctions of the primary cooling system.

- Discussion of safety systems and administrative controls to ensure that the system or procedures for adding makeup water will not lead to significant loss of primary coolant and will prevent leakage of contaminated coolant into the potable water supply.

- Discussion of TS requirements for the primary coolant makeup water system, including the bases and SRs.

5a2.6 Nitrogen-16 Control System

When ordinary oxygen is irradiated with neutrons of sufficient energy, nitrogen-16, a high-energy beta and gamma emitter with a 7-second half-life, is formed. In water-cooled reactors operated above a few hundred kilowatts, the radioactivity of this nuclide may require specific systems or procedures for limiting personnel exposure.

In reactors with forced convection cooling, the coolant carrying the nitrogen-16 out of the core may be passed through a system such as a large shielded and baffled tank. This delay allows the radioactivity to decay significantly before the coolant emerges from the shielding. Another method of radiation control is to shield the entire primary cooling system.

The applicant should analyze the potential for personnel exposure to nitrogen-16 and propose control systems or procedures that include the following:

- Design bases and functional design of the nitrogen-16 control system or procedures. The design bases should be derived from analyses in Chapter 11 of the SAR.

- Schematic drawings and system and component specifications for the nitrogen-16 control system.

- The method used by the nitrogen-16 control system to reduce exposure rates and potential doses in occupied areas. Potential doses with and without the nitrogen-16 controls should be analyzed in Chapter 11 and summarized in this section of the SAR.

- The effect of the nitrogen-16 control system on overall reactor safety and operation.

- Other reactor design features affected by the nitrogen-16 control system. For example, a large shielded decay tank may affect coolant flow parameters, pump sizes, access for surveillance or inservice testing, or other factors for the primary cooling system.

- An assessment that the nitrogen-16 control system would not lead to an uncontrolled loss of primary coolant or the release of contaminated primary coolant that exceeds the requirements in 10 CFR Part 20 and the facility's ALARA program guidelines. Methods for analyzing radiation exposures as a result of coolant release should be consistent with the analyses in Chapter 11.

- Discussion of any TS requirements for the nitrogen-16 control system, including the bases and SRs.

5a2.7 Auxiliary Systems Using Primary Coolant

In addition to the systems discussed above that are associated with the primary cooling system, other auxiliary cooling systems may require the use of primary coolant and may affect the operation or safety of the reactor. If the reactor design includes an emergency core cooling system, it should be described and discussed in Chapter 6.

The applicant should provide the following information about these systems in this section:

- Design bases and functional requirements of the auxiliary systems based on discussions elsewhere in the SAR.

- Schematic drawings and flow diagrams that show the source of water, locations of sensors and instruments, and locations of the components cooled.

- Tables of the range of important parameters of the systems and specifications of materials and components.

- Discussion of components to be cooled, the source of heat, the source of the coolant water, heat transfer to the coolant, and coolant heat dissipation.

- Discussion of the provisions in the auxiliary system designs to prevent interference with safe reactor shutdown.

- Discussion of the provisions in the auxiliary system design to prevent the uncontrolled release of primary coolant or radiation exposures that would exceed the requirements in 10 CFR Part 20 and the facility's ALARA program guidelines.

- Requirements for minimum water quality.

- Discussion of any TS requirements for the auxiliary cooling systems, including the bases and SRs.

5b Radioisotope Production Facility Cooling Systems

A radioisotope production facility that separates fission products from irradiated SNM may involve process inventories or batches containing high concentrations of fission products that require engineered safety features (ESF's) or auxiliary systems to prevent the release of radioactive material from the process apparatus or the confinement systems. One concern about the safe handling of production process batches that should be addressed is the potential heat load contained as a result of the radioactive decay of the fission-product inventory.

License applications for radioisotope production facilities should present an analysis of the thermal characteristics of the anticipated process that considers the following:

- The operating power of the SNM during irradiation in the reactor.

- The decay time allowed after the end of irradiation in the reactor before the separation process progresses.

- The volumetric heat load and the resultant thermal flux at heat transfer surfaces of the process containment apparatus throughout the process.

- Calculations of the resultant maximum temperature of material in process with the objective of determining the need for auxiliary cooling to maintain the temperature and

pressure within the processing components at safe levels to prevent the failure of the process apparatus or the containment system.

In the event auxiliary cooling is required to maintain the process temperature within acceptable limits, the applicant should provide a complete description of the cooling system. The description should include the design basis, the physical characteristics, and the operation of the system. Discussion topics should be similar to those identified in Section 5a2.7. Any safety-related operating limits should be determined and included in the appropriate TS in Chapter 14 of the SAR.

6 ENGINEERED SAFETY FEATURES

NUREG-1537, Part 1, Chapter 6 of the format and content guide, as augmented by this ISG, is applicable to providing 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 1, Chapter 6, should be used as guidance in preparing this chapter.

6a2 Aqueous Homogeneous Reactor Engineered Safety Features

Since NUREG-1537 is basically written for a heterogeneous reactor with fuel in solid form that has cladding to serve as the primary fission-product barrier, it may be used as the basic guidance for preparing this part of an AHR SAR, provided that the basic differences between these two types of reactors are addressed. For example, any reference to fuel cladding as the primary barrier for fission products should, in the case of an AHR, be taken to mean the reactor vessel and the gas management system. Otherwise, the guidance in this section is general enough to apply to any type of reactor facility, as long as the unique features of each are addressed and appropriate ESF's are provided to ensure that operations are conducted within safe limits.

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, the NRC has determined that the Integrated Safety Analysis (ISA) methodology and designation of IROFS described in 10 CFR 70 Subpart H would be found acceptable by NRC staff for certain operations with SNM. Under 10 CFR Part 70 Subpart H, 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.

Because certain processes and hazards in an isotope production facility are similar to those at fuel cycle facilities, certain Part 70 Subpart H acceptance criteria and methodologies, including the use of ISA, would be appropriate for a medical isotopes production facility licensing review. An ISA, performed adequately, would systematically identify potential accident sequences, designate IROFS to prevent or mitigate them, and describe management measures to be applied to assure IROFS' reliability and availability.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR Part 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 medical isotopes production facility. Applicants are free to 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.

The SNM in an AHR serves a dual purpose as the fuel as well as the isotope production target and, as such, will be routinely cycled through reactor operation, isotope extraction, and fuel reconditioning operations. Other types of production facilities will be processing irradiated SNM outside of the reactor as well. Certain operations with the fuel or irradiated SNM will be subject to the requirements of 10 CFR Part 70. License conditions under 10 CFR Part 70 that are derived from accident analyses are defined as items relied on for safety (IROFS). Some of these IROFS may be comparable or equivalent to ESF's that are required under 10 CFR Part 50. Section 6.0 of NUREG-1537 may be applied to guidance for a production facility SAR with the following three provisions:

(1) Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

(2) Change the third paragraph list of bullets 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

(3) Add the following paragraph:

With respect to chemical consequences of accidents, 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.

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 would be found acceptable by staff. Chemical exposure criteria different from those described in this ISG will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

6b.1 Summary Description

Section 6.1 of NUREG-1537 is applicable to a radioisotope production facility, provided that whenever the term “reactor” appears, it is understood to mean a “non-power reactor facility,” a “radioisotope production facility,” or both, as applicable.

6b.2 Detailed Descriptions

Section 6.2 of NUREG-1537 is applicable to radioisotope production facilities, provided that wherever the term “reactor” or “non-power reactor” appears, it is understood to mean “radioisotope production facility,” as appropriate.

6b.2.1 Confinement

Section 6.2.1 of NUREG-1537 is applicable to a radioisotope production facility if wherever the term “reactor” or “non-power reactor” appears, it is understood to mean “radioisotope production facility,” as appropriate.

6b.2.2 Containment

Section 6.2.2 of NUREG-1537 is applicable to a radioisotope production facility with the following changes:

- First paragraph: The term “reactor facility” in this sub-section means “radioisotope production facility.”

- Second paragraph: The second sentence should read “A possible scenario for such a release could be a significant loss of integrity of the radioisotope extraction system or the irradiated fuel processing system.”

- Second paragraph: The third sentence should read “The containment is designed to control the release to the environment of airborne radioactive material that is released in the facility even if the accident is accompanied by a pressure surge or steam release.”

6b.2.3 Emergency Cooling System

Section 6.2.3 of NUREG-1537 is applicable to a radioisotope production facility with the following change:

- First paragraph: The first sentence should read “In the event of the loss of any required primary or normal cooling system, an emergency cooling system may be required to remove decay heat from the fuel to prevent the failure or degradation of the gas management system, the isotope extraction system or the irradiated fuel processing system.”

The remaining parts of this section of NUREG-1537 are applicable as written, provided that any reference to a “reactor” or “reactor facility” is understood to mean “radioisotope production facility,” as appropriate.

6b.3 Nuclear Criticality Safety in the Radioisotope Production Facility

This section establishes the recommended contents of the nuclear criticality safety (NCS) section of the application. In general terms, the applicant should design a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of SNM outside of the reactor.

The application should meet the 10 CFR Part 50 requirements for the NCS-related areas. The regulatory requirements for the license application review should comply with the general requirements of an application. The license application must propose equipment, facilities, and procedures to protect health and minimize danger to life or property, and to ensure that the design provides for criticality control, including adherence to the double-contingency principle, which basically requires that more than one safety-related engineered feature or management measure must fail or be compromised before a criticality accident can occur. Requirements for criticality monitoring and alarms also apply.

Although 10 CFR Part 50 does not directly require a nuclear safety program, an applicant should provide commitments pertaining to NCS in the following areas:

- Establishing and maintaining NCS safety practices and procedures.
- Establishing and maintaining NCS safety limits and procedures for determining LSSS's and LCO's.
- Conducting NCS evaluations to ensure that, under normal and credible abnormal conditions, all nuclear processes remain subcritical, with an approved margin of subcriticality for safety.
- Providing training in procedures for criticality-related possession and use of nuclear material and for response to an inadvertent nuclear criticality event.
- Protecting against the occurrence of any identified accident sequence that could lead to an inadvertent nuclear criticality event.
- Meeting 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 following additional guidance may be used to supplement the contents of the NCS program:

- NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001.
- NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998.

The applicant should describe a program that ensures compliance with the double-contingency principle, where practicable. Processes in which there are no credible accident scenarios that lead to criticality meet the double-contingency principle by definition. This principle, as given in American National Standards Institute/American Nuclear Society (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.

The applicant may use the guidance in ANSI/ANS-8.10-1983, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement," as modified by Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," in determining the consequences of criticality accident sequences. In general, such events should be considered high-consequence events (applicants may refer to 10 CFR 70.61, "Performance Requirements") unless controls are in place to provide shielding or other isolation between the source of radiation and facility personnel. Provide justification for considering events resulting in other than high-consequence.

The application should describe the NCS program in sufficient detail to enable an understanding of its objectives, structure and organization, and administration. The NCS program described in the application should have SR's pertinent to the following topics:

- Training (refer to Chapter 12, Section 12.10, of this ISG concerning licensing of production facility operators).

- Procedures.

- Audits and assessments.

The NCS technical practices should include evaluations performed using accepted methods to ensure that all processes remain subcritical. The margin of subcriticality for safety is an allowance for any unknown uncertainties that have not been accounted for in validation and a measure of the degree of confidence that systems calculated to be subcritical are actually subcritical. The margin is used to define an upper subcritical limit, as follows:

$$k\text{-subcritical} = 1.0 - \text{bias} - \text{bias uncertainty} - \text{margin of subcriticality for safety}$$

In general, a margin of subcriticality for safety of 0.05 has been found acceptable for typical nuclear processes involving LEU, without a detailed justification. The use of increasingly smaller margins should require increasingly more rigorous justification, and the SAR should include evaluations of other physical systems on a case-by-case basis.

For each methodology used to perform an NCS analysis, a validation report should be generated. The methodology must be sufficiently rigorous and be applied in a manner consistent with its assumptions.

Additional commitments to the NCS should include a description of measures to implement the facility change process requirements in 10 CFR 50.59. The applicant should describe a change control process that is sufficient to ensure that the safety basis of the facility will be maintained during the lifetime of the facility. The change control process should be connected to the facility's configuration management system to ensure that changes to the NCS basis are incorporated into procedures, evaluations, postings, drawings, and other safety-basis documentation.

The applicant may use standards as a means to meet regulatory requirements. Regulatory Guide 3.71 endorses the national standards in the ANSI/ANS-8 series, with some exceptions.

The NRC endorsement of these standards means that they provide procedures and methodology generally acceptable to the NRC staff for the prevention and mitigation of nuclear criticality accidents. However, application of a standard is not a substitute for detailed NCS analyses for specific operations.

6b.3.1 Criticality Safety Controls

The applicant should provide a list briefly describing all criticality safety controls in sufficient detail to permit an understanding of their safety functions. The applicant could demonstrate that the likelihood of each credible criticality event will result in low overall risk. To reduce common-mode failures, the applicant should favor design features that use independent sources of motive force.

6b.3.2 Surveillance Requirements

The applicant should review Sureveillance Requirements (SR's) to ensure the availability and reliability of safety controls when they are required to perform their safety functions. SR's of controls may be graded commensurate with risk.

The applicant should state clearly how the design of the new facility or process provides for criticality control. The discussion should identify how the following were considered in the design:

- Subcriticality under normal and abnormal conditions.
- Criticality accident alarm system per the requirements of 10 CFR 70.24, "Criticality Accident Requirements."
- Implementation of the double-contingency principle.

6b.3.3 Technical Specifications

The applicant should identify those ESF's, administrative controls, and surveillance measures that are required to either prevent or mitigate the consequences of a criticality accident and include them in the license TS as prescribed in 10 CFR 50.36, "Technical Specifications," and described in the guidance in NUREG 1537, Chapter 14, as augmented by this ISG.

6b.4 References

American National Standards Institute/American Nuclear Society, ANSI/ANS-8.3-1997, "Criticality Accident Alarm System," ANS, La Grange Park, IL.

ANSI/ANS-8.7-1975, "Guide for Nuclear Criticality Safety in the Storage of Fissile Materials," ANS, La Grange Park, IL.

ANSI/ANS-8.9-1987, "Nuclear Criticality Safety Guide for Pipe Intersections Containing Aqueous Solutions of Enriched Uranyl Nitrate," ANS, La Grange Park, IL.

ANSI/ANS-8.10-1983, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement," ANS, La Grange Park, IL.

ANSI/ANS-8.23-1997, “Nuclear Criticality Accident Emergency Planning and Response,” ANS, La Grange Park, IL.

ANSI/ANS-15.7-1977, “Research Reactor Site Evaluation,” ANS, La Grange Park, IL.

Atomic Safety and Licensing Appeal Board, “In The Matter of Trustees of Columbia University in The City of New York”, 4 A.E.C. 849, (1972).

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.U.S. Nuclear Regulatory Commission, “Nuclear Criticality Safety Standards for Fuels and Material Facilities,” Regulatory Guide 3.71, October 2005.

7 INSTRUMENTATION AND CONTROL SYSTEMS

NUREG-1537, Part 1, Chapter 7 of the format and content guide, as augmented by this ISG, is applicable to providing 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"

Guidance for each of these options follows.

As of the date of this ISG, the NRC was preparing 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 guidance at the time of ISG issuance. Applicants for licenses subsequent to the issuance of this ISG should check for any new guidance at the time of application, particularly in the area of NPR digital I&C.

7a1 Heterogeneous Reactor Instrumentation and Control Systems

NUREG-1537, Part 1, Chapter 7, should be used for guidance in preparing this chapter.

7a2 Aqueous Homogeneous Reactor Instrumentation and Control Systems

NUREG-1537, Part 1, Chapter 7, should be used for guidance in preparing this chapter.

7b Radioisotope Production Facility Instrumentation and Control Systems

NUREG-1537, Part 1, Chapter 7, applies to I&C systems for a reactor. It could also apply to I&C systems for a radioisotope production facility. Where the guidance specifically refers to the "reactor system," it should be interpreted to mean the "radioisotope production facility," as appropriate (i.e., radioisotope extraction and purification processes or the SNM preparation and handling processes outside of the reactor).

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

Bibliography

The current status of cited reference material is as follows:

- ANSI/ANS 10.4, “Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry,” was updated in 2008.

- ANSI/ANS 15.15, “Criteria for the Reactor Safety Systems of Research Reactors,” was withdrawn in 1996.

- ANSI/ANS 15.20 (draft), “Criteria for the Reactor Control and Safety Systems of Research Reactors,” was never issued.

- Institute for Electrical and Electronic Engineers (IEEE) Standard 7-4.3.2, “Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations,” was updated in 2010.

Appendix 7.1

NRC Regulatory Guide 1.152, Revision 1, “Criteria for Use of Computers in Safety Systems of Nuclear Power Plants,” issued January 1996, should be replaced with the current version, Revision 3, issued July 2011.

8 ELECTRICAL POWER SYSTEMS

NUREG-1537, Part 1, Chapter 8 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the electrical power 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:

- 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 1, Chapter 8, should be used for guidance in preparing this chapter.

8a2 Aqueous Homogeneous Reactor Electrical Power Systems

NUREG-1537, Part 1, Chapter 8 should be used for guidance in preparing this chapter.

8b Radioisotope Production Facility Electrical Power Systems

NUREG-1537, Part 1, Chapter 8, should be used for guidance in preparing this chapter, provided that where there is a reference to the the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable. Where the reactor and production facility share a common electrical supply system, that fact should be noted, and it is not necessary to duplicate the information here.

8b.1 Normal Electrical Power Systems

This section of NUREG-1537 can apply to the radioisotope production facility. References to the "reactor" should be interpreted to mean the "production facility," as appropriate.

8b.2 Emergency Electrical Power Systems

This section can apply to any reactor system and the radioisotope production facility. Wherever the "power system" is applied to the reactor and auxiliary systems, it should be interpreted to include "safety-related radioisotope production equipment," as appropriate.

9 AUXILIARY SYSTEMS

NUREG-1537, Part 1, Chapter 9 of the format and content guide, as augmented by this ISG, is applicable to providing 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 is specified for each of these options as follows.

9a1 Heterogeneous Reactor Auxiliary Systems

NUREG-1537, Part 1, Chapter 9, should be used for guidance in preparing this chapter.

9a2 Aqueous Homogeneous Reactor Auxiliary Systems

NUREG-1537, Part 1, Chapter 9, should be used for guidance in preparing this chapter, provided that the differences between the heterogeneous and homogeneous designs are considered. For example, any reference to fuel cladding should, in the case of homogeneous reactors, be taken to mean the primary fission-product barrier.

9b Radioisotope Production Facility Auxiliary Systems

NUREG-1537, Part 1, Chapter 9, should be revised as follows.

The introduction to this chapter summarizes the typical auxiliary systems and components that should be included in the SAR. The introduction also describes the information that should be included in describing the design and function of each system. The current NUREG-1537 primarily addresses a heterogeneous reactor design. This introductory section should be interpreted to apply to auxiliary systems associated with the radioisotope and SNM processing that is conducted in a production facility. In general, Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable.

A section is added to the list of typical auxiliary systems as follows:

- The first bullet should read: "HVAC systems for normal operation of the fission-product (FP) radioisotope and irradiated SNM processing facilities. The applicant should…."

- The next-to-last bullet of the suggested auxiliary systems list should read: "Compressed air or gas systems and vacuum systems for the operation, control, or both of radioisotope production processes and processes with SNM outside of the reactor."

9b.1 Heating Ventilation and Air Conditioning Systems

This section, as it exists in the current version of NUREG-1537, is adequate to describe the heating, ventilation, and air conditioning (HVAC) systems, except that the wording applies to th**e** **r**eactor alone. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable. The following changes and additions should be inserted in this section of NUREG-1537 to emphasize this.

The second sentence of the second paragraph of this section should be replaced with the following:

> The interactions among airflow patterns in the reactor and radioisotope and SNM processing areas should be discussed. The balance of supply and exhaust ventilation systems should be described. Design requirements for maintaining atmospheric pressure differences among the various structures and components should be discussed in this section. Air monitoring within controlled areas, ventilation components and exhaust stacks should be described. If the HVAC systems also are….

The last paragraph of this section should read as follows:

> The applicant should discuss the possible effects of malfunctions of the HVAC system on the operations of the reactor and radioisotope production facilities with particular attention to the potential for any release of airborne radioactive material during normal operation of the facility. The radiological effects of malfunctions should be discussed in Chapter 11.

9b.2 Handling and Storage of Reactor Fuel

Modifications to make this section more appropriate for a radioisotope production facility are as follows.

The last sentence of the first paragraph should read: "The discussion should include descriptions of apparatus that is employed in handling, processing, or storing the fuel. Particular attention should be paid to the design features and use of the equipment as well as administrative controls for the prevention of fuel mishandling or accidents."

The second paragraph, last sentence, should be: "The applicant must address the applicability of 10 CFR 70.24 concerning criticality monitoring, but any detailed discussion of any required system may be presented in Chapter 6 of the SAR."

The fourth paragraph should read as follows:

> The applicant should address the handling, storage, and shipment of new and irradiated fuel (or SNM) in either solid or liquid form. There should be a discussion of the design and operation of equipment or systems for loading and removing fuel (or SNM) into or out of the core or processing facilities and also the administrative controls that will be employed. The details should also include the design and operation of all equipment that will be employed in the receipt, storage, chemical processing, and shipment of both unirradiated and irradiated

fuel (or SNM). Discussions of procedures and systems employed in the handling and storage of irradiated fuel (or SNM) should include radiation shielding, protection from physical damage, change in chemical characteristics, security from diversion, and protection from overheating. Descriptions of facilities and procedures employed in operations with irradiated fuel may be addressed in Chapter 4b.1 of the SAR and therefore it need not be repeated here. Descriptions of irradiated fuel (or SNM) cooling systems and procedures may be included in Chapter 5 of the SAR if they are part of the primary cooling system.

The first sentences of the fifth paragraph should read as follows:

If any loss of fuel (or SNM) or fuel containment could result in the release of fission products, the applicant should discuss the mechanisms and analyze the consequences in Chapter 13, "Accident Analyses," of the SAR. Detailed discussions of radiological considerations during normal operations in handling and storing fuel should be discussed in Chapter 11, "Radiation Protection Program and Waste Management."

9b.3 Fire Protection Systems and Programs

The following should be added just before the last paragraph:

Radioisotope production facilities sometimes possess fairly large inventories of radioactive fission products, which are stored in containment vessels and filter systems. The potential risks and consequences of fire involving these containment vessels and filter systems should be addressed.

The potential for producing free H_2 or other combustible gases in an AHR should be considered. The reactor radiolytic gas management systems are designed to control and eliminate these gases. This system should be discussed in great detail in Chapter 4 of the SAR; however, the possibility of some failure of this system by which hydrogen could escape from the reactor containment should be evaluated and addressed. There may also be a possibility of H_2 accumulation in the irradiated fuel processing and storage systems. This potential hazard should be analyzed and addressed.

The last paragraph should be amended to read as follows:

The reviewer will use nationally recognized codes and standards to provide reasonable assurance of fire safety. These include, but are not limited to, the National Fire Protection Association (NFPA) National Fire Codes, Factory Mutual (FM) Data Sheets and Approval Guides, Underwriters Laboratories (UL) Standards and Building Material Directory, ANSI Standards, and American Society for Testing and Materials (ASTM) Standards. Commitments to specified standards will normally be considered an acceptable means of meeting the acceptance criteria. The staff recognizes NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials," as one standard that specifies acceptable facility fire safety design criteria; however, the applicant may use other nationally recognized codes and standards if appropriate.

9b.4 Communication Systems

NUREG-1537, Part 1, is applicable, as written, to a radioisotope production facility.

9b.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

NUREG-1537, Part 1, is applicable, as written, to a radioisotope production facility.

Possession and use of byproduct material in an aqueous homogeneous reactor facility is authorized and regulated under a 10 CFR Part 50 license.

9b.6 Cover Gas Control in Closed Primary Coolant Systems

The cover gas system in any AHR facility, which could be associated with a production facility, is such an integral part of the reactor that it is described in detail in Chapter 4 of this ISG. There could be potential for radiolytic gas production in the radioisotope extraction and processing systems and also in any irradiated fuel storage and reconditioning systems or vessels. The need for a radiolytic gas management system associated with these operations should be analyzed and addressed.

9b.7 Other Auxiliary Systems

Radioisotope production facilities may have other auxiliary systems that are important to the safety of the worker, the public, and the environment. These systems should be described and analyzed for safety per the guidance in NUREG-1537, Part 1, provided that Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both, as applicable. Examples of these systems include process equipment decontamination or storage facilities; remote manipulator repair facilities; waste (liquid and solid) processing, storage, and disposal facilities; and any unique final-product packaging and shipment facilities.

9b.8 References

The following references should be added:

- U.S. Nuclear Regulatory Commission, SECY-09-0101, Policy Issue Notation Vote, "Licensing of a Babcock and Wilcox Medical Isotope Production System," July 9, 2009.

- National Fire Protection Association, NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials," NFPA, Quincy, MA.

10 EXPERIMENTAL FACILITIES

NUREG-1537, Part 1, Chapter 10 of the format and content guide, as augmented by this ISG, is applicable to providing 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.

Any type of non-power reactor could be designed for conducting experiments in and adjacent to the reactor core. The current guidance in NUREG-1537 should be used for addressing such operations in the SAR.

A production facility could include experimental facilities. In such cases, Chapter 10 of the SAR should include the information in Chapter 10 of NUREG-1537, Part 1, as appropriate. The definition of production facility in 10 CFR 50.2 states that laboratory scale facilities designed or used for experimental or analytical purposes related to processing of irradiated materials containing special nuclear material are not production facilities. This type of facility would typically be part of the experiment program at a utilization facility licensed pursuant to 10 CFR Part 50, and Chapter 10 of the SAR should include the appropriate information in Chapter 10 of NUREG-1537, Part 1.

11 RADIATION PROTECTION AND WASTE MANAGEMENT

NUREG-1537, Part 1, Chapter 11 of the format and content guide, as augmented by this ISG, is applicable to providing 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.

11.1 Radiation Protection

NUREG-1537, Part 1, Section 11.1, and the ensuing subsections are adequate for radioisotope production facilities without modification in this ISG.

11.1.1 Radiation Sources

11.1.2 Radiation Protection Program

11.1.3 As Low As Is Reasonably Achievable 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:

11.1.5.1 Controlled Area

Meeting 10 CFR 70.61(f) would likely be a satisfactory means for an applicant to meet the emergency planning requirements in 10 CFR 50.34.b.6(v). Applicants may provide and justify alternative means of meeting these requirements. 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.

These emergency planning requirements distinguish between accident consequences to workers and consequences to individuals located outside the controlled area as set forth in 10 CFR 70.61(b) and (d). NRC staff have determined that the application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate radiological and chemical consequence and likelihood criteria.

An applicant may elect to demonstrate that the facility would meet the requirements set forth in 10 CFR 50.34.b.6(v) by utilizing the criteria for controlled areas as set forth in 10 CFR 70.61(f) in conjunction with the requirements of 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. In addition, the licensee should retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance

requirements of 10 CFR 70.61, 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 integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance criteria of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of 10 CFR 70.61; 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 integrated safety analysis, 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 criteria for workers specified in paragraphs (b) and (c) of 10 CFR 70.61 may be applied to these individuals.

NUREG-1537, Part 1, Chapter 11, should be used for guidance in preparing the SAR for the following subsections:

11.1.6 Contamination Control

11.1.7 Environmental Monitoring

11.2 Radioactive Waste Management

NUREG-1537, Part 1, Section 11.2, and the following subsections are adequate for radioisotope production facilities without modification in this ISG:

11.2.1 Radioactive Waste Management Program

11.2.2 Radioactive Waste Controls

11.2.3 Release of Radioactive Waste

11.3 Respiratory Protection Program

This section is added to address the requirements for a respiratory protection program.

The applicant should describe how it plans to meet the requirements of 10 CFR Part 20 Subpart H, Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas' by one of three methods.

- Pursuant to 10 CFR 20.1701 and in conjunction with ventilation equipment described in Chapter 9, "Auxiliary Equipment."

- Pursuant to 10 CFR 20.1702 and in conjunction with the use of other controls as discussed in this section or as referenced in this section and discussed elsewhere in the application.

- Pursuant to 10 CFR 20.1703 and in conjunction with individual respiratory protection equipment used and maintained under a program described in this section of the application and in compliance with 10 CFR 20.1703".

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 1, Chapter 12 of the format and content guide, as augmented by this ISG, is applicable to providing 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.

The applicant should describe and discuss 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 this ISG 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.

Note also 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."

As written, the following sections of NUREG-1537, Part 1, are applicable to non-power reactors and radioisotope production facilities.

12.1 Organization

12.1.1 Structure

12.1.2 Responsibility

12.1.3 Staffing

12.1.4 Selection and Training of Personnel

The last sentence references ANSI/ANS 15.4-1988, which has been replaced with ANSI/ANS 15.4-2007, "Selection and Training of Personnel for Research Reactors."

12.1.5 Radiation Safety

The third and fourth sentences should read: "The radiation protection staff can be part of the reactor facility staff or may be provided as a service by a corporation-wide group or by an independent group. The radiation protection staff can report to either the managers of the facility or to the management chain above the facility."

The last sentence references ANSI/ANS 15.11-1993, which has been replaced with ANSI/ANS 15.11-2009, "Radiation Protection at Research Reactor Facilities."

12.1.6 Production Facility Safety Program

Per 10 CFR Part 50, the radioisotope production facility must have an established safety program. NRC recommends licensees utilize the methods described in 10 CFR 70.61 and 10 CFR 70.62. This program may be integrated with a similar program established for other functions on site such as the reactor, but as a minimum if the safety program includes the methods set forth in 10 CFR 70.62(a)-(d), NRC staff may find this an acceptable way of demonstrating an appropriate facility safety program.

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 medical isotopes 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 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.

12.2 Review and Audit Activities

As written, this section is applicable to a non-power reactor and radioisotope production facility.

12.2.1 Composition and Qualifications

The last two sentences should read: "The applicant should discuss the use of committee members from outside the reactor and production facility organization. It is desirable to have some members on the committee from outside the facility management to increase the independence of the committee."

12.2.2–12.2.4

As written, these subsections are applicable to non-power reactor and radioisotope production facilities.

12.3 Procedures

The sixth sentence references ANSI/ANS 15.1-1990, which has been replaced with ANSI/ANS 15.1-2007, "The Development of Technical Specifications for Research Reactors."

12.4–12.6

These sections are applicable as written in NUREG-1537.

12.7 Emergency Planning

In this section of the SAR, the applicant should give a brief overview of the overall emergency plan for the combined reactor and production facility.

For the reactor and production facility, the applicant should follow the guidance of ANSI/ANS 15.16-2008, "Emergency Planning for Research Reactors," which is endorsed and amplified by Regulatory Guide 2.6, Revision 1, "Emergency Planning for Research and Test Reactors," issued March 1983. The applicant should also review NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," issued October 1983.

In addition, NUREG-1520, Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," issued May 2010, describes the details about the production facility that should be included. Section 12.7 of Part 2 of this ISG specifies the portions of NUREG-1520 that should be addressed.

The applicant must ensure that the terminology for releases discussed in the emergency plan matches that used in the revision of 10 CFR Part 20 that became mandatory on January 1, 1994. Specifically, effluent concentrations have replaced maximum permissible concentrations, although use of dose values in millisieverts (mSv) (millirem (mrem)) would be a more appropriate protective action guideline because dose is the ultimate criterion specified. The applicant should ensure that the action levels discussed in the emergency plan for each emergency class follow the guidance. If it is impossible for an event at a particular facility to reach a given action level, that emergency class is not possible, and the plan should state that fact.

12.8 Security Planning

In this section of the SAR, the applicant should briefly discuss security planning for the entire facility. The information in the SAR must be public and must not contain proprietary information (10 CFR 2.390), Safeguards Information -Modified Handling (10 CFR 73.21 and 10 CFR 73.23) or Safeguards Information (SGI) (10 CFR 73.21 and 10 CFR 73.22). The proprietary or SGI version of the security plan is protected from disclosure by the regulations referenced above. The applicant should refer to the guidance in Regulatory Guide 5.59, Revision 1,"Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," issued February 1983, (appears in NUREG-1537, Part 1, Appendix 12.3), when developing the combined security plan for the facility, including for the processing facility. New facilities may be subject to additional security requirements in the form of Security Orders (Orders) and may be subject to a security assessment conducted by the NRC staff.

12.9 Quality Assurance

The third sentence references ANSI/ANS 15.8-1976, which has been replaced with ANSI/ANS 15.8-2005, "Quality Assurance Program Requirements for Research Reactors."

12.10 Operator Training and Requalification

The current wording of this section predominantly addresses training requirements for the non-power reactor staff. The section should be titled:

12.10a Reactor Operator Training and Requalification

NUREG-1537 is applicable to a non-power reactor 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

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.

In addition to stating the general and specific training requirements for licensing utilization facility operators and senior operators contained in 10 CFR Part 55, the applicant should prepare basic topics to be part of a training program to be made a license condition that define the knowledge and skills of the staff of a radioisotope production facility conducting safety-related operations with SNM outside of the reactor such as:

- 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
- ESFs
- TS
- 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.

In 10 CFR 50.54(i-1), the NRC 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). The regulations in 10 CFR Part 55 apply specifically to reactor operating licenses. With regard to production facilities, the proposed operator training license conditions should comply with the same requirements of 10 CFR 50.54(i) and (i-1).

NUREG-1537, Part 2, Section 12.10b, of this ISG presents specific information about the content of a radioisotope production facility training and qualification program.

12.11 Startup Plan

In this section, startup operations involving fuel should be described as processes with fuel in liquid or solid form, as appropriate.

Operations with the fuel or SNM that are conducted outside of the reactor may be subject to the requirements of 10 CFR Part 70. Applicable portions of 10 CFR Part 70 may be incorporated into the Part 50 license as license conditions. Examples of such operations include the following:

- receipt, unpacking, and internal transfer and storage of new fuel or SNM
- preparation of fuel for use in the reactor
- preparation of SNM for use as irradiation targets or experiments
- processing of fuel for reuse in the reactor or for disposal
- packing of spent fuel or SNM for transport to a reprocessing facility
- These startup operations should be included in the safety program and ISA, and IROFS should be identified if necessary to meet ISA performance requirements and to provide assurance of adequate safety.

12.12 This section has been vacated.

In this ISG, Section 12.12, "Environmental Report" of NUREG-1537 is superceded 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 Program

In this section, the applicant should present information about the material control and accounting (MC&A) program. The description should be sufficient to ensure that the program can fulfill its functions. The applicant should consult NUREG-1065, Revision 2, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities," issued November 1995. The information in this section should include the following:

- MC&A organization;
- Measurements;
- Measurement control program;
- Statistics;
- Physical inventories;
- Item control;

- Shipper-receiver comparisons;
- Assessment and review of the MC&A program;
- Resolving indications of missing uranium or other SNM of significance;
- Informational aid for assisting in the investigation and recovery of missing uranium; and
- Recordkeeping.

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 15.11-2009.

Reference ANSI/ANS 15.16-1978 has been replaced with ANSI/ANS 15.16-2008.

13 ACCIDENT ANALYSES

NUREG-1537, Part 1, Chapter 13 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the accident analysis 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"

13a1 Heterogeneous Reactor Accident Analyses

NUREG-1537, Chapter 13, Part 1, applies to heterogeneous non-power reactors and is applicable without further revisions to this chapter, except that recent changes have been made to the radiation dose limits prescribed in 10 CFR Part 20. Applicants should review the current regulations and include the current radiological dose criteria in a SAR for license applications for either a new facility or revisions to an existing facility.

13a2 Aqueous Homogeneous Reactor Accident Analyses

In the other chapters of the SAR, the applicant should discuss and analyze the safety considerations and functional requirements at a non-power reactor facility for the design bases that ensure safe reactor operation and shutdown and acceptable protection of the public, the operations and user staff, and the environment. In those chapters, the applicant should not only discuss potential equipment malfunctions, deviations of process variables from normal values, and potential effects of external phenomena on the facility, but should also describe how equipment will work when needed in accident situations. In this chapter of the SAR, the applicant should submit information and analyses showing that the health and safety of the public and workers are protected and that the applicant has considered potential radiological consequences in the event of malfunctions and the capability of the facility to accommodate such disturbances. The purpose of this chapter is to provide guidance to the applicant to assist in demonstrating that the facility design features, SLs, LSSSs, and LCOs have been selected to ensure that no credible accident could lead to unacceptable radiological consequences to people or the environment.

Unlike in solid fuel reactors, in an AHR the fuel is in a liquid solution, and the resulting fission products—both liquid and gaseous—must be contained within the facility rather than within cladding. The primary boundary consists of all structures that prevent the release of fuel, fission gases, and other fission products that remain in the liquid solution. For an AHR, the primary boundary includes the reactor vessel (and associated penetrations such as control rod guide tubes), the primary cooling system (e.g., cooling coils), the gas management system (including waste gas storage), and associated pumps, heat exchangers, valves, and piping.

The accidents analyzed should range from such anticipated events as a loss of normal electrical power to a postulated fission-product release with radiological consequences that exceed those of any accident considered to be credible. This limiting accident is named the maximum hypothetical accident (MHA) for non-power reactors; the details are reactor specific. Because

the MHA may be a non-mechanistic failure assumed to establish an outer limit consequence, the scenario need not be entirely credible. The initiating event and the scenario details do not require analysis, but the potential consequences should be analyzed and evaluated.

The information on the credible postulated accidents should achieve the following objectives:

- Ensure that enough events have been considered to include any accident with significant radiological consequences. Rejection of a potential event should be justified.

- Categorize the initiating events and scenarios by type and likelihood of occurrence so that only the limiting cases in each group are quantitatively analyzed.

- Develop and apply consistent, specific acceptance criteria for the consequences of each postulated event.

The selection of accident scenarios to be analyzed should be based on the consideration of phenomena unique to an AHR that could limit safe operation. Limiting phenomena refer to those physical phenomena that could occur during the course of a transient or accident that significantly affects the subsequent likelihood of failure of the primary boundary. Identification and understanding of these limiting phenomena are useful in classifying the consequences of potential transients and accidents, as well as in determining appropriate operating limits. For AHRs, the limiting phenomena include bulk boiling, fuel precipitation, fission-product precipitation, detonation and deflagration of radiolytic gases, and excessively high radiolytic gas release. These phenomena are defined as follows:

- Bulk boiling of fuel solution (i.e., change of phase occurs as liquid evaporates into gas)

  Bulk boiling refers to the formation of vapor in the AHR due to phase change of the solution. Bulk boiling could lead to several adverse effects for the AHR; for example, increased fission-product release from the core and potentially increased reactivity [see reference 1 of section 13a4]. Bulk boiling could result in the transport of aerosols from the reactor core and lead to hot spots elsewhere in the plant system. While AHRs are generally characterized by strong negative void/temperature reactivity feedback, the potential consequences in terms of reactor dynamic power level, as well as the redistribution of fuel and fission products, could challenge primary boundary integrity.

- Precipitation of fission products/precipitation of fuel (uranium)

  Precipitation refers to the formation of solids in the AHR fuel solution. Precipitation of the fuel or fission products should be avoided in AHRs [see references 1 and 3 of section 13a4]. Precipitation of the fuel or fission products will result in the collection of these precipitates in the bottom of the reactor, leading to core heterogeneity. Collection of radioactive fission products or fuel in concentrated areas near the reactor core primary boundary could lead to excessive local heating and high temperatures on the reactor vessel or cooling coils. Subsequent chemical and thermal-mechanical effects could then challenge primary boundary integrity.

- Detonation or deflagration of combustible gas mixtures

The formation of radiolytic gases (hydrogen and oxygen) is characteristic of AHRs (which have historically been referred to as water boilers for this very reason) [see reference 2 of section 13a4. The hydrogen and oxygen produced by these reactors could ignite, causing a detonation or deflagration within the primary boundary. Such an event could compromise the integrity of the primary boundary.

- Excessively high radiolytic gas release

  Excessively high radiolytic gas release refers to a specific condition where instantaneous radiolytic gas generation rates exceed the capacity of the plant systems to recombine the gases. Under these circumstances, it is possible for the formation of the gases to result in vessel pressurization. Given that AHRs typically have a strong negative void reactivity feedback, it is possible for excessively high radiolytic gas generation rates to initiate a positive feedback in the AHR system, whereby power continues to increase and the system pressure continues to increase [see reference 3 of section 13a4]. High pressure or rapid increases in pressure could challenge the primary boundary integrity.

  Additionally, excessive radiolytic gas release above the capacity to recombine necessarily implies the presence of hydrogen and oxygen gases in the associated gas management system. The explosion of these gases could pose a challenge to the primary boundary integrity in parts of the gas management system away from the core region.

Accordingly, for an AHR with noncirculating fuel (i.e., the fuel is not circulated to other components of the plant such as steam generators during operation), the following postulated event categories should be evaluated:

Reduction in cooling events

- MHA
- Insertion of excess reactivity
- Reduction in cooling

  Events previously categorized as loss of coolant and loss-of-coolant flow have been redefined for the AHR more generically as “reduction in cooling” events. The purpose of redefining these events is to address unique aspects of the heat removal from an AHR. The AHR fuel is liquid, and therefore, the cooling systems may differ significantly from those for more conventional solid fuel reactors. Additionally, since the fuel is liquid and lacks a cladding, gaseous fission products may escape from the core region and be transported to other areas of the plant. A reduction in cooling event is characterized by a reduced capacity to remove fission or decay heat from the fission products.

Mishandling or malfunction of fuel

Fuel malfunction has historically referred to events where there is fuel damage or failure of the cladding to retain fission products. For AHRs, the fuel is in liquid form. The function of the primary barrier is served by the primary system boundary instead of a cladding. Therefore, fuel malfunction in the context of the AHR must be redefined to

address aspects of the fuel that could result in a failure of the primary boundary. The fuel is therefore considered to "malfunction" or to have been "mishandled" if the physical state of the fuel solution is subjected to any of the identified limiting phenomena of bulk boiling, fuel precipitation, or fission-product precipitation, or if the corrosion rates become excessively high.

Fuel temperature/void-reactivity feedback

- Loss of normal electric power.
- External events (include natural hazards and man-made events).
- Mishandling or malfunction of equipment.
- Large and undamped power oscillations.

Experience with AHR operation has indicated very strong fuel temperature/void reactivity feedback [see references 1, 2, 3, and 4 of section 13a4]. While in most cases the experience has shown that the stochastic power oscillations in AHRs are bounded, the nature of power oscillations at high power density depends on the specific design [see reference 3 of section 13a4] and there have been no models that have been successful in calculating the power spectrum of the oscillations. It is expected that normal operation of an AHR will include stochastic and variable power oscillations owing to the dynamics of radiolytic gas formation and reactivity feedback. These conditions will not pose a challenge to the primary barrier, provided these power oscillations do not grow (which is indicative of an unstable condition).

Reactivity feedback coupled with plant response could yield conditions that are not inherently stable. An example of this phenomenon includes positive feedback due to radiolytic gas formation and vessel pressurization under conditions where the recombiner capacity of an AHR is exceeded. Such conditions where positive feedback is possible must be examined to determine if the reactor remains stable or, if the reactor becomes so unstable that the power oscillations are large and undamped, whether these unstable power oscillations can be acceptably detected and suppressed.

Detonation and deflagration

For AHRs, formation of radiolytic gases introduces the possibility of detonation or deflagration by chemical reaction between hydrogen and oxygen gases. Explosion within the primary boundary presents two potentially challenging consequences: (1) the explosion will send a pressure wave throughout the system, which could result in a reactivity insertion, and (2) the explosion itself could compromise primary boundary integrity and at the same time result in the energetic dispersal of the contents of vessels holding fuel and fission products.

Unintended exothermic chemical reactions other than explosion

Depending on the fuel solution, the formation of radiolytic gases other than oxygen and hydrogen introduce the possibility of exothermic chemical reactions other than the recombination of hydrogen and oxygen. For example, the oxidation of NOx gases is exothermic.

Facility system interaction events

For radioisotope production AHRs, the reactor (or reactors at a multi-unit facility) supply feed products to chemical processing facilities. Therefore, events occurring within the processing facility could have an influence on the reactor. Additionally, for multi-reactor facilities, shared systems could initiate transient or accident events that affect more than a single reactor. Facility system interaction events generally classify the influence of shared systems and coupled systems to the reactor or reactors. An example of such an event is the common-mode failure of external chemical processing systems that challenge (simultaneously) the primary boundary integrity for multiple reactor units. Within this category, event propagation to other units should also be considered. For example, an event initiated in one reactor unit could influence an adjoining unit through phenomena such as pipe rupture caused by an explosion, whereby the ruptured pipe could physically interact with another system or the shock wave could affect other systems.

Events in each of the above categories should be evaluated systematically to identify the limiting event selected for detailed quantitative analysis. Limiting events in each category should have potential consequences that exceed all others in that group. The MHA selected should bound all credible potential accidents at that facility.

13a2.1 Accident-Initiating Events and Scenarios

In this section of the SAR, the applicant should describe potential accident-initiating events and scenarios. For documents on general accident scenarios and analysis, radiological consequences, and fuel types, see Section 13a.4, “References.” The following sections discuss selecting and categorizing postulated accidents.

13a2.1.1 Maximum Hypothetical Accident

The MHA could be based on a breach of the primary boundary of the various vessels that results in unrestricted dispersal of the radioactive material. 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., by 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).

For multi-reactor AHR facilities, the MHA could be a facility-wide event that simultaneously releases a radioactive inventory from within the facility that exceeds that of a single reactor. For multi-reactor AHR facilities, consideration should be given to hypothetical events that could release radioactivity from multiple vessels, holdup tanks, and processing systems holding both liquids and fission gases.

Possible MHAs for a multi-reactor AHR facility could be one or both of the following events:

- Manmade external event that breaches the primary boundary of more than one unit.

- Facility-wide external event that breaches various systems containing radioactive fluids.

13a2.1.2 Insertion of Excess Reactivity

For AHRs, the insertion of excess reactivity can become an initiating event that leads to a challenge to the integrity of the primary fission-product boundary. The following AHR-specific reactivity insertion events should be considered along-side more traditional reactivity insertion events, such as control rod withdrawal or ejection and experiment malfunction.

For AHRs, the following events leading to insertion of excess reactivity should be considered:

Pressurization of the fuel fluid

> This event should be considered for an AHR given the large, negative void reactivity coefficient characteristic of this reactor type.

Excessive cool down via cooling system malfunction

> This event should be considered for an AHR given the large, negative temperature reactivity coefficient characteristic of this reactor type.

Moderator addition due to cooling system malfunction (e.g., cooling tube rupture)

> AHRs are expected to have internal cooling heat exchangers (e.g., coils) submerged in the liquid reactor fuel. A breach of this heat exchanger piping could introduce additional moderator to the fuel and potentially increase reactivity. Moderator (water) addition can also occur if the reactor core vessel itself is breached and if the pool water intrudes into the vessel.
>
> The normal operating condition of an AHR could be over-moderated. However, positive reactivity will be inserted directly if the water makes a layer that works as a reflector in the vessel.
>
> Indirectly, there could be several possible reactivity insertion scenarios. For example, a hypothetical event whereby water is injected in the middle of the vessel could confer negative reactivity (depending on the under- or over-moderation) and power could decrease. Radiolytic gas formation will also be reduced, and such a reduction in void could add reactivity. Such reactivity effects will be dependent on the core geometry, plant system configurations, and solution characteristics.

Fuel injection

> Liquid-fueled reactors are expected to have systems for defueling and refueling the primary boundary vessel. Therefore, failures in plant systems or control systems could add liquid fuel to a critical reactor, thus increasing reactivity.

Realistic, adverse geometry changes

For liquid-fueled AHRs, the core geometry is variable. Therefore, a phenomenon such as sloshing of the reactor fuel because of vibration or other mechanisms could reduce neutron leakage and increase reactivity.

Reactivity insertion due to moderator lumping effects

AHRs are expected to have internal cooling heat exchangers (e.g., coils) submerged in the liquid reactor fuel. Void formation within the heat exchanger changes the moderation profile within the reactor. Since the moderating effect of the cooling system is separate from the fuel solution, such changes have the potential to introduce negative or positive reactivity depending on the design-specific geometry and neutron spectrum. The reactivity effect of lumped moderator changes within the primary cooling system should be considered.

Inadvertent introduction of other material into the fuel solution

AHRs are expected to have systems for adding additional materials into the reactor core. Nitrate-based systems will generally require the addition of nitric acid to compensate for the radiolytic formation and loss of NOx. Malfunction of such makeup systems could introduce other material into the reactor.

13a2.1.3 Reduction in Cooling

The effect of reduction in cooling should be considered for all AHRs. The cooling systems include all systems and components that remove heat from the reactor vessel and the fission gases as identified in Section 5.1 of the SAR. They consist of the cooling coils inside the vessel, the pool that provides external cooling of the vessel, and cooling systems in the off-gas handling system for removing heat from the gases generated in the fission process. The reduction in cooling caused by an initiating event such as: loss of electric power; failure of an active component in the heat removal system; a cooling coil or heat exchanger tube rupture; flow obstruction in a heat exchanger or other event, could lead to a negative effect. These effects include a high temperature, subsequent adverse chemical effects, or excessive thermal stress, or reduction in cooling, which could induce a reactivity insertion that could ultimately challenge the integrity of the primary boundary. For example, a reduction or fluctuation of cooling to the recombiner could result in a local hot spot in the primary boundary and a subsequent failure of the primary boundary due to thermal stress or burnout.

13a2.1.4 Mishandling or Malfunction of Fuel

Since the fuel in the AHR is liquid, fuel mishandling events can be characterized as fuel spills or leaks where some amount of this fuel could gather or migrate to unintended locations. One immediate concern for the outcome of such a spill or leak is the accumulation of a sufficient mass of fuel in a geometry leading to an unintended criticality. The applicant should address these events and the consequences of fuel spills and leaks in the SAR under this Section 13a for accidents in the reactor facility and also under Section 13b for accidents in the radioisotope production facility.

Fuel leakage or excessive fuel leakage should be considered within the context of this class of accidents.

Fuel malfunction events for an AHR may be thought of as those events where the physical or chemical form of the fuel or solvent undergoes a change resulting in adverse chemical effects such as fuel precipitation or excessive corrosion. The following initiators need to be considered in this event category:

- Failure to control pH of the fuel solution (e.g., failure to add proper chemicals at prescribed times to the fuel solution).

- Failure to control solution temperature (e.g., excessive cooling of the fuel during off-normal operation, resulting in fuel crystallization or precipitation).

- Failure to control solution pressure (e.g., exposing the primary vessel to a vacuum, thereby initiating fuel boiling).

13a2.1.5 Loss of Normal Electrical Power

This accident initiator can result from an onsite or offsite power failure. Emergency power is assumed to operate. Failure of emergency power coincident with loss of normal power can create a station blackout condition. It is assumed that control rods will operate under gravity to make the reactor subcritical. However, the consequent loss of all active heat removal capability and its impact on removing decay heat from the primary vessel, the off-gas system, and the waste gas storage tank should be analyzed.

13a2.1.6 External Events

These events include natural phenomena, such as extreme winds, tornadoes, floods, or seismic events, as well as manmade events, such as explosions or toxic releases in the vicinity of the reactor building. For example, the impact of seismically induced changes in the geometry of the fuel solution should be considered.

13a2.1.7 Mishandling or Malfunction of Equipment

The applicant should consider the consequences of mishandling or malfunction of equipment that could result in the spillage or leakage of contaminated fluids. Additionally, since fission gases are not retained in the fuel for the AHR, the applicant should consider the leakage or release of fission gases. For example, a stuck-open relief valve or inadvertent opening of a valve in the waste gas storage systems or holdup tanks is an equipment malfunction that could allow radioactive gases to leak out of the primary boundary at an excessive rate. Such an equipment malfunction would constitute a loss of integrity of the boundary of the waste gas holding tank that allows escape of fission gas and radiolysis gas into the building confinement.

13a2.1.8 Large Undamped Power Oscillations

The AHR design is expected to experience a strong temperature and density feedback. The SAR should include a discussion of those conditions that could lead to positive feedback and result in growing power oscillations that are large and undamped. Such large, undamped power oscillations could challenge the integrity of the primary barrier.

In its determination of reactor stability, the applicant should evaluate plant system behavior. For instance, pressurization caused by excessive radiolytic gas formation could result in a positive feedback mechanism.

13a2.1.9 Detonation and Deflagration

The formation and release of radiolytic gas from the fuel solution introduces the potential for deflagration or combustion of these gases within the primary boundary. The applicant should identify and evaluate the consequences of postulated deflagration and detonation events.

13a2.1.10 Unintended Exothermic Chemical Reactions Other Than Detonation

This class of accidents is characterized by the unintended reaction of gases other than the hydrogen/oxygen reaction that could challenge the integrity of the primary boundary. An example of an event in this category is the exothermic reaction of NOx with oxygen. It may be postulated that a large quantity of NOx has evolved in a hypothetical AHR waste gas system. The rapid oxidation of these gases could increase system pressure and temperature, which could, in turn, breach the waste gas system primary boundary.

13a2.1.11 Facility System Interaction Events

This class of accident initiators is characterized by the dynamic interactions of connected or co-located plant systems. For the AHR isotope production facility, in particular, licensees should review potential system interactions that could occur between the reactor side and the isotope separation side of the facility. This includes malfunctions or accidents in isotope processing operational facilities, such as hot cells, that could impact the reactor. Since the facility can consist of multiple reactors and processing units that potentially share systems, structures and components, interactions between these systems could exacerbate consequences relative to a single reactor facility. Initiators in this class include the following:

- Common-mode failures affecting multiple units.

- Propagation of a failure to then impact another unit (e.g., pipe whip).

13a2.2 Accident Analysis and Determination of Consequences

In this section of the SAR, the applicant should discuss each event and give information consistently and systematically that will lead to a clear understanding of the specific reactor and facilitate comparisons with similar reactors. Many of the steps used to select the limiting event in each category are semi-quantitative. However, the analyses and determination of consequences of the limiting events should be as quantitative as possible. Licensees should take the following steps when selecting the limiting event in each category:

- State the initial conditions of the reactor and equipment. Discuss relevant conditions depending on fuel burn-up, experiments in the reactor, core configurations, or other variables. Use the most limiting conditions in the analyses.

- Identify the causes that initiate the event; the causes include equipment malfunction, operator error, solubility, precipitation, chemical accidents, or other natural phenomenon

or ones caused by humans. Base the scenario on a single initiating malfunction rather than on multiple causes.

- List the sequence of events, assumed equipment operation and malfunction, and operator actions until a final stabilized condition is reached. Discuss functions and actions assumed to occur that change the course of the accident or mitigate the consequences, such as reactor scrams or initiation of such ESFs as emergency core cooling. If credit is taken for mitigation of the accident consequences, discuss the bases used to determine that the systems are operable and discuss the system functions.

- Classify damage that might occur to components during the accident until the situation is stabilized. Discuss all components and barriers that could affect the transfer of radiation and radioactivity from the reactor to the public and that ensure continued stability of conditions after the accident.

- Prepare realistic analyses to demonstrate a detailed, quantitative evaluation of the accident evolution, including the performance of all barriers and the transport of radioactive materials to the unrestricted area. Include the assumptions, approximations, methodology, uncertainties and degree of conservatism, margins of safety, and both intermediate transient and ultimate radiological conditions. Justify the methods used. Further, ensure that the information is sufficiently complete to allow the results to be independently reproduced or confirmed. Demonstrate the validation of the computational models, codes, assumptions, and approximations by comparison with measurements and experiments when possible. Describe in detail computer codes that are used; include the name and type of code, the way it is used, and its validity on the basis of experiments or confirmed predictions for similar operating non-power reactors. Include estimates of the accuracy of the analytical methods. Chapter 11, “Radiation Protection Program and Waste Management,” of the SAR discusses the methods and assumptions used to analyze the release and dispersion of radioactive materials from normal operations. Adapt these methods as appropriate for accident analyses.

- Define and derive the radiation source terms, if any are involved. Include in the source terms the quantity and type of radionuclides that could be released, their physical and chemical forms, and the duration of potential releases. Describe potential radiation sources that could cause direct or scattered radiation exposure to the facility staff and the public.

- Evaluate the potential radiological consequences using realistic methods. Discuss the degree of conservatism in the evaluation. For example, include a discussion of the degree of conservatism introduced by the use of postulated release fractions or assumption of an infinite hemispherical cloud.

- Include specific environmental and meteorological conditions for the facility site to illustrate consequences of the accident. Give an account of the exposure conditions for the facility staff until the situation is stabilized (including staff evacuation and reentry), the most exposed member of the public in the unrestricted environment until the accident conditions are terminated or the person is moved, and the integrated exposure at the facility boundary and the nearest permanent residence. The radiological consequences should include external and internal exposures. Address contamination

of land and water where applicable, and include exposure control measures to be initiated.

13a3 Summary and Conclusions

In this section of the SAR, the applicant should summarize the important conclusions about the postulated accidents and the potential consequences. The applicant should compare the projected radiological consequences with the acceptance criteria discussed previously in this chapter. The information should demonstrate that all reasonable measures have been incorporated into the facility design bases to prevent undue radiation exposures and contamination of the unrestricted environment. The discussions should show that ESFs have been incorporated where necessary to limit consequences to acceptable levels.

13a4 References

1. International Atomic Energy Agency, IAEA-TECDOC-1601, "Homogeneous Aqueous Solution Nuclear Reactors for the Production of Mo-99 and Other Short Lived Radioisotopes," September 2008.

2. Los Alamos National Laboratory, LA-UR-10-02947, "Lessons Learned from 65 Years of Experience with Aqueous Homogeneous Reactors," May 2010.

3. Lane, James A., ed., *Fluid Fuel Reactors*, "Part 1 Aqueous Homogeneous Reactors," Addison-Wesley, 1958.

4. Los Alamos National Laboratory, LA-UR-10-04318, "Stability Analysis of the SUPO Reactor," June 2010.

5. 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.

6. Dunenfeld, M.S., "Summary Review of the Kinetics Experiments on Water Boilers," NAASR-7087, Atomics International, Canoga Park, CA, 1963.

7. McLaughlin, T.P., Process criticality accident likelihood, consequences, and emergency planning, Nuclear Energy, Vol. 31, No. 2, April, 1992.

8. 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, 2000.

References for non-power reactors in the current version of NUREG-1537 remain applicable.

ANSI/ANS 5.1, "Decay Heat Power in Light Water Reactors," has been updated. The current version, at the time of publication of this ISG, is dated 2005.

13b Radioisotope Production Facility Accident Analyses

Sections 13a1 and 13a2 of this chapter provide guidance concerning hazards and accident analyses that should be included in any license application SAR for non-power reactors. According to the requirements in 10 CFR Part 50, the analyzed accident consequences, as mitigated by plant and administrative safety measures, are evaluated against the acceptable dose limits of 10 CFR Part 20 or 10 CFR Part 100, as appropriate.

This section (13b) of Chapter 13 of the ISG addresses the analysis of potential hazards and accidents that could be encountered in production facility operations with SNM (irradiated and unirradiated) that are conducted outside of the reactor and operations with radioisotopes and hazardous chemicals that are related to operations involving licensed material.

Operations with SNM and hazardous chemicals outside of the reactor in a non-power reactor and radioisotope production facility are licensed under 10 CFR Part 50; guidance applicable to these licenses can be found in NUREG-1537. Relevant sections of 10 CFR Part 70 and NUREG-1520 that are not addressed in NUREG-1537 are included in this ISG. The guidance for conducting accident analyses under both 10 CFR Part 50 and 10 CFR Part 70 is basically the same regarding the elements of the analysis and the use of a graded approach, which requires protective measures that are commensurate with the severity of any consequences from abnormal or accident conditions.

NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR Part 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, and establishment of management measures are an acceptable way 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 section 13b and elsewhere in this ISG, the term “performance requirements” is not intended to mean that the performance requirements of 10 CFR 70.61 are required for a medical isotope production facility license, only that their use as accident consequence and likelihood criteria may 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.

Applicants and licensees of a radioisotope production facility shall limit the probability of accident occurrence according to the magnitude or severity of post-accident consequences. Accidents resulting in more serious consequences require more extensive measures to prevent their occurrence. The post-accident consequences that are specified in 10 CFR 70.61 (performance requirements) call for protective measures against higher consequence accidents to be more robust than those for lower consequence accidents. This regulation is intended to make accidents with high consequences much less likely to occur than the accidents with low consequences. All processes involving licensed material should be examined through an ISA and through a well-defined safety program (refer to Section 12.1.6 of this ISG). The ISA identifies protective devices, called IROFS, and management measures applied to the IROFS to

ensure they are available and reliable to perform their function when needed. The IROFS protecting against accidents are analogous to, and may be incorporated into the license as TS under 10 CFR 50.36.

10 CFR 50.36(b) requires that utilization and production facility license applications include TS that are derived from the SAR. Licensees are required to submit the SAR according to 10 CFR 50.34, "Contents of Applications; Technical Information," and the guidance in NUREG-1537 for non-power reactors and radioisotope production facilities. For utilization and production facilities, 10 CFR 50.36 prescribes a graded approach to establishing TS. SLs and limiting control settings are those specifications that are intended to protect against or mitigate the consequences of the more serious abnormal or accident conditions. LCOs, surveillance requirements, design features, and administrative controls are other categories of TS that are required for safe operation. Another application of a graded approach to establishing realistic and practicable TS is the latitude allowed licensees in the required responses to deviations from TS. As provided in 10 CFR 50.36, remedial actions need not include stopping operations as long as safe and effective alternative means of maintaining safe operations, as justified in the pertinent safety analyses, are allowed within the stated specification.

Except for analyzing accidents involving hazardous chemicals, the guidance in NUREG-1537, as supplemented by NUREG-1520, applies to operations with SNM and radioactive materials outside of the reactor. Section 13b.3 below provides guidance for analyzing accidents involving hazardous chemicals.

13b.1 Radioisotope Production Facility Accident Analysis Methodology

Operations with SNM and radioisotopes fall into distinct categories according to the type of process performed in the facility and the nature of the processing hazards. An integrated safety analyses (ISA) should be performed for each process or process segment. Licensees should perform the accident analyses systematically for each process or process segment to ensure that the analysis addresses each credible accident event.

13b.1.1 Processes Conducted Outside of the Reactor

Processes that are conducted outside of the reactor and that must be analyzed under accident conditions are divided into three general categories:

- 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.
- Radiochemical operations.
- Operations with hazardous chemicals.

13b.1.2 Accident-Initiating Events

The ISAs for the above categories of operations and any other planned operations with SNM that may be conducted and that are not listed above 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.
- Facility fire.
- Any other event that could be related to unique operations within the facility.

13b.2 Analyses of Accidents with Radiological Consequences

The applicant for a license should discuss in this section of the SAR the MHA and credible accident conditions that could result in a release of radioactive material or hazardous chemicals into or outside of the controlled areas of the facility. These analyses should include accident scenarios within the operating categories listed in Section 13b.1.1 and, as a minimum, include accidents caused by those initiating events listed in Section 13b.1.2 within each operating category. The following steps are suggested for each analysis:

- State the initial conditions of the process, such as the potential source term, the condition of processing components, and control equipment.
- Identify the initiating condition of the event, whether natural external phenomena, process equipment failure, human error, or other. Base the scenario on a single initiating event.
- Describe the sequence of actions that occur during the course of the accident (e.g., equipment operations, operator actions) until a final stable condition is reached. If credit is taken for any mitigation of the accident consequences, state the bases used for determining that the systems are operable by TSs and describe their function.
- Discuss the function of each component or barrier that affects the transfer of radioactive material from the process to uncontrolled areas during the event and continuing after a stable condition has been achieved.
- Prepare realistic analyses to demonstrate a detailed and quantitative evaluation of the accident evolution, including the performance of all barriers regarding the transport of radioactive materials to uncontrolled areas. The analyses should include basic assumptions, methodology, uncertainties, degree of conservatism, margins of safety, and intermediate and ultimate radiological conditions. Justify the methods used.

Demonstrate the validity of any models, codes, assumptions, and approximations by comparison with relevant data or experiments. Provide enough detail to allow the results to be independently reproduced or confirmed. Provide some estimate of the accuracy of the methods employed. Methods used in the accident analyses should be consistent with those used in Chapter 11 of the SAR for the analyses of dispersion of radioactive material to the environment under normal operating conditions.

- Define the radiation source terms by identity, quantity, physical and chemical forms, and the duration of their releases.

- Evaluate the potential radiological consequences using realistic methods. Discuss the degree of conservatism in the evaluation (e.g., the use of worst meteorological conditions, the use of minimum effects of mitigating circumstances, use of maximum release fractions).

- Identify IROFS and their function as preventive, mitigative, or both. Qualify IROFS as either an ESF or some form of TS per 10 CFR 50.36 and ensure their analyses and inclusion in appropriate sections of the SAR.

Radiation dose estimates should include estimates for the operating staff throughout the event and during recovery operations and also for the maximally exposed individual in the uncontrolled areas and at the nearest permanent residence. The radiological consequences should be in terms of TEDE. The evaluation should include potential contamination of surrounding land, surface water, and ground water. As stated in Part 2, Section 13a2.5.1, *Maximum Hypothetical Accident*, both external radiation dose and inhalation doses should be considered.

13b.3 Analyses of Accidents with Hazardous Chemicals

The applicant should ensure that the application for the proposed facility addresses the following areas:

Chemical Accidents Description

This section should include:

- A general description of the accident involving hazardous chemicals interacting with licensed material or the chemical risks of plant conditions that affect the safety of licensed materials.

- A description of the chemical hazards that could result in unacceptable consequences. Each accident description identified by the applicant should include a chemical hazard evaluation of potential interactions of process chemicals with confinement vessels, process equipment, and facility personnel. The hazard evaluation should use appropriate accepted methods.

- A conclusion that the applicant has reasonable assurance that measures to mitigate the consequences of accidents are consistent with actions described in the emergency plan.

Chemical Accident Consequences

This section should include:

- An estimate of the concentrations for releases of hazardous chemicals interacting with licensed material or by abnormal plant conditions that could affect the safety of licensed materials. This estimate should use appropriate techniques and valid assumptions.

- Evidence that the dispersion models used to determine whether a release of chemicals might affect worker or public health and safety are appropriate. The applicant should demonstrate that the models used lead to a conservative estimate of potential consequences.

- Consequence analyses that conform to the guidance on atmospheric and consequence modeling in NUREG/CR-6410.

- If the applicant does not use the methods in NUREG/CR-6410, it may propose an alternative method accompanied by supporting documentation to justify the selection of such an alternative (e.g. code benchmarking, peer review, cross comparisons, etc.).

- A description of the quantitative standards (chemical concentration limits) used to assess the unmitigated and mitigated consequences to an individual outside the control area (public) or to a worker from acute chemical exposure to licensed material, chemicals produced by licensed materials, or chemicals in contact with licensed materials that are on site or expected to be on site.

Notes regarding the treatment of accident consequences:

- Acceptable exposure standards include, but are not limited to, the Emergency Response Planning Guidelines established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and the exposure limits established by the U.S. Occupational Safety and Health Administration. The applicant needs to verify that the selected standard applies to the worker or the individual outside the control area. Note that all the standards mentioned above apply to airborne exposure to gases, vapors, and particulates. Those limits are not intended to evaluate the consequences of chemical exposures through other exposure paths.

- If the applicant does not use a published exposure standard or knows of no such standard for a chemical, it may propose an alternative, accompanied by supporting documentation to justify it (e. g. research results from targeted studies, analogs to published studies, etc.).

- Consequence categorization is acceptable.

Chemical Process Controls

This section should include:

- A discussion that identifies the design basis for chemical process safety for normal operation and demonstrates that the proposed equipment and facilities adequately protect public health and safety and the environment. Based on a comparison of the unmitigated chemical consequences determined, the applicant should provide a list of chemical-process safety controls suitable to prevent or mitigate potential accidents. This list should also briefly describe the controls in sufficient detail to permit an understanding of their safety functions in relation to the performance requirements. The application should also identify controls for those accidents containing a chemical system or process failure that could ultimately lead to radiological consequences that exceed the performance requirements. The applicant should demonstrate that the consequences of each credible event will be reduced after the implementation of controls, so that the consequences of the event will be low. Preventive controls are preferable to mitigative controls. Chemical safety-related controls should be included in the license technical specifications as appropriate.

Chemical Process Surveillance Requirements

This section should include:

- A description of the engineering approach, basis, or schemes employed to maintain safety during normal operations.
  - A discussion of the administrative and engineered controls to prevent or mitigate a chemical process risk (the hazard being mitigated). The applicant should also explain how it graded the surveillance requirements and how this grading is commensurate with the reduction in risk that the controls are designed to achieve. Surveillance requirements related to serious accident prevention should be included in the license technical specifications.
- A demonstration that the surveillance requirements ensure that the chemical safety controls are available and reliable by briefly describing the following:
  - procedures to ensure the reliable operation of ESFs, TS, or both (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 ESFs 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)

13b.4 References

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Nuclear Regulatory Commission, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” NUREG-1520, Revision 1, May 2010.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

14 TECHNICAL SPECIFICATIONS

NUREG-1537, Part 1, Chapter 14 of the format and content guide, as augmented by this ISG, is applicable to providing 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:

TS will be developed after all reactor and radioisotope production facility operating characteristics are known and all credible accident conditions are evaluated. This ISG includes supplemental information and guidance from NUREG-1520, which provides direction for performing ISAs and deriving any required IROFS while working with SNM outside of the reactor. IROFS could be the equivalent of the TS as prescribed in 10 CFR 50.36 and as ESFs identified in Chapter 6 of NUREG-1537, and they will be designated TS and ESFs, as appropriate.

Appendix 14.1

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"

ISG for each of these options follows.

14a1 Heterogeneous Reactor Technical Specifications

NUREG-1537 is applicable to a heterogeneous non-power reactor without any further guidance in this ISG.

14a2 Aqueous Homogeneous Reactor Technical Specifications

NUREG-1537 can be used as guidance for writing an SAR for an AHR facility with the following modification: The numbering system for the various sections of NUREG-1537, Appendix 14.1, is revised in accordance with the following expanded sections for the AHR.

14a2.1 Introduction

The current wording of NUREG-1537, Appendix 14.1, is applicable to an AHR without changes in this ISG.

14a2.2 Safety Limits and Limiting Safety System Settings

The current wording of NUREG-1537, Appendix 14.1, Section 2 Safety Limits and Limiting Safety System Settings, is applicable to an AHR with the following additional ISG:

14a2.2.1 Safety Limits

The following sentence is added to the first paragraph: "For aqueous homogeneous core reactors, the gas management system is also part of the primary fission-product barrier."

The following sentence should be added to the end of the section: "For aqueous homogeneous reactors, there may be limits on the character and quality of the fuel that might warrant setting additional safety limits (i.e., the operating-power density, the uranium concentration, the volume, the pH, and the temperature and pressure of the fuel solution)."

14a2.2.1.1 Important Process Variables

The following should be added as a last paragraph: "When addressing safety limits for cooling systems in AHRs, the cooling requirements of the gas management system (i.e., recombiner and condenser) should be included in any analyses of SLs."

14a2.2.1.2 Criteria—Reactors with Engineered Cooling Systems

This section of the current NUREG-1537 refers to cooling requirements to prevent damage to fuel cladding. In the case of an AHR, the term "cladding" should be interpreted to mean primary "fission-product barrier," which includes the core vessel and the components of the gas management system. Also, in the case of AHRs, excessive fuel temperatures could lead to bulk boiling of the fuel solution, reactivity instability, and consequent failure of the primary fission-product barrier by means other than high-temperature failure of the core or the gas management system vessels. SLs to prevent these events could be more limiting.

14a2.2.1.3 Criteria—Reactors without Engineered Cooling Systems

As in the preceding Section 14a.2-2.1.2, this section refers to cooling requirements to prevent damage to fuel cladding. In the case of an AHR, the term "cladding" should be interpreted to mean "primary fission-product barrier," which includes the core vessel and the gas management system components. Appropriate limits should be established to prevent all mechanisms that would cause failure of the primary fission-product barrier.

14a2.2.2 Limiting Safety System Settings

The current wording applies to an AHR.

14a2.3 Limiting Conditions for Operation

The following section should be added:

> 14a2.3.1(6)(e) AHR fuel
>
> The SAR must include the LCOs required by 10 CFR 50.36(c)(2) for liquid fuel including volume of the fuel solution, uranium burnup, uranium concentration in solution, U-235 enrichment, fuel ambient and operating temperature limits, fuel solute concentration and pH limits, and others that could be necessary.

14a2.3.2 Reactor Control and Safety Systems

14a2.3.2.4 Scram Channels

Add channels deemed necessary for AHR operating limits, such as reactor vessel and gas management system component pressure, fission-product gas holdup tank pressure(s), recombiner temperature, recombiner coolant temperature, fuel solution pH, fuel solution level in the core vessel, inert cover gas concentration or flow rate, etc.

14a2.3.3, 3.4, 3.5, 3.6, 3.7, 3.8, and 3.9

The current wording of these sections applies to an AHR facility without modification or augmentation by this ISG.

14a2.4 Surveillance Requirements

14a2.4.1 Reactor Core Parameters

The SAR should include the surveillance requirements for liquid fuel, including fuel physical and chemical parameters. If fuel is characterized as a routine function of normal operations, the surveillance measures could be the calibration of the various analytical methods used to perform routine characterization.

14a2.4.2 and 14a2.4.3

The current wording of these sections applies to an AHR without modification or augmentation by this ISG.

14a2.4.4 Containment and Confinement

14a2.4.4.1 Containment

The reactor vessel and gas management system (primary fission-product barrier) of an AHR or the structure that houses them can be considered the containment.

14a2.4.4.2 Confinement

The confinement of an AHR may consist of the structure around the reactor vessel and gas management system, the structure, or part of the structure in which they are housed. It could also serve as a biological shield. Surveillance of the function and efficiency of the confinement components should be conducted periodically.

14a2.4.5 Ventilation Systems

The current wording of this section applies to an AHR.

14a2.4.6, 4.7, 4.8, 4.9

The current wording of these sections applies to an AHR.

14a2.5, 14a2.6, 14a2.7, 14a2.8

The current wording of these sections applies to an AHR.

14b Radioisotope Production Facility Technical Specifications

14b.1 Introduction

The TS for SNM, radiochemical, and chemical processing that is conducted outside of the reactor are derived from ISAs, in particular as described in 10 CFR 70.61(e). The ISAs of these processes indicate that certain limits on process variables and engineered or administrative control measures may become necessary to demonstrate safe operation of the radioisotope production facility. One such method would be demonstrating an ability to meet the criteria specified in 10 CFR 70.61(b), (c), and (d), which would demonstrate an acceptable Integrated Safety Analysis and also meet the criteria for TS in 10 CFR 50.36. Certain engineered or administrative control measures will be designated as IROFS, and they should be listed in these TS to ensure that they will be available and reliable to perform their intended functions if needed.

As used in Section 14b of this chapter and elsewhere in this ISG, the terms “integrated safety analysis (ISA)” and “items relied on for safety (IROFS)” are not intended to mean that the accident analysis required by 10 CFR 50 must take the form of an ISA with designated IROFS as described in 10 CFR 70.61 and 70.62, only that the use of ISA and designation of IROFS that meet the performance requirements of 10 CFR 70.61 may be found acceptable by NRC staff. Alternate accident analysis methodologies and designation of engineered safety features may be found acceptable if the applicant demonstrates tha the proposed equipment and facilities are adequate to protect health and minimize danger to life or property, and that the proposed procedures to protect health and to minimize danger to life or property are adequate.

The format and content of the TS for radiochemical, chemical, and SNM processing outside of the reactor may be presented as prescribed below (per Appendix 14.1 to this chapter of NUREG-1537).

The assignment of TS for a radioisotope production facility must comply with the regulations in 10 CFR 50.36 pertaining to a fuel reprocessing facility, which is a specific type of production facility akin to a radioisotope separation facility. The TS should be assigned using a graded approach. SLs and control setpoints should be placed on those process variables that, if breached, would lead to the uncontrolled release of radioactive material. Ideally, these would apply to a critical few variables. The majority of the process variables would be assigned to the other specification categories that are less critical.

The format of the TS may be as suggested in appendix 14.1 to Chapter 14 of NUREG-1537, or the TS may be organized differently as necessary for the particular purpose of the specifications. Responses or reactions to deviations from TS depend on the severity of the situation, and appropriate response actions should be included as part of the specification.

14b.2 Safety Limits and Limiting Safety System Settings

The SL and limiting control settings are derived from ISAs. They are primarily engineered controls that are put in place to ensure that operations are maintained within adequate margins

of safety. NUREG-1537, Part 1, Appendix 14.2, applies to operations with radioactive material, SNM, and hazardous chemicals, as well as to reactor operations.

The format and content of the TS for radiochemical, chemical, and SNM processing outside of the reactor may be presented as prescribed below (per Appendix 14.1 to chapter 14 of NUREG-1537).

14b.2.1 Safety Limits for Processing Irradiated Special Nuclear Material Outside of the Reactor

The paramount concern with any work involving SNM is to avoid criticality accidents. Limits should be derived using the guidance and criteria for criticality accident prevention in Section 6b.3 and also as derived from performing ISAs according to Sections 13b.1 and 13b.2 of this ISG. Limits should be specified, using the double-contingency principal, to avoid a criticality accident. Limits should be set with a conservative margin.

Containment of fission products is necessary when processing irradiated SNM. Appropriate limits must be imposed pursuant to 10 CFR 50.36(c)(1) to ensure that fission products will be controlled to prevent excessive releases from the containment components, systems, or structures, particularly those structures, systems, and components containing large inventories of byproduct material.

14b.2.2 Safety Limits for Processing Unirradiated Special Nuclear Material Outside of the Reactor

The paramount concern with any work involving SNM is to avoid criticality accidents. Limits should be specified, using the double-contingency principal, to avoid a criticality accident. Limits should be set with a conservative margin.

14b.2.3 Safety Limits for Radiochemical Processing

Operations with radioactive materials must be conducted within limits pursuant to 10 CFR 50.36 to protect the staff and the public (refer to Section 14b.1, Introduction). The amount of radiation should be limited so as not to exceed the shielding and confinement capabilities of the systems and components in which the materials are processed or stored.

14b.2.4 Safety Limits for Chemical Processing

If operations with hazardous chemicals are conducted coincident to operations with SNM or radioactive material, the licensee must propose relevant safety limits in accordance with 10 CFR 50.36. These safety limits could take the form of IROFS designated in an ISA and defined in 10 CFR 70.4 and described in 10 CFR 70.61(e). The terms “integrated safety analysis (ISA)” and “items relied on for safety (IROFS)” are not intended to mean that the accident analysis required by 10 CFR 50 must take the form of an ISA with designated IROFS as described in 10 CFR 70.61 and 70.62, only that the use of ISA and designation of IROFS that meet the performance requirements of 10 CFR 70.61 may be found acceptable by NRC staff. Alternate accident analysis methodologies and designation of engineered safety features may be found acceptable if the applicant demonstrates that the proposed equipment and facilities are adequate to protect health and minimize danger to life or property, and that the proposed procedures to protect health and to minimize danger to life or property are adequate.

14b.2.5 Limiting Safety System Settings

For each process variable or parameter for which an SL is specified and for which monitoring instruments are employed, a protective operating limit should be set to avoid exceeding the SL. This setpoint should be calculated to provide a conservative margin below the SL and to account for overall measurement uncertainty, operating characteristics of control systems, and accuracy of control instrumentation.

LSSSs should be established, as much as possible, to ensure adequate safety margins for each of the processes listed in Sections 14b.2.1, 14b.2.2, 14b.2.3, and 14b.2.4 above.

14b.3 Limiting Conditions for Operation

LCOs are derived from SARs and ISAs. They are administrative or engineered controls in addition to LSSSs that are put in place to ensure that operations are maintained within safe limits. The wording in NUREG-1537, Part 1, Appendix 14, Section 14.3, applies to operations with radioactive material, SNM, and hazardous chemicals, as well as to reactor operations.

14b.3.1 Primary Process Components and Systems

Processing structures, systems, or components and procedures that are designed and constructed to ensure that processing is conducted safely must have LCOs established for each of the processes defined in Sections 14b.2.1, 14b.2, 14b.3, and 14b.4 above. These limiting conditions should be operable when each of the corresponding processes are conducted. This section should enumerate these components and systems.

14b.3.2 Containment and Confinement

Any confinement or containment systems that are required as a result of the SAR or ISA for a particular process must be defined as an LCO and must be listed as such in this section pursuant to 10 CFR 50.36(c)(1).

14b.3.3 Ventilation Systems

If the SAR or ISA for any of the above-referenced processes prescribes the need for certain ventilation configurations, they must be listed here as an LCO pursuant to 10 CFR 50.36(c)(1).

14b.3.4 Emergency Electrical Power

If the SAR or ISA for any of the above-referenced processes prescribes the need for emergency electrical power, the power supply must be listed as an LCO pursuant to 10 CFR 50.36(c)(1).

14b.3.5 Radiation Monitoring Systems and Effluents

Refer to NUREG-1537, Chapter 14, Appendix 14.1, Section 3.7. The requirements of this section must be specified here as they pertain to any of the above-referenced processes pursuant to 10 CFR 50.36(c)(1).

14b.4 Surveillance Requirements

Surveillance requirements for any of the LSSSs and LCOs listed in the previous sections pertaining to the processing of SNM, radioactive materials, and hazardous chemicals must be established and also be listed as a TS pursuant to 10 CFR 50.36(c)(3). Surveillance requirements should exist for the LSSSs and LCOs in the following categories:

- Process control instrumentation
- Process cooling systems
- Process containment/confinement systems
- Process-related ventilation systems
- Emergency power supplies
- Radiation monitoring systems

14b.5 Design Features

Refer to NUREG-1537, Chapter 14, Appendix 14.1, Section 5. The requirements of 10 CFR 50.36(c)(4) must be specified here as they pertain to any of the above-referenced processes.

14b.6 Administrative Controls

Refer to NUREG-1537, Chapter 14, Appendix 14.1, Section 6. The requirements of 10 CFR 50.36(c)(5) must be specified here as they pertain to any of the above-referenced processes.

14b.7 References

The references cited in Appendix 14.1 to NUREG-1537, Chapter 14, apply. The following references have been updated:

- ANSI/ANS 15.1 was updated in 2007.
- ANSI/ANS 15.4 was updated in 2009.
- NRC Regulatory Guide 2.4, 1977, “Review of Experiments for Research Reactors.”

15 FINANCIAL QUALIFICATIONS

NUREG-1537, Part 1, Chapter 15 of the format and content guide, as augmented by this ISG, provides 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.

In the second paragraph, the reference to 10 CFR 2.790 has been replaced with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." This provides the regulatory basis forSections 15.1 through 15.3 below.

15.1 Financial Ability To Construct a Non-power Reactor

The first paragraph is replaced with: "An applicant for a construction permit to build a non-power reactor shall submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. Pursuant to 10 CFR 50.33(f)(1) the applicant shall submit estimates of the total construction estimates of the facility and related fuel cycle costs and shall indicate the sources of funds to cover these costs."

15.2 Financial Ability To Operate a Non-power Reactor

The first paragraph is replaced with: "An applicant for an operating license shall submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant shall submit estimates for total annual operating costs for each of the first 5 years of operation of the facility. Pursuant to 10 CFR 50.33(f)(2) the applicant shall also indicate the sources of funds to cover these costs. An applicant for renewal of an operating license for a non-power reactor shall include the financial information that is required in an application for an initial license pursuant to 10 CFR 50.33."

15.3 Financial Ability To Decommission the Facility

The fourth sentence of the first paragraph is replaced with: "The decommissioning report must contain a cost estimate for decommissioning the facility, an indication of which method or methods described in 10 CFR 50.75(e) are to be used to provide funds for decommissioning, and a description of the means of adjusting the cost estimate and associated funding level periodically over the life of the facility to account for changes in the costs of such items as labor, energy, and waste disposal."

The first sentence of the third paragraph is replaced with: "The acceptable methods of providing financial assurance for decommissioning are discussed in 10 CFR 50.75(e)(1)."

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 requiested 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 1, Chapter 16 of the format and content guide, as augmented by this ISG, is applicable to providing a description of other licensing 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 1, Chapter 17 of the format and content guide, as augmented by this ISG, is applicable to providing 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.

Most of the current content of this introductory section is outdated. For the purpose of this ISG, it should read: "The NRC has developed a systematic approach for licensee and NRC actions to terminate facility licenses. Regulation 10 CFR 50.82 requires that an application for termination of a license be preceded or accompanied by a proposed decommissioning plan (DP). The following guidance is offered to facilitate the composition and review of such DPs."

17.1 Decommissioning

The following new section has been added to NUREG-1537, Part 1:

17.1.0 Decommissioning Report

> Under 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, how reasonable assurance will be provided that funds will be available to decommission the facility. At a minimum, 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. Additional information on funding can be found in NUREG-1537, Chapter 15, 'Financial Qualifications.'

17.1.1 Preliminary Decommissioning Plan

This section is amended to read:

> Under 10 CFR 50.75(f)(4), licensees must submit a preliminary DP 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 [(1) through (5)] in this section of the NUREG-1537 apply to a non-power reactor and radioisotope production facility, except that the regulation referenced in (1) should be changed to 10 CFR 50.82(b)(4)(i).

The last paragraph of this section is amended to read: "The preliminary DP only needs to address the five factors listed above and may be substantially less detailed than the final DP. Additional information on financial aspects of decommissioning may be found in Chapter 15, 'Financial Qualifications,' of this guide."

17.1.2 Decommissioning Plan

The current NUREG-1537 remains unchanged except as follows:

- In the second paragraph, the references to sections of the regulations are 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).

- In the fourth paragraph, the reference to the section of the regulations is changed from 10 CFR 51.53(b) to 10 CFR 51.53(d).

17.1.3 Decommissioning Alternatives

The current NUREG-1537 remains valid except in the last paragraph, where the reference to the regulations is changed from 10 CFR 50.82(b)(1)(iii) to 10 CFR 50.82(b)(4)(i) in the first sentence.

17.1.4 Release Criteria and Final Survey

The current wording of this section no longer applies. It's revised to read: "As set forth in 10 CFR 20.1402, prior to terminating a license, the NRC shall determine that the health and safety of the public will continue to be protected after the facility and site are released. The requirements for terminating a non-power reactor license are found in 10 CFR 50.82(b). The criteria that must be met to release sites that are licensed under 10 CFR Part 50 (and others) for unrestricted use are in 10 CFR 20.1402, which requires that the residual radioactivity be reduced to a level that is ALARA and that any radiation above background radiation will not result in an annual TEDE to an average member of the critical group greater than 0.25 mSv (25 mrem), including the dose from ground water sources of drinking water."

17.1.5 Format and Content of Decommissioning Plan

The last paragraph of this section should be changed to read: "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. This recently developed guidance is contained in 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." Therefore, NUREG-1537, Appendix 17.1, "Format and Content of Decommissioning Plan for Non-Power Reactors," may serve as the basic outline for the DP, but the content should be augmented by including appropriate parts of NUREG-1757."

17.2 Possession-Only License Amendment

This section, as currently worded, applies to a non-power reactor and radioisotope production facility. The references to the regulations in this section is changed as follows: in the second paragraph, the reference to 10 CFR 50.82(b)(1)(iii) is changed to 10 CFR 50.82(b)(4)(i).

17.2.1 Application for a Possession-Only License

The section and subsections of NUREG-1537, Part 1, as currently worded, apply to a non-power reactor and radioisotope production facility.

Appendix 17.1

As stated in Section 17.1.5 of this chapter, this appendix should be used in conjunction with the newer document 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.

17.10 References

The current list of references applies, with the exception of ANSI/ANS 15.1, which was updated in 2007.

18 HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSION

NUREG-1537, Part 1, Chapter 18 of the format and content guide, 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.

This portion of the ISG describes the data that should be included in the environmental report(s) (ER) that are submitted as part of an application to construct, operate, or decommission a radioisotope production facility. The applicant should submit ER(s) to assist the NRC in conducting an expeditious environmental review.

Because of the broad range of technologies, designs, and construction methods to build and operate radioisotope production facilities, the NRC staff wrote the ISG using a conservative approach that covers a range of potential technologies and construction methods. As such, certain data needs may not be applicable for some applications. The information provided in the ER should address the likelihood of significant impacts to the human environment posed by the proposed action. Consistent with the provisions set forth in 10 CFR 51.45(b)(1), impacts should be discussed in proportion to their significance. For example, construction and operation of a new nuclear facility at a previously undisturbed site near sensitive environmental resources would require more detail than construction and/or modification and operation of a facility within an existing building at an industrial site.

The ER should present a thorough description of each affected resource area for the evaluation of potential impacts to the environment. It may not be necessary for every resource to receive the same level of detailed review, and every action may not require all the information discussed in this section. Likewise, the proposed action may present unique issues and may require additional information. This is consistent with one of the goals of NEPA, which is to concentrate on issues significant to the proposed action and their potential environmental impacts, and further, that affected resources are analyzed in proportion with their importance and the expected level of impact to them.

The applicant may benefit from a pre-application meeting with the NRC licensing and environmental project managers (PMs) to discuss the information needed to support the environmental review. The goal of such a meeting is to define the scope and detail of

information that should be provided in the ER. NUREG 1537, Part 2, Section 12.12 describes how the NRC staff uses the information in the ER to prepare an EA or EIS.

The information that applicants/licensees should provide in each section of the ER is described in the following sections.

19.1 Introduction of the Environmental Report

The introduction should include a brief description of the proposed action, location of the proposed action, and any other relevant background information.

19.1.1 Purpose and Need for the Proposed Action

This section should explain the purpose and need for the proposed action and should not be written merely as a justification for the proposed action. Examples of purpose and need include a benefit provided if the proposed action is licensed and implemented and/or descriptions of the disadvantages that would be experienced without the proposed action. For example, a description of the purpose and need can be supported by describing how the proposed action would satisfy global, national, or regional projected demands for the radioisotope 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.

19.1.2 Regulatory Provisions, Permits, and Required Consultations

As described in 10 CFR 51.45(d), this section should list and summarize the status of all applicable federal, state, local, and other regulatory requirements, permits, and consultations that would be required for the proposed facility to be constructed and operated. The following information should be provided in the ER, as applicable:

- Name of each regulatory agency involved in a consultation, review, approval, and authorization, and the applicable law, ordinance, or regulation;
- Activity to be covered by the consultation, review, approval, or authorization;
- Current status of each consultation, review, approval, and authorization;
- Potential administrative delays or other problems preventing agency consultation, review, approval, or authorization; and
- Summary of any surveys required to complete consultation (such as threatened and endangered species or archaeological surveys) and the status of such surveys.

19.2 Proposed Action

The applicant should describe the proposed action and briefly summarize the information provided in the ER, referencing other sections for more detail. As described in the introduction to this ISG, the information requested below may not be applicable for all applications:

- Detailed description of the proposed action and the general progression of the project including construction, pre-operational, operational, and post-operations activities, as appropriate;

- A schedule showing the major phases of the proposed action, including construction (including existing facility modifications), pre-operational, operational, and post-operational activities;

- Estimated total amount of land that would be temporarily affected by construction activities (e.g., land clearing, material and equipment lay-down areas) and permanently affected by operational activities (e.g., building and support facility footprints) in acres or percent of total acreage at the site of the proposed action;

- Projected number of full-time onsite workers during each of the major phases of the proposed action including the number of construction workers (average and peak) as well as pre-operations, operations, and post-operations workers in full-time equivalents (FTEs);

- Estimated amount of materials (e.g., fuel oil, gasoline, construction and process materials) and equipment requirements including average number of truck deliveries and shipments of waste material offsite per day, week, or month during each of the major phases of the proposed action during construction, pre-operations, operations, and post-operations;

- Full names of all organizations sharing ownership of the proposed action.

Site Location and Layout

- Site location, including distance and direction from the nearest major city, nearby towns, nearby inhabitants, sensitive populations (e.g., schools, daycare facilities, retirement homes, etc.), and landmarks, including highways, rivers, or other bodies of water within 5 mi (8 km) of the facility;

- Facility latitude and longitude coordinates;

- Size in acreage of the site and/or sites and facility layout, including the site boundary;

- Any infrastructure improvements, including electrical and water supply, needed to support the proposed action (e.g., substations, onsite wells, treatment facilities);

- List of current or proposed buildings or areas used for chemical, oil, diesel fuel, and other hazardous material storage, waste management (radioactive and nonradioactive), vehicle cleaning, administration, operations and maintenance, shipping and receiving, generating electricity, health and security, parking, etc.;

- Underground storage tanks, wells, pipelines, water supply, sewage and stormwater systems; and

- Air, groundwater, surface water, meteorological, and/or ecological monitoring stations or proposed monitoring stations.

Non-Power Reactor and Utilization or Production Facility

Non-Power Reactor

- The number and description of each reactor;

- Fuel description, total quantities of uranium, percentage U-235 enrichment, and the planned average irradiation level of spent fuel[1]; and

- A simplified flow diagram for the reactor-power conversion system.

Radioisotope Production Facility

- A description of the radioisotope production system, including any relevant flow diagrams.

Other Systems

- A description of any other relevant production system, including any relevant flow diagrams.

Water Consumption and Treatment

- A narrative description and water-use diagram for the reactor and processing facility showing flow rates to and from the various water systems (e.g., circulating water system, sanitary system, radwaste and chemical waste systems, service water systems), water system interconnections and interdependence, points of consumption, and source and discharge locations;

- For water sources independent of a municipal or commercial supply, the data and narrative description for maximum water consumption, water consumption during periods of minimum water availability (e.g., low-flow conditions), and average water consumption by month and by facility operating status; and

- A description of water treatment systems used in the facility

  - Identification, quantities, and points of addition of chemicals and additives to be used by each system;

  - Operating cycles for each water treatment system for normal facility operation.

Cooling and Heating Dissipation Systems

- System descriptions;

- In cases where water intake and discharge systems are proposed, include:

  - A drawing of the intake and discharge lines and structures showing the relationship of the inlets and outlets to the water surface, bottom geometry, and shoreline;

  - A description of any cooling water pumping facility;

[1] This may be considered used fuel for facilities that do not use reactor technology.

- A description of any trash racks, traveling screens, trash baskets, and fish return devices;

- Performance characteristics (i.e., flow rates, intake and discharge velocities, and discharge temperature and temperature differential) for normal facility operation; and
- The location and description of components for the addition of chemicals (e.g., corrosion inhibitors, antifouling agents) to the intake and discharge system.

- For heat-dissipation systems, include:

  - The location of heat dissipation system components relative to other site features;

  - The design details of heat dissipation system components affecting system performance; and

  - Heat dissipation system performance characteristics for normal facility operation.

Waste Systems

- Descriptions of all (i.e., nonradioactive, radioactive, mixed, and hazardous waste materials) proposed or current waste systems, including quantities, composition, and frequency of waste generation (Effluent discharges do not need to be discussed here if they will be covered in other Sections in 12.12.3 (i.e., air effluents in Section 12.12.3.2 (Air Quality) and liquid effluents in Section 12.12.3.4 (Water Quality).);

- Information on proposed or current hazardous material disposal activities including transportation, size, and location of hazardous material disposal sites both on and offsite;

- Identification of all sources of radioactive liquid, solid, and gaseous waste material within the facility and nearby operating facilities;

- Identification of direct radiation sources stored onsite or near the site (i.e., independent fuel storage, low-level radioactive waste storage, or storage of radiation facility equipment);

- Identification of the type and quantity of radionuclides and hazardous materials associated with the facility;

- Description of any pollution prevention and waste minimization program.

Storage, treatment, and transportation of radioactive and nonradioactive materials, including fuel, waste, radioisotopes, and any other materials

- A summary of how radiological and hazardous materials would be stored, handled, and utilized;

- The capacity of the onsite storage facilities to store target or reactor fuel materials, irradiated fuel, and radioisotope products, as applicable, and the storage time between removal from the reactor and transportation offsite;

- Identification of treatment and packaging procedures for radioactive and nonradioactive wastes and radioisotope products;

- Transportation packaging systems to be used for fresh fuel and targets, spent fuel, and other wastes and radioisotopes;

- Estimated transportation distance from the fuel fabrication facility to the reactor and from the reactor to the facilities to which irradiated targets, fuel, radioactive waste, nonradioactive wastes, and radioisotopes would most likely be sent; and

- Estimated transportation distance, number of shipments, and mode of transportation that would be used to transport radioisotopes from the proposed facility to other purification and processing facilities.

19.3 Description of the Affected Environment

The affected environment describes baseline (existing) conditions at the site of the proposed action. Baseline conditions are used to measure changes in the affected environment caused by the proposed action, the impacts of which are discussed in Section 12.12.4. Descriptions of affected resources should be of sufficient detail to permit the evaluation of changes from baseline conditions because of the proposed action.

Depending on the scope of the proposed action and immediate environs, it may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below. Consistent with NRC's regulations in 10 CFR 51, Appendix A (6) "Affected Environment," applicants should provide data and analyses commensurate with the importance of the impact, with less important material summarized, consolidated, or simply referenced.

19.3.1 Land Use and Visual Resources

The applicant should describe existing on and offsite land use conditions and land cover. The following information should be provided in the ER:

Land Use

- Land uses, both on and offsite, that could be affected by the proposed action;

- Maps of the site(s) showing current and proposed site boundaries, exclusion areas, site structures, infrastructure, restricted areas, and current and proposed facilities;

- Maps showing major land uses in the region, such as U.S. Geological Survey land use categories within 5 mi (8 km) of the facility;

- Special land use classifications (e.g., American Indian or military reservations, wild and scenic rivers, parks, forests, designated coastal zone areas, wildlife and wilderness areas, and U.S. Department of Agriculture Natural Resources Conservation Service (NRCS)-designated prime and important farmland soils) within 5 mi (8 km) of the facility;

- Federal facilities, including national parks, national forests, national wildlife refuges and wilderness areas, American Indian and/or Bureau of Indian Affairs lands held in trust for American Indians, and Indian tribes' lands and distances within 5 mi (8 km) of the proposed site;

- Information from NRCS on the relative value of the land acquired for the new facility if it involves farmland;

- Principal agricultural products within the area, facilities, agricultural practices, game harvests, or food processing operations;

- Mineral resources within the area;

- Description of the regional setting, transportation corridors, residential areas, airports, industrial and commercial facilities, and railroads; and

- Land-use plans involving the site(s) affected by the proposed action including current and future plans.

Visual Resources

- Description of the visual setting (i.e., viewshed) of the area being affected;

- Identification and description of the height, color, shape and visibility of the tallest proposed structures, as well as direction and distances from which these structures would be visible;

- Identification of any sensitive viewsheds that might be affected by the proposed action, including any associated tourist or scenic areas of interest; and

- Rating of the aesthetic and scenic quality of the site in accordance with the U.S. Bureau of Land Management (BLM) Visual Resource Management System.

19.3.2 Air Quality and Noise

The applicant should characterize atmospheric transport and diffusion processes and the acoustic (noise) environment at and near the site of the proposed action. The following information should be provided in the ER, as applicable:

- Description of the general climate of the region (e.g., climatological averages of parameters such as temperature, precipitation, and wind speed/direction);

- Summarized monthly and annual meteorological data, including averages, measured extremes, and diurnal range, measured as near as possible to the site for the most recent 5-year period;

- Summary of wind flow data for the site, if available, or as measured at the nearest recording station (e.g., airport, national weather service office, etc.);

- Discussion of severe weather phenomena (e.g., tornadoes, hurricanes, thunderstorms, atmospheric stagnation episodes) with expected frequencies of occurrence and measured extremes of parameters such as temperature, precipitation, and wind speed;

- Description of regional air quality, including the locations of mandatory Federal Class I areas and identification of pollutants which are in non-attainment or maintenance areas and the relationship of the site to these areas;

- Description of programs or policies to reduce greenhouse gas emissions;

- Discussion of any current or past noise studies and analyses conducted at the proposed site or within an audible range of the site;

- List of the loudest noise generating facilities and activities at the proposed site or audible from the proposed site; and

- Description of sensitive noise receptors that could be affected by the proposed action.

If appropriate meteorological data are not available specifically for the site, applicable data from nearby sources (e.g., airport, federal or state-maintained ambient air quality station) may be used.

19.3.3 Geologic Environment

The applicant should identify the geological, seismological, and geotechnical characteristics of the site and surrounding area. The following information should be provided in the ER, as applicable:

- Stratigraphy and structures, including descriptions of geologic units, major structural and tectonic features (e.g., faults), and any other significant geological conditions;

- Summary of geotechnical investigations conducted to characterize the site;

- Characteristics of soil, including a physical description of the soil units and descriptions of features related to soils at the site and nearby;

- Identify any soils that are prime, unique, or farmland of statewide or local importance on or adjacent to the proposed site;

- Description of erosion potential at the site and current onsite erosion control and run-off best management practices;

- Description of seismic potential at the site and seismic history;

- Summary of the historical local and regional seismic activity, volcanism, or any information that may indicate a geologic hazard at the site (e.g., tsunamis), including

whether any identified geologic faults are “capable” (potentially active) per 10 CFR 100, Appendix A; and

- Other geologic hazards such as onsite or nearby landslide areas, areas of land subsidence, karst features, and/or soils with a high shrink-swell potential, etc.

19.3.4 Water Resources

The applicant should describe site-specific and regional data on the physical and hydrological characteristics of surface water and groundwater in sufficient detail to provide the basic data for the evaluation of impacts on waterbodies and aquifers within the potentially affected area. The following information should be provided in the ER, as applicable:

- For freshwater streams potentially affected by the proposed action, provide the following:
  - Historic monthly flow information, including maximum, average-maximum, average, average-minimum, and minimum flow; and
  - Historical drought stages and discharges by month, and the 7-day once-in-10-yr low flow;
- For lakes and impoundments potentially affected by the proposed action, provide the following:
  - Elevation-area-capacity curves;
  - Reservoir operating rules, if applicable; and
  - Annual yield and dependability;
- For estuaries and oceans potentially affected by the proposed action, provide the following:
  - Shoreline and bottom descriptions, including seasonal variations due to sediment transport; and
  - Monthly river discharge including maximum and minimum discharge and, for estuaries, flushing characteristics.
- For facilities that would use water from a public water supply system, provide the following:
  - The amount of water that would be obtained from the public water supply system;
  - Current supply system capacity; and
  - Other major water users of the public water supply system.
- The following groundwater characteristics should be provided for features that could be affected by the construction, operation, and decommissioning of proposed facilities:

- Historical and seasonal trends in groundwater elevation or piezometric levels;
- Piezometric contour maps, water table contour maps, and hydraulic gradients (historical, if available, and current);
- Depth to water table for unconfined aquifer systems;
- Historical and current data from site wells (e.g., monitoring, background, corrective action, or other uses);
- Hydrostratigraphy of the site, including cross sections and hydrostratigraphic unit descriptions; and
- Qualitative description of groundwater aquifers, including identification of U.S. Environmental Protection Agency (EPA)-designated sole-source aquifers.

- A description of present and reasonably foreseeable future surface water uses (withdrawals, consumption, and returns, including but not limited to, domestic, municipal, agricultural, industrial, mining, recreation, navigation, and hydroelectric power); groundwater withdrawals; and nonconsumptive water uses (e.g., recreational, navigational, instream, etc.) that may affect or be affected by construction, operations, and decommissioning. This should include any bodies of water or aquifers at distances close enough to affect or be adversely affected by the facilities;
- Descriptions of past, present, and reasonably foreseeable pollutant sources with discharges to water that may interact with the facility, including locations relative to the site and the affected waterbodies, and the magnitude and nature of the pollutant discharges, including temporal variations.

19.3.5 Ecological Resources

The applicant should describe the ecological resources potentially affected by construction, operation, and/or decommissioning. Ecological resources include members and attributes of aquatic, terrestrial, riparian, and wetland plant and animal communities. Wetlands and riparian habitats are the interface between aquatic and terrestrial habitats and as defined by EPA in 1993 as follows:

> [Wetlands are] those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.
>
> [Riparian areas are] vegetated ecosystems along a waterbody through which energy, materials, and water pass. Riparian areas characteristically have a high water table and are subject to periodic flooding and influence from the adjacent waterbody. These systems encompass wetlands, uplands, or some combination of these two land forms; they do not in all cases have all of the characteristics necessary for them to be classified as wetlands.

The following information should be provided in the ER, as applicable:

Offsite

The ER should describe:

- the ecoregion, ecosystems, and habitats surrounding the site;
- the geomorphic, or physiographic, province;
- characteristic vegetation and animal species, including climax vegetation and typical succession in the area of the site; and the ecological province of the ocean if the facility is located near an ocean or estuary.

Onsite

The ER should describe:

- the local environment of the site;
- vegetation and animal communities;
- quantification and a description of physiographic habitats (such as upland forest, swamp marshes, wetlands, rivers, streams, etc.) onsite and quantification of the extent of habitats to be directly and indirectly affected by proposed construction, operation, and decommissioning.

The ER should also include topographic maps and descriptions, as appropriate.

History

The ER should provide a short historical description of the ecological environment. This description should include major changes or modifications to the land and/or waterbodies (e.g., channelization, navigation, pollution, habitat degradation or fragmentation, urbanization, development, and pond or reservoir creation). The ER should briefly describe major wildlife species and populations currently and historically living within the potentially affected area .

Places and Entities of Special Interest

The ER should provide the occurrence, location, and description of communities and habitats of special interest within the potentially affected area, such as wetlands; natural heritage areas and other areas of public or scientific interest; other areas that may be particularly sensitive or susceptible either directly or indirectly to the effects of the proposed construction, operations, or decommissioning; important ecological systems that are especially vulnerable to change or that contain important species habitats, such as areas used for breeding, (nesting and nursery areas), feeding, resting, overwintering, or other areas containing seasonally high concentrations of individuals of important species.

Aquatic Communities and Potentially Affected Waterbodies

The ER should describe the relative significance of various aquatic habitats in a regional context. Additionally, the ER should briefly describe the aquatic communities within potentially affected waterbodies based on available information (e.g., present and past studies, federal and state sources). This description should focus on a subset of representative and important species, such as those with the following characteristics:

- potential or reported susceptibility to construction or operational impacts;
- dominance, commonness, or rarity in numbers or biomass;
- importance to the structure and function of the ecosystem, such as 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 shell fishing;
- those species with fish consumption advisories; and
- those species that provide unique ecosystem services.

Terrestrial Communities

The ER should describe the terrestrial communities briefly using available information (e.g., present and past studies, federal and state sources). This description should include:

- a summary of representative species of plants, mammals, birds, reptiles, amphibians, and insects;
- a description of endemic species, sensitive or indicator species, keystone species, or important recreationally hunted species;
- a description of bird species that nest within the potentially affected area, migratory species and their seasonal use of habitat within the affected area, known migratory bird rookeries within the affected area, and, if applicable, the location of the site in relation to any nearby flyways;
- a description of the types of vegetative communities, especially any delineated wetlands or potential wetland habitat found within the potentially affected area;
- any applicable correspondence with the U.S. Army Corps of Engineers or other Federal or State agencies regarding any applicable Clean Water Act 404 or other wetland-related permits;
- any available botanical surveys conducted within the potentially affected area, within an area with similar vegetation as the proposed site, or within an area recommended by local, State, or Federal natural resource agencies; and

- a description of the relative significance of various terrestrial habitats in a regional context.

Invasive Species

The ER should provide occurrences of aquatic and terrestrial invasive species within the potentially affected area. The ER should document any management activities undertaken by the facility to control such species.

Procedures and Protocols

The ER should describe management plans for aquatic and terrestrial ecosystems and best management practices (if applicable), including pesticides and herbicides used and ground-disturbing activities performed routinely to maintain the site.

Studies and Monitoring

The ER should briefly summarize any aquatic or terrestrial studies or monitoring programs within the potentially affected area or within an area that has similar aquatic or terrestrial resources as the proposed site. The summary of surveys should include the location, dates, objective, methods, and results applicable to the application. The ER should also identify any data or data summaries that may be available for NRC review.

Protected Species and Habitats

This section of the ER should include information on species and habitats protected under the Endangered Species Act of 1973, as amended (ESA), habitat protected under the Magnuson-Stevens Fishery Conservation and Management Act, as amended through 2007 (MSA), as well as any species that are protected under other legislations, including State regulations, the Marine Mammal Protection Act (MMPA), the Migratory Bird Treaty Act (MBTA), and the Bald and Golden Eagle Protection Act (BGEPA), as outlined below:

- The ESA was enacted to protect threatened and endangered species and the ecosystems on which they depend. In accordance with Section 7 of the ESA, Federal agencies must review actions they undertake or support (such as issuing permits and licenses) to determine whether they may jeopardize the continued existence of any listed endangered or threatened species or their habitats.

  If such review reveals the potential to adversely affect listed or candidate species, the Federal agency must consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service (NMFS) (collectively, the Services), as appropriate. The Services implement the interagency cooperation provisions of Section 7 at 50 CFR Part 402, “Interagency Cooperation— Endangered Species Act of 1973, As Amended.”

  The ER should describe the action area (all areas that would be affected directly or indirectly by the proposed action, as defined at 50 CFR 402.02) that the applicant considered for its ESA analysis. The applicant should then determine if Federally listed, proposed, or candidate species; or designated or proposed critical habitat, occurs or have the potential to occur within the action area. For such species and habitats, the ER should provide sufficient information on the species’ life history, historical occurrences,

population size and trends, critical habitat, and potential habitat to aid the NRC in developing its biological assessment. The ER should discuss any activities, including construction, operations, maintenance, transportation, or decommissioning activities, that may directly or indirectly affect such species and habitats. The ER should reference applicable studies and surveys conducted within the action area and available scientific literature on the specific species.

- The MSA includes provisions to protect essential fish habitat (EFH). Federal agencies must consult with NMFS for actions that they authorize, fund, or undertake, or that may adversely affect EFH.

  The applicant should determine if designated EFH exists within the affected area, or within an area recommended by NMFS. For those species with EFH, the ER should provide sufficient information on the species' life history, historical occurrences, population size and trends, the location and description of EFH to aid the NRC in developing its EFH Assessment. The ER should discuss any activities, including construction, operations, maintenance, transportation, or decommissioning activities, that may directly or indirectly affect designated EFH. The ER should reference applicable studies and surveys conducted within the action area and available scientific literature on the specific species.

- Each state promulgates its own regulations to protect state-endangered, threatened, and rare species. The ER should identify state-listed species that occur or have the potential to occur in the action area. Include information on these species similar to that provided for ESA-listed species and habitats.

- Several additional federal laws, including the MMPA, the MBTA, and the BGEPA, also mandate the protection of certain habitats and species. Protected species that have the potential to occur within the affected area, or within an area recommended by local, state, or federal natural resource agencies, should be discussed in the ER. Documentation of related correspondence with the appropriate Federal and State agencies should be included in the ER.

19.3.6 Historic and Cultural Resources

The applicant should identify and describe all historic and cultural resources located on or near the site of the proposed action. Historic and cultural resources include, but are not limited to: prehistoric era and historic era archaeological sites, artifacts, and remains; historic sites, districts, and buildings; and traditional cultural properties (TCPs) that are important to a group, such as an Indian Tribe, for maintaining their culture. The applicant should also identify any historic property that is eligible for listing on the *National Register of Historic Places* (NRHP). "Historic property" is the legal term for a historic and/or cultural resource that is eligible for listing on the NRHP (36 CFR 60) (e.g., more than 50 years old). TCPs can also meet National Register criteria and can be considered historic properties.

Descriptions of historic properties and historic and cultural resources should be of sufficient detail to permit the assessment and evaluation of impacts from the proposed action. The following information should be provided in the ER, as applicable:

- Describe known historic and cultural resources within the affected area and provide an overview of the area's cultural history, including summaries of historical and cultural resource surveys conducted in the area and the types of resources discovered;

- Summarize the results of any archaeological or historical surveys conducted at or near the proposed site(s), including the following:

  – Map and description of the physical extent of the survey, and/or the area of potential effect (APE). The APE is 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.

  – If the entire site was not surveyed, the basis for the limited survey is needed;

    - Brief description of the survey techniques used to conduct the survey;

    - Qualifications of the surveyors; and

    - Survey findings in sufficient detail to permit an assessment of the potential impact of the proposed action on historic and cultural resources;

- Provide a description of any reconnaissance or pedestrian surveys of the proposed site and consultation efforts with the State Historic Preservation Office (SHPO),Tribal Historic Preservation Offices (THPO), American Indian Tribe(s), and/or members of the public used to assess the presence of historic and cultural resources within the APE;

- List of historic properties located within the proposed site or within the APE (These properties are included in State or local registers or inventories of historic and archaeological resources. Guidance can be found on the U.S. National Park Service website at http://www.cr.nps.gov/nr/publications);

- Provide a statement of the significance or importance of each historic property potentially affected; and

- Provide comments from SHPO, THPO, or any organizations and individuals contacted by the applicant who provided significant information concerning the location of historic properties.

19.3.7 Socioeconomics

The applicant should briefly describe socioeconomic conditions in the region (affected counties where construction and operations workers would reside) around the proposed site. Socioeconomic information should be of sufficient detail to permit the evaluation of impacts from the proposed action. The following information should be presented in the ER, as applicable:

- U.S. Bureau of Census information and data on the affected counties, including:

  - Population and demographic information by race and ethnicity and historic and projected population growth rates by county;
  - Median household and per capita income;
  - Civilian labor force by county;
  - Unemployment;
  - Percent of individuals and families living below the Census poverty threshold;
  - Housing: total number of units, number of occupied units, number of vacant units, vacancy rate, and median value;
  - Transient (seasonal) population including students attending colleges and universities within 5 mi (8 km) of the facility;

- Provide local public water supply system information by source (groundwater or surface water, average daily production, system design capacity, and population served);
- Provide information about local public schools: school district(s) and enrollment;
- Map identifying places of significant population grouping, such as cities and towns;
- Provide information on local road networks used to access the proposed site and major regional transportation systems used for the transport of construction materials, radioisotopes, and waste;
  - General condition of site access roads, average annual daily traffic volume and road capacity, if available;
- Provide applicant's tax payment information including information about local tax authorities (i.e., county, municipality, and public school district) that would be directly affected by the proposed action; and
- Provide a brief description of public recreational facilities, (e.g., distance from the site , purpose of the recreational facility, etc.).

19.3.8 Human Health

The applicant should describe existing public and occupational health issues. The following information should be provided in the ER, as applicable:

- Maps, in an appropriate scale, showing the distances from the proposed action to the following points or areas for radial sectors centered on the cardinal compass directions:
  - Nearest site boundary;
  - Nearest full-time resident;

  - Nearest drinking water intake (see Section 12.12.3.4 Water Resources*);* and

  - Nearest sensitive receptors (e.g., schools and hospitals).

- Major sources and levels of background radiation exposure, including natural and man-made sources, expressed in mrem/yr (mSv/yr);

- Description of the radioactive and nonradioactive hazardous liquid, gaseous, and solid waste management and effluent control systems;

- Information on radioactive and nonradioactive effluents released into the environment;

- Radioactive and nonradioactive hazardous material stored on site;

- Current onsite or nearby sources and levels of exposure to members of the public and workers from radioactive materials;

- Major onsite or nearby sources and levels of exposure to members of the public and workers from chemicals;

- Historical exposures to radioactive materials to both workers and members of the public;

- For proposed facilities located near operating facilities using radioactive materials:

  - A description of the radiological environmental monitoring program and environmental data (from the applicant's annual Radiological Environmental Monitoring Reports);

  - Historical maximum individual doses to members of the public (from the applicant's annual Radioactive Effluent Release Reports).

- Relevant occupational injury rates and occupational fatality rates; and

- Summary of relevant health effects studies applicable to the proposed action.

19.4 Impacts of Proposed Construction, Operations, and Decommissioning

The applicant should describe the potential impacts of the proposed action for each resource area described in Section 12.12.3, *Affected Environment*. Environmental impacts, or effects, including direct effects, indirect effects, and cumulative effects. The Council on Environmental Quality (CEQ) regulations at 40 CFR Part 1508, "Terminology and Index," define the three types of effects. In particular, 40 CFR 1508.7, "Cumulative Impact," provides the following definition:

> "Cumulative impact" is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can

result from individually minor but collectively significant actions taking place over a period of time.

In addition 40 CFR 1508.8, "Effects," defines direct and indirect effects as follows:

"Effects" include:

a. Direct effects, which are caused by the action and occur at the same time and place.

b. Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable.

Construction, operation, and decommissioning activities under the proposed action should be evaluated in sufficient detail to determine the significance of potential impacts. Resources should be considered separately, and if necessary, in combination with other resources or conditions (e.g., noise impacts on wildlife, or transportation impacts on land use). In addition, the ER should summarize any mitigation measures that the applicant could take to reduce adverse impacts and describe the anticipated cost-effectiveness of such mitigation measures in reducing adverse impacts.

In general, data needs that are described in Section 12.12.3, *Affected Environment,* are not repeated below. Data provided in Section 12.12.3 should be included in Section 12.12.4 to the extent necessary to describe impacts from the proposed action.

As described above, due to the wide range of potential designs, technologies, and operational methods to build and operate radioisotope production facilities, certain data needs may not be applicable for some applications. Consistent with 10 CFR 51.45(b)(1), impacts should be discussed in proportion to their significance. If any applicant has questions regarding the scope of the data needs for its ER, the applicant may benefit from a pre-application meeting with the NRC licensing and environmental PMs to discuss the information needed to support the environmental review.

19.4.1 Land Use and Visual Resources

This section describes land use and visual resources (aesthetic impacts) caused by the proposed action. The following information should be provided in the ER:

<u>Land Use</u>

- Description of any on- and offsite land-use changes caused by the proposed action, including the number of acres and location of each land use type that would be changed on a temporary and permanent basis during construction, operation, and decommissioning;

- Impacts to any special land-use categories, Federal facilities, or prime or other important farmland; and

- Description of mitigation measures that reduce or minimize adverse impacts.

Visual Resources (Aesthetic Impacts)

- Photos or illustrations of changes to the site caused by the proposed action superimposed on the current viewshed;
- Description of any significant visual changes, including:
  - Facilities that would be out of character with existing architectural features;
  - Structures that may partially or completely obstruct views of existing landscape;
  - Structures that create visual intrusions in the existing landscape character (e.g., radar towers, cooling towers, effluent stacks, etc.);
  - Features of the proposed action that may require the removal of natural or built barriers, screens, or buffers; and
  - Structures that create visual, audible, or other elements that are out of character with the site or alter its setting;
- A determination if the visual impact is compatible or in compliance with any regulations, ordinances, and requirements; and
- Description of mitigation measures that reduce or minimize adverse impacts.

19.4.2 Air Quality and Noise

This section presents key factors and guidance for evaluating air quality and noise impacts caused by the proposed action, including consideration of associated meteorological and climatological conditions. The following information should be provided in the ER:

Air Quality

- Description of gaseous effluents (i.e., type, quantity, and origin), permits needed, and the status of those permits;
- Table comparing effluent (or emission) concentrations to regional air quality parameters (effluent or emission concentrations should be provided for both short- and long-term impacts);
- Estimates of onsite and offsite vehicle and other emissions resulting from construction, operations, and decommissioning, including fugitive dust;
- Release point characteristics (i.e., elevation above grade, inside vent or stack diameter, physical shape, flow rate, effluent temperature, exit velocity, release frequency, or other appropriate information to allow calculation of transport and diffusion);
- Description of gaseous effluent control systems;

- Detailed descriptions of the models and assumptions used to determine normalized concentration and/or relative deposition*;*

- Normalized concentration and/or relative deposition 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*;*

- Description of visibility impacts (e.g., plume);

- Greenhouse gas emissions, including both direct emission from construction, operation, and decommissioning of the proposed facilities and indirect emissions from activities such as commuting, etc.; and

- Description of mitigation measures that reduce or minimize adverse impacts.

Noise

- Predicted noise levels using the decibel A-weighted (dBA) scale;

- Major sources of noise, including all models, assumptions, and input data;

- Comparison to appropriate standards or guidelines;

- Potential impacts to sensitive receptors (e.g., hospitals, schools, residences, wildlife); and

- Mitigation measures to reduce or minimize adverse impacts.

19.4.3 Geologic Environment

This section presents key factors and guidance for evaluating site geologic and soils conditions and geologic resource impacts. The applicant should consider those geologic and soil resources and conditions that could be affected by construction, operation, and decommissioning activities, as well as those geologic conditions and hazards that could affect the proposed action and alternatives. Conditions that could affect the proposed action and specific facilities include large-scale geologic hazards (e.g., earthquakes, volcanic activity, landslides, land subsidence, and erosional processes) and local hazards associated with the site-specific attributes of the soil and bedrock beneath facility sites. The major analysis for seismic and other geologic hazards can usually be found in the Preliminary Safety Analysis Report (PSAR) or similar documentation and only needs to be summarized in this section of the ER. A summary of management practices, design considerations, or policies that would minimize these impacts should be provided.

In addition to the summary of the analysis of the potential impacts of seismic and other geological hazards the applicant should provide the following information in the ER:

- Depth of excavation for below-grade portions of facilities and for such activities as trenching for utilities and piping, roadway construction, etc.;

- Description of the potential for exposing contaminated soil and proposed methods to remediate and/or dispose of any encountered soil contamination;

- Depth of bedrock and whether blasting may be required;

- Estimate of the volume of geologic resources required for project activities (e.g., borrow for backfill, sand and gravel aggregate for construction, etc.);

- Impacts to any rare or unique geologic resources or to rock, mineral, or energy rights and assets (also see Section 12.12.4.1, Land Use*)*; and

- Description of mitigation measures that reduce or minimize adverse impacts.

19.4.4 Water Resources

This section presents key factors and guidance for evaluating impacts on water use and water quality to include impacts for both radiological and nonradiological effluents.

The applicant should consider surface water and groundwater uses that could affect or be affected by the construction, operation, and/or decommissioning of the proposed facility. Other water uses may include, but are not limited to, domestic, municipal, agricultural, industrial, mining, recreation, navigation, and hydroelectric power. The applicant should also consider impacts on the physical, chemical, and biological water-quality characteristics of surface water and groundwater. Because water quality and water supply are interdependent, changes in water quality should be considered simultaneously with changes in water supply.

The following information should be provided in the ER:

- Identification of potentially impacted ground and surface waters, including those receiving effluents and the expected average and maximum flow rates, physical characteristics (e.g., temperature, sediment load, velocities), and composition of radiological and nonradiological pollutants in these effluents;

- Impacts on surface water and groundwater quality including comparison of predicted effluent and receiving-water quality with applicable effluent limitations and water quality standards for both radiological and nonradiological constituents (include conclusions regarding project compliance with these standards, the physical impacts of consumptive water uses [e.g., groundwater depletion] on other water users, and adverse impacts on surface-oriented water users [e.g., fishing, navigation, etc.] resulting from facility activities);

- Identification of hydrological system impacts both onsite and offsite, such as:

  - Water quantity and availability, water flow, and movement patterns,

  - Erosion and sediment transport,

  - Water drainage characteristics, the flood handling capability of the floodplains, and flow and circulation patterns, and

- Subsidence resulting from groundwater withdrawal, and erosion and sediment transport;

- Withdrawals and returns of surface and groundwater during construction, operation, and decommissioning;

- For facilities that would use water from a public water supply system, discuss whether the amount of water required for the proposed action is available from the public water supply system; and

- Descriptions of mitigation measures that reduce or minimize adverse impacts, such as proposed best management practices and measures to control impacts to water quality and/or quantity (e.g., protection of natural drainage channels and waterbodies, protection of shorelines and beaches, restrictions on access to and use of surface water, protection against saltwater intrusion, and handling of fuels, lubricants, oily wastes, chemical wastes, sanitary wastes, herbicides, and pesticides).

Monitoring

- Monitoring plans should be commensurate with the importance of the potential impacts and consider the results of consultation with local, state, and other federal agencies. For water quality monitoring, provide a description of the applicable monitoring plans, including the following:

  - Chemical and physical parameters to be measured;

  - Number and location of sample collection points, measuring devices used, and pathway sampled or measured;

  - Sample size, sample collection frequency, and sampling duration;

  - Method and frequency of analysis including lower limits of detection;

  - Quality assurance procedures.

19.4.5 Ecological Resources

This section presents key factors and guidance for evaluating terrestrial and aquatic ecological impacts from the proposed action. The following information should be provided in the ER:

- Site map showing proposed buildings, land to be cleared, areas to be cleared along stream banks, areas proposed for dredge material, areas to be dredged, and waste disposal areas;

- Total area of temporary and permanent impacts for each habitat type, and an estimate of the amount of these habitats that would be impacted relative to the total amount present in the region;

- Area to be used on a short-term basis during construction or facility modification, and plans for restoration of this land;

- Maintenance practices such as use of chemical herbicides, roadway maintenance, and mechanical clearing that are anticipated to effect biota;

- Estimate of the potential impacts of elevated construction equipment or structures on species (e.g., birds collisions, nesting);

- Tolerances and/or susceptibilities of important biota to physical and chemical pollutants;

- Clearing methods, erosion, run-off and siltation control methods (both temporary and permanent), dust suppression methods, and other construction practices to control or minimize adverse impacts to ecological resources;

- Special maintenance practices used in important habitats (e.g., marshes, natural areas, bogs) including those that result in unique beneficial effects on specific biota;
- Wildlife management practices; and

- Description of mitigation measures that reduce or minimize adverse impacts, such as best management practices or alternative designs to minimize adverse impacts.

Protected Species and Habitats

In addition to the information described above that would be relevant to protected species and habitats, the applicant should provide:

- Documentation of consultations with the FWS and NMFS on the impact of the proposed action on protected species and habitats, especially those protected under the ESA and MSA;

- Documentation of consultations with State and local agencies regarding the impact of the proposed action on important species;

- Any proposed activities expected to impact communities or habitats that have been defined as rare or unique or that support protected species or habitats;

Monitoring

- Monitoring plans should be commensurate with the importance of the potential impacts and include the results of consultation with local, state, and other federal agencies. For ecological monitoring, provide a description of the applicable monitoring plans, including the following:

  - Maps showing major ecological communities, important habitats, and sampling stations and monitoring locations;

  - List of monitoring program elements or parameters including action or reporting levels for each element;

- Sampling design, such as the type, frequency, and duration of observations or samples to be taken at each location;

- Sampling equipment to be used;

- Method of chemical analyses, as applicable;

- Data analysis, statistics or other biological indices that would be calculated as part of the proposed sampling program, and reporting procedures;

- A summary of the quality assurance procedures;

- Documentation of applicant consultations with the FWS, NMFS, appropriate state agencies (e.g., fish and wildlife agency), and American Indian tribal agencies; and

- Documentation of the environmental monitoring programs in policy directives designating a person or organizational unit responsible for reviewing the program on an ongoing basis.

19.4.6 Historic and Cultural Resources

This section presents key factors and guidance for evaluating impacts on historic and cultural resources. Adverse effects occur when a proposed action's effect on a cultural resource diminishes the integrity of its location, design, setting, materials, workmanship, feeling, or association. Adverse effects include, but are not limited to: (i) physical destruction, damage, or alteration of all or part of the historic property; (ii) isolation of the property from or alteration of the character of the historic property's setting when that character contributes to the historic property's qualification for listing on the *National Register of Historic Places;* (iii) introduction of visual, audible, or atmospheric elements that are out of character with the historic property or alter its setting; (iv) neglect of an historic property resulting in its deterioration or destruction; and (v) transfer, lease, or sale of the historic property.

The following information should be provided in the ER:

- Discussion of impacts to historic and cultural resources during construction, operation, or decommissioning, including impacts resulting from land use and visual changes or denial of access;

- Documentation of consultations with the SHPO and/or THPO, as appropriate, concerning the impact of the proposed action on historic properties and other cultural resources and any conclusions resulting from the consultations;

- Discussion of any State laws and plans for historic preservation, if available;

- Discuss the potential for and the process to be followed upon the discovery of human remains at the proposed site; and

- Description of mitigation measures that reduce or minimize adverse impacts, such as practices and procedures or alternative designs that could be used to minimize

adverse impacts. Mitigation measures could include: (i) limiting the scale of the project; (ii) modifying the project through redesign, reorientation, or construction on the proposed action; (iii) repair, rehabilitation, or restoration of an affected historic property as opposed to demolition; (iv) preservation and maintenance operations involving historic properties; (v) documentation [e.g., drawings, photos, histories] of building or structures that would be destroyed or substantially altered; (vi) relocation of historic properties; and (vii) salvage of archaeological or architectural information and materials.

19.4.7 Socioeconomics

This section describes impacts to regional socioeconomic conditions, such as changes in the population, the economy, housing availability, public services, and offsite land use from the proposed action. The following information should be provided in the ER:

Socioeconomics

- Description of impacts to housing, public services (i.e., water supply), public education, and local transportation;
- Description of any tax revenue-related impacts;
- Discussion of methodology used to determine impacts; and
- Description of mitigation measures that reduce or minimize adverse impacts.

Transportation

- Description of construction and/or modification of any access roads, railroads, or other transportation infrastructure that would be utilized to support construction, operations, and decommissioning (see Section 12.12.4.1, Land Use);
- Transportation route(s) and mode for conveying construction material, equipment, and workers to the proposed site;
- Traffic pattern impacts (e.g., impacts from any increase in traffic during construction or shift changes); and
- Description of mitigation measures that reduce or minimize adverse impacts.

19.4.8 Human Health

This section describes public and occupational health impacts from both nonradiological and radiological sources.

Nonradiological Impacts

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- A description of nonradioactive chemical sources (location, type, strength);
- A description of the nonradioactive liquid, gaseous, and solid waste management and effluent control systems;
- Information on nonradioactive effluents released into the onsite and offsite environment;
- Calculated chemical exposure to the public or calculated average annual concentration of nonradioactive releases to air and water; including all models, assumptions, and input data in order to determine compliance (e.g., 40 CFR 50, 59, 60, 61, 122, 129, 131, etc.);
- An assessment of the physical occupational hazards;
- The calculated exposure to the workforce including all models, assumptions, and input data in order to determine compliance with Occupational Safety and Health Standards (OSHA) 29 CFR 1910;
- For facilities located near operating industrial facilities using radioactive materials:
  - A description of the nonradiological environmental monitoring program and environmental data (from the applicant's Environmental Monitoring Reports or other source document).
- A description of the environmental monitoring program; and
- Description of mitigation measures that reduce or minimize adverse impacts.

Radiological Impacts

This section describes the public and occupational health impacts from radioactive material.

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- Physical layout of the site, describing or showing the location of radioactive materials that are expected to be present;
- Characteristics of radiation sources and expected radioactive effluents (i.e., radioactive liquid, gaseous, and solid wastes);
- Baseline radiation levels at the site. Measured radiation dose rates, airborne

radioactivity concentrations, and waterborne radioactivity concentrations at specific current locations where environmental radiological monitoring data exist;

- Calculated radiation dose rates, annual averaged airborne radioactivity concentrations, and annual averaged waterborne radioactivity concentrations at the site boundary, including a description of the methodology and assumptions; or

- Calculated annual total effective dose equivalent to a maximally exposed member of the public in the unrestricted area, including a description of the methodology and assumptions;

- Calculated annual dose to the maximally exposed worker, including a description of the methodology and assumption; and

- Description of mitigation measures that reduce or minimize public and occupational exposures to radioactive material.

Radiological Monitoring

This section describes the monitoring programs used to monitor radioactive effluents released from the proposed facility and to obtain data on measurable levels of radiation and radioactive materials in the environment.

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

Radiological Effluent Monitoring

- For radiological effluent monitoring, provide a general description of the in-plant monitoring plan, including the following:

  – Number and location of sample points, type of measuring devices, and pathways sampled or measured.

Radiological Environmental Monitoring

- For radiological environmental monitoring, provide a general description of the onsite and offsite monitoring plan, including the following:

  – Number and location of sample collection points, type of measuring devices, and pathways sampled or measured.

19.4.9 Waste Management

This section describes the types of radiological and nonradiological waste expected to be generated and the management program used to safely handle, process, and dispose of the waste.

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- Description of the sources, types, and approximate quantities of solid, hazardous, radioactive, and mixed wastes expected from the proposed action;

- Description of proposed waste management systems designed to collect, store, and process the waste;

- Anticipated disposal plans for the waste (i.e., transfer to an offsite waste disposal facility, treatment facility, or storage onsite); and

- Description of waste-minimization plan(s) to reduce or minimize the generation of waste.

19.4.10 Transportation

This section describes the transportation of nuclear and non-nuclear materials, including radioactive waste, nonradioactive waste, and radioisotopes and the associated potential impacts.

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- Transportation mode (i.e., truck, plane, rail, or barge) and projected destinations of the radioactive waste, nonradioactive waste, and radioisotopes;

- Estimated transportation distance from the originating site to the projected destinations of the radioactive waste, nonradioactive waste, and radioisotopes;

- Treatment and packaging for radioactive and nonradioactive wastes;

- Calculated radiological dose to members of the public and workers from incident-free transportation scenarios;

19.4.11 Postulated Accidents

This section describes the radiological and nonradiological impacts from postulated accidents at the facility. The type of data and information needed in the ER will depend on site and plant-specific factors, and the anticipated magnitude of the potential impacts.

The following information should be presented in the ER. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- A list of credible accidents having a potential for releases into the environment (see Section 13, Accident Analysis); and

- An analysis of the radiological and nonradiological consequences from the postulated accidents.

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," 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, CEQ issued, *Environmental Justice Guidance Under the National Environmental Policy Act*. The Council developed this guidance to, "further assist Federal agencies with their National Environmental Policy Act (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.

The scope of this section should include an analysis of impacts on minority and low-income populations and the location and significance of any environmental impacts from the proposed action including proposed facility construction, operations, and decommissioning. The descriptions to be provided by this review should be of sufficient detail to permit the assessment and evaluation of human health and environmental effects, in particular whether these effects are likely to be disproportionately high and adverse to minority and low-income populations.

The following information should be provided in the ER:

- Map showing the location of minority and low-income populations and/or communities, including American Indian and Hispanic populations (as appropriate), as well as any American Indian reservations and other special communities within 5 mi (8 km) of the proposed site;

- A discussion of the methods used to identify the location of these populations and/or communities;

- An assessment (qualitative or quantitative, as appropriate) of the degree to which minority or low-income population could be disproportionately affected during construction, operations, or decommissioning as compared to the effect on the general population;

- An assessment (qualitative or quantitative, as appropriate) of whether the human health and environmental effects on minority and low-income populations are significantly high and adverse. Significance is determined by considering the disproportionate exposure as well as multiple-hazard and cumulative hazard conditions; and

- A description of mitigation measures that reduce or minimize adverse impacts.

19.4.13 Cumulative Effects

Discuss any past, present, or reasonably foreseeable future actions that could result in cumulative impacts when combined with the proposed action. Cumulative impact is defined by the CEQ in 40 CFR 1508.7. In addition, CEQ's "Considering Cumulative Effects Under the National Environmental Policy Act," dated January 1997, provides additional guidance on considering cumulative effects.

Actions to be considered in cumulative impact analyses include proposed and continuing activities that are conducted, regulated, or approved by a federal agency or a non-federal entity. The cumulative impacts analysis takes into account all actions, however minor, since impacts from individually minor actions may be significant when considered collectively over time. The ER should identify other actions (including related and nonrelated federal and non-Federal actions) that could contribute to cumulative impacts, such as:

- Information about current or planned local economic development programs or projects (e.g., commercial, industrial, and/or residential); and

- Information about current or planned infrastructure improvements (e.g., transportation, electric and water utility).

19.5 Alternatives

19.5.1 No-Action Alternative

Consistent with the provisions set forth in 10 CFR 51.45(b)(3) an analysis of the no-action alternative should be included. For applications to construct and operate a new non-power reactor, the no-action alternative usually considers the environmental impacts if the construction permit or operating license is denied. In such case, the environmental impacts would generally be the same as the status quo. The depth and extent of the discussion in the ER should include the expected results from taking no-action, including the potential and reasonably foreseeable programmatic consequences of taking no-action relative to the proposed action.

19.5.2 Reasonable Alternatives

The applicant should summarize the history and process used to formulate the reasonable alternatives. Reasonable alternatives may include, but is 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. If new construction is proposed, at least one alternative location should be analyzed. Additional sites should be analyzed depending on the context, degree, and intensity of potential impacts.

The following information should be provided to summarize the process used to formulate the reasonable alternatives:

- Describe the process used to determine reasonable alternatives to the proposed action;

- Describe all alternatives considered;

- Indicate which alternatives were eliminated from further study and which alternatives are described in further detail; and

- Briefly describe any alternatives considered that would reduce or avoid adverse effects.

The following information should be provided for each reasonable alternative, as applicable:

- A description of the alternative;

- The major direct, indirect, and cumulative impacts, similar to the impacts assessed in 12.12.4; and

- A description of mitigation measures that reduce or minimize adverse impacts.

19.5.3 Cost-Benefit of the Alternatives

This section should discuss the costs and benefits of each alternative and the proposed action, including a qualitative discussion of environmental impacts. The applicant should also provide assumptions and uncertainties in the analyses. The following information (major costs and benefits) should be provided in the ER:

- Qualitative discussion of environmental degradation (e.g., impacts to air and water quality, biotic and aesthetics resources, 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;

- Other costs (e.g., lost tax revenue, decreased recreational value, transportation, as appropriate);

- Qualitative discussion of the environmental benefits (comparable to the discussion of cost and environmental degradation);

- The average annual production of commercial products;

- Expected increase (if any) of tax payments to State and local tax jurisdictions during (1) the construction period and (2) operations;

- Creation and improvement of transportation infrastructure and other facilities; and

- Other benefits.

19.5.4 Comparison of the Potential Environmental Impacts

The applicant should present the impacts of the proposed action and alternatives (including the no-action alternative) in a summary chart or table.

19.6 Conclusions

The following information should be provided in the ER:

- Unavoidable adverse environmental impacts of the proposed action;
- The relationship between short-term uses of the environment and the maintenance and enhancement of long-term productivity; and
- Irreversible and irretrievable commitments of resources used to support the proposed action.

19.7 References

The applicant should provide full citations for all references cited throughout the ER.