OFFICE OF NUCLEAR REACTOR REGULATION

REGULATORY AUDIT TOPICS

REGARDING ACCIDENT ANALYISS AND CRITICALITY SAFETY DESCRIBED IN

OPERATING LICENSE APPLICATION

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), and March 27, 2020 (ADAMS Accession No. ML20105A295), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of the SHINE operating license application, questions have arisen related to SHINE's accident analysis and criticality safety program for which additional information is needed to determine that there is reasonable assurance of adequate protection of public health and safety and that applicable regulatory requirements are met. The topics below identify areas where additional information is needed for the NRC staff to continue its review of the SHINE accident analysis and criticality safety program may become formal requests for additional information following the regulatory audit.

Audit Topic 1 – Alignment of Accident Dose Acceptance Criterion

Purpose

The NRC staff seeks to gain alignment between the accident dose criteria proposed by the Nuclear Regulatory Commission (NRC) described in the *Federal Register*, Volume 82, Number 60, dated March 30, 2017, with SHINE's for an operating license for its Medical Isotope Production Facility.[1]

Regulatory Analysis Basis

The Atomic Energy Act of 1954, as amended, (AEA or Act) is the fundamental U.S. law on both the civilian and the military uses of nuclear materials.[2] The AEA was written to promote the development and use of atomic energy for peaceful purposes and to control and limit its radiological hazards to the public. The Act requires that civilian uses of nuclear materials and facilities be licensed, and it empowers the NRC to establish by rule or order, and to enforce, such standards to govern these uses as "the Commission may deem necessary or desirable in order to protect health and safety and minimize danger to life or property." Title 10 of the *Code of Federal Regulations* (10 CFR), Parts 1 to 199 contains the regulations established by the NRC. A production facility for the separation of byproduct material from special nuclear material is subject to licensing pursuant to 10 CFR Part 50. Sections 50.20 through 50.22 of Title 10 specify two classes of licenses to be issued to applicants by the NRC: Class 104 for medical therapy and research and development facilities; and, Class 103 for commercial and industrial facilities.

The regulations of Title 10 apply, in part, to both power reactors and non-power facilities. Based on NUREG 1537, Part 1, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-power Reactors*, Chapter 13, *Accident Analysis*, the principal safety issues that differentiate non-power production or utilization facilities from nuclear power reactors are the site requirements and the potential doses to the public that could result from a serious accident. The licensed thermal power levels of a production facility are several orders of magnitude lower than current nuclear power reactors. Therefore, the accumulated inventory of radioactive fission products is proportionally less than nuclear power reactors and requires less stringent and less prescriptive measures to give equivalent protection to the health and safety of the public. Thus, even though many of the regulations of Title 10 apply to both power and non-power reactor facilities, the regulations may be implemented in a different way for each facility category with the intention of being consistent with protecting the health and safety of the public.

When licensing non-power production or utilization facilities, there have been questions as to what standards and criteria should be used in evaluating design-basis accidents to evaluate the design basis of systems, structures and components that mitigate radiological releases to the environment (exposure to any individual in the unrestricted area). Presently, no radiological accident dose criterion is set forth in regulation and subsequent guidance to assess the risk to public health and safety resulting from the operation of non-power production or utilization facilities. Instead, the standards of 10 CFR Part 20, *Standards for Protection Against Radiation*, have been applied for evaluating the effects of a postulated accident, for instance:

[1] See 82 FR 15643, March 30, 2017.
[2] See NUREG-0980, *Nuclear Regulatory Legislation*

- Before January 1, 1994, the accident dose criteria used to license a research reactor were generally compared to the public dose limits of 10 CFR Part 20.1 through 20.602 and Appendices. Therefore, the accident criteria the staff generally found acceptable for accident analyses were less than the public dose limits of 0.5 rem whole body and 3 rem thyroid for members of the public.

- On January 1,1994, the NRC amended 10 CFR Part 20 to reduce the dose limit to a member of the public to 0.1 rem TEDE with an implementation date of January 1, 1994. In lieu of an accident dose criterion, under §20.1301(d), a licensee or license application may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem. The 0.5 rem refers to the TEDE, defined in 10 CFR Part 20.1003, as the sum of the effective dose equivalent and the committed effective dose equivalent.

However, as discussed in NUREG-1537, there are several instances the staff has accepted very conservative accident analyses that exceed the 10 CFR Part 20 public dose limits discussed above.

In the FRN, the NRC proposed to amend its regulations that govern the license renewal process for non-power reactors, testing facilities, and other production or utilization facilities, licensed under the authority of Section 103, Section 104a, or Section 104c of the AEA, as amended, that are not nuclear power reactors.[3] In this rule, the NRC collectively refers to these facilities as non-power production or utilization facilities (NPUFs). The NRC has determined that the public dose limit of 0.1 rem (0.001 Sv) TEDE is unduly restrictive to be applied as accident dose criteria for NPUFs, other than those NPUFs subject to 10 CFR part 100.[4] However, the NRC considers the accident dose criteria in 10 CFR part 100 applicable to accident consequences for power reactors, which have greater potential consequences resulting from an accident, to be too high for NPUFs other than testing facilities. For these reasons, the NRC proposed to amend its regulations in 10 CFR 50.34 to add an accident dose criterion of 1 rem TEDE for NPUFs not subject to 10 CFR part 100.

This is consistent with the guidance found in NUREG-1537, Part 2, which provides discussion on a postulated accident scenario whose potential consequences are shown to exceed and bound all credible accidents. For non-power facilities, this accident is called the maximum hypothetical accident. Since the consequences of the postulated maximum hypothetical accident should exceed those of any credible accident at the facility, the accident is not likely to occur during the life of the facility. The maximum hypothetical accident is used to demonstrate that the maximum consequences of operating the facility at a specific site are within acceptable limits.

The accident dose criterion of 1 rem TEDE in the proposed NPUF rule is based on the Environmental Protection Agency's (EPA) Protection Action Guides (PAGs), which were published in the EPA document, 400-R-92-001, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents*. In January 2017, the EPA published an update to its

[3] See 82 FR 15643, March 30, 2017.

[4] The NRC Atomic Safety and Licensing Appeal Board stated that the standards in 10 CFR part 20 are unduly restrictive as accident dose criteria for research reactors (Trustees of Columbia University in the City of New York, ALAB–50, 4 AEC 849, 854–855 (May 18, 1972)).

PAGs in EPA-400/R-17/001, "*PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents*. This update to the EPA PAGs did not change the basis for the 1 rem TEDE early phase PAG published in 1992. The purpose of the EPA PAGs is to support decisions on protective actions to provide reasonable assurance of adequate protection of the public from unnecessary exposure to radiation.

The EPA PAGs are dose guidelines to support decisions that trigger protective actions such as staying indoors or evacuating to protect the public during a radiological incident. The PAG is defined as the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Three principles considered in the development of the EPA PAGs include: (1) prevent acute effects; (2) balance protection with other important factors and ensure that actions result in more benefit than harm; and, (3) reduce risk of chronic effects. In the early phase of the nuclear incident, which may last hours to days, the EPA PAG recommends the protective actions of sheltering-in-place or evacuation of the public to avoid inhalation of gases or particulates in an atmospheric plume and to minimize external radiation exposures between 1 rem to 5 rem. So, if the projected dose to an individual from an incident is less than 1 rem, no protective action for the public is recommended.

Technical Basis

In its operating license application, SHINE selected accident dose criteria (in lieu of a criterion stated in the regulation) for members of the public as follows:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 500 mrem total effective dose equivalent (TEDE) for the duration of the accident; and,

  Radiological consequences to workers do not exceed 5 rem TEDE during the accident. [SHINE justifies applying this criterion to a worker within the facility as opposed to the "control room" since immediate operator action inside the facility is not required to stabilize accident conditions. The SHINE irradiation units do not share systems and components. Therefore, the design basis accidents assume no interconnective failures. As generally assumed in the sequence of events, SHINE states facility personnel evacuate the immediate area [the facility confinement] within 10 minutes upon actuation of the radiation area monitors.]

The SHINE FSAR Chapter 13, *Accident Analysis*, provides the design basis accident analyses which are evaluated against the dose criterion.[5] The intent of these analyses is to evaluate the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

[5] ADAMS Accession Number ML19211C323

The SHINE FSAR Chapter 14, *Technical Specifications,* provides limiting conditions for operation of the production facility.[6] The safety margins contained within the design basis accidents are products of specific values and limits contained in the facilities technical specifications and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

For a Part 50 license, the following is considered:

- Accident dose criteria, when compared against the maximum hypothetical accident, is a helpful aid in evaluating a proposed site with the objective of assessing the risk to public health and safety resulting from operation of the facility.

  As discussed in the ISG Augmenting NUREG-1537, the maximum hypothetical accident is used to demonstrate that the maximum consequences of operating the nuclear facility at a specific site is within the acceptable accident dose limits. The maximum hypothetical accident is an accident with radiological consequences that bound all other credible accidents likely to occur over the life of the nuclear facility. Therefore, the assumed fission product release from the maximum hypothetical accident should be based upon a major accident, hypothesized for purposes of siting analysis or postulated from considerations of possible accidental events, that would result in potential hazards not exceeded by those from any accident considered credible.

- There is no 10 CFR Part 50 regulatory requirement for a worker accident dose criteria, other than the requirements in 10 CFR Part 20, *Standards for Protection Against Radiation*.[7] However, the SHINE Design Criterion 6 – Control Room, states:

  > A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

  This criterion is similar to 10 CFR 50, Appendix A, General Design Criterion-19, *Control Room*, which is not applicable to NPUFs such as the SHINE facility. It is required for light water reactor nuclear power plant control room design where the operator's necessity to appropriately respond during an accident is properly viewed as having a potential impact on the public health and safety. The purpose is to provide a control room from which actions can be taken to operate the facility safely under normal conditions and to maintain the facility in a safe condition under accident conditions.[8]

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[6] ADAMS Accession Number ML19211C339

[7] Note: 10 CFR Part 70 does contain a regulatory requirement for accident dose to workers because of lessons learned from fatal and near miss accidents at fuel cycle facilities involving chemicals commingled with special nuclear material.

[8] It is generally understood that an objective of the criteria is to ensure that the design of the control room and its habitability systems is such that a "shirt-sleeved" environment is provided for the control room operators. Such an environment is perceived to be supportive of facilitating operator response to normal and accident conditions and would minimize errors of omission or commission. Another objective is to ensure that the radiation dose levels in the control room would make it the "safest" location on site, thereby allowing the operators to remain in the control room and not evacuate. Any reduction in the ability of the operators to respond appropriately during an accident is properly viewed as having a potential impact on the public health and safety.

At the SHINE facility, in the event of a design basis accident or transient, the other irradiation units will presumably be operating, and control room operators would need to take actions to continue to operate the facility safely and to maintain the facility in a safe condition. It therefore seems appropriate to assess the radiological consequences of the control room operator, given General Design Criteria 6, as their required operations are necessary to continue operation of the other irradiation units and maintain the facility in a safe condition under accident conditions.

It is noted that the NRC staff views the accident dose design criterion as a "figure of merit" and does not represent actual doses received due to a design-basis event or transient. The shielding design of the facility ensures the applicable limits in 10 CFR 20, *Standards for Protection Against Radiation,* are met and thus protecting the worker which is discussed in Chapter 11, *Radiation Protection Program and Waste management,* of the SHINE FSAR. Lastly, ALARA program practices such as work planning and source term minimization, coupled with existing radiation exposure procedural controls ensure worker doses are not adversely impact the licensee's ability to maintain doses resulting from plant operation within the applicable limits.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

1-A. Confirm the NRC staff's understanding of the SHINE-proposed accident dose criteria of 500 mrem TEDE to members of the public to serve the purpose as the site evaluation factor, as discussed in the *Federal Register*, Volume 82, Number 60, dated March 30, 2017. Given the NRC-proposed draft rule, discuss a technical justification for the SHINE-proposed accident dose criterion, as necessary for the licensing of the SHINE Medical Isotope Production Facility; this should include a comparison to the basis for the NRC-proposed accident dose criterion of 1 rem TEDE in the draft NPUF rule (see 82 FR 15643).

OR

Discuss whether SHINE would adopt, with justification, the accident dose criterion proposed in the NRC rule described in FRN 82 FR 15643, which provides reasonable assurance of adequate protection of the public in the unlikely event of radiological incident.

1-B. In light of the discussion provided above, provide a technical justification for why the worker dose criterion is assumed to be analyzed for facility personnel and not the operator(s) for the SHINE facility. Please provide accident analysis results for control room operators to be consistent with the SHINE Design Criteria, Criterion 6 – Control Room.

1-C. Clarify what 10 CFR Part 50 regulatory requirement SHINE is demonstrating to meet with the proposed worker accident dose criteria, and the basis for the dose value of 5 rem TEDE. Also clarify the purpose of the proposed worker accident dose criteria as there appears to be no necessary actions by the worker to maintain the facility in a safe condition under accident conditions. If there are necessary actions to control or mitigate

the accident, provide these procedures and programmatic controls which can be implemented in the Technical Specifications (Administrative Controls or otherwise).

OR

If there are no necessary actions by the worker outside the control room to maintain the facility in a safe condition under accident conditions, then discuss whether it would be appropriate to remove from the SHINE FSAR, with justification, the proposed worker dose accident dose criteria.

Audit Topic 2 – Alignment of Accident Analysis Dosimetry Methodologies

Purpose

The NRC staff seeks to gain alignment between dosimetry methodologies found acceptable by the NRC staff to those applied by SHINE with regard to the computation of the radiological consequences of design-basis accidents in terms of total effective dose equivalent (TEDE).

Regulatory Analysis Basis

The regulations that are most relevant to radiation protection are contained in 10 CFR Part 20, *Standards for Protection Against Radiation*, and 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*. Additional requirements, specific to particular uses or classes of facilities, are found in other portions of the regulations.

Both 10 CFR Part 50 and 10 CFR Part 20 refer to various dose-based criteria and limits based on dosimetry methodologies defined by the International Commission on Radiological Protection (ICRP) in Publication 26, *Recommendations of the ICRP,* and Publication 30, *Limits for Intakes of Radionuclides by Workers*. The ICRP 30 dosimetry methodologies are applied in:

- 10 CFR Part 50 – through the TEDE criteria (defined in §50.2) for the design, construction, and operation of the facility under normal and accident conditions.

  10 CFR Part 20 – through the TEDE limits (defined in §20.1003) to establish standards and practices for radiation protection purposes for occupational and public health during normal operation. 10 CFR Part 20, Appendix B, *Appendix B to Part 20—Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage*, to provides direction in how to determine external and internal exposures. The appendix provides an appropriate method to derive the Annual Limits on Intake and Derived Air Concentrations based on ICRP 30 tissue weighting factors.

The tissue weighing factors are directly codified by §20.1003, *Definitions*, within the table labeled, *Organ Dose Weighting Factors*, as follows:

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red Bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bong surfaces	0.03
Remainder	0.30
Whole Body	1.00

Technical Analysis Basis

For both 10 CFR Parts 50 and 20, the TEDE is defined as the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). Acceptable practices for computing design-basis accident radiological

consequences in terms of TEDE are to apply the exposure-to-committed effective dose equivalent factors for inhalation of radioactive material found in Table 2.1 of Federal Guidance Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*. The factors in the column headed "effective" yield doses corresponding to the committed effective dose equivalent. These tables are derived from the data provided in ICRP Publication 30 and have been found acceptable to the NRC staff as they meet the applicable regulatory requirements. Likewise, the exposure-to-effective dose equivalent factors for external exposure of radioactive material apply Federal Guidance Report No. 12, *External Exposure to Radionuclides*.

Therefore, by default, compliance with the dose-related regulations of Parts 50 and 20 are demonstrated when applying the exposure-to-dose conversion factors of Federal Guidance Reports 11 and 12.

The SHINE FSAR Chapter 13, *Accident Analysis*, design basis accident analyses are evaluated against the applicant-selected accident dose criteria. The design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. To compute radiological consequences, the SHINE FSAR states that the dose conversion factors were taken from ICRP Publication 119, *Compendium of Dose Coefficients based on ICRP Publication 60*, and Federal Guidance Report No. 12. It appears SHINE has applied a dosimetry methodology inconsistent with applicable dose-related regulations under 10 CFR Part 50. Therefore, by applying dose conversion factors based on ICRP Publication 60 dosimetry methodologies for a Part 50 license application, the applicant does not comply with the applicable regulations. To be compliant with the dose-related regulations of Parts 50, the exposure-to-committed effective dose equivalent factors for inhalation of radioactive material should apply those found in Table 2.1 of Federal Guidance Report No. 11 and 12.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

- Discuss how SHINE's selected dosimetry methodology satisfies applicable regulatory requirements and whether it will be necessary to re-compute the radiological consequences of all design-basis accidents in terms of TEDE to be in compliance with the NRC's regulations.

Audit Topic 3 – Atmospheric Dispersion Models for the Purposes of Assessing Offsite Radiological Consequences of Postulated Design Basis Accidents

Purpose

The NRC staff seeks to gain alignment on computing offsite radiological consequences of postulated design basis accidents and emergency planning and preparedness.

Regulatory Analysis Basis

In 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Section 50.34, *Contents of Applications; Technical Information*, requires that each applicant for a construction permit or operating license provide an analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility.

NUREG-1537, *Guidance for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,* Part 2, provides NRC staff guidance on the conduct of reviewing non-power reactor licensing applications, as supplemented by:

- 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, Interim Staff Guidance Augmenting NUREG-1537, Part 1*.

- 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, Interim Staff Guidance Augmenting NUREG-1537*.

Regulatory Guide 1.145, Rev 1, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants*, presents criteria for characterizing atmospheric dispersion conditions for evaluating the consequences of design basis accidents radiological releases at the site boundary as they relate to the applicable siting requirements where short-term atmospheric dispersion factors (χ/Q values) are computed at the 95^{th}-percentile value (i.e., χ/Q value that is equal to or exceeded no more than 5 percent of the total time). Both NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537 refer to Regulatory Guide 1.145 with respect to accident analyses.

Regulatory Guide 2.2, *Development of Technical Specifications for Experiments in Research Reactors*, as it pertains to the development of technical specifications based on the SHINE FSAR for the purposes of crediting natural consequence-limiting features such as solubility, absorption, and dilution and for installed features such as filters may be taken provided each such feature is specifically identified and conservatively justified by specific test or physical data or well-established physical mechanisms. In addition, with respect to installed features credit taken for their effectiveness should depend on the adequacy of the related quality assurance procedures undertaken, including the extent to which surveillance tests simulate the conditions to be met in practice. If assumptions regarding atmospheric dilution are involved, they should not be less conservative than those used in the analysis of design basis accidents.

It is noted here for further discussion that Regulatory Guide 1.111, "*Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors*, provides regulatory positions on long-term atmospheric dispersion estimated for routine releases of effluent. For these assessments, it is typical regulatory practice to accept 50th-percentile χ/Q value.

Technical Analysis Basis

The SHINE FSAR Chapter 13, *Accident Analysis*, design basis accident analyses are evaluated against the applicant-selected accident dose criterion. As presented by SHINE, the design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. SHINE identified these design basis accidents using the following sources of information:

- NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537;
- Process hazard analysis method within the integrated safety analysis process; and,
- Experience of the hazard analysis team.

SHINE selected accident dose criteria for members of the public as follows:

- Radiological consequences to an individual located in the unrestricted area following the onset of a postulated accidental release of licensed material would not exceed 500 mrem total effective dose equivalent (TEDE) for the duration of the accident; and,
- Radiological consequences to workers do not exceed 5 rem TEDE during the accident.

The intent of these analyses is to evaluate the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility.

SHINE computed long-term 50th percentile (average) χ/Q values at the nearest point along the site boundary and at the nearest resident location. This is consistent with the staff guidance found in NUREG-1537, Chapter 11, *Radiation Protection*, for the purposes of demonstrating compliance with the limits of 10 CFR Part 20, *Standards for Protection Against Radiation* to assess routine releases. These 50th percentile χ/Q values were also applied to the Chapter 13 design basis accident analyses which is non-conservative to demonstrate compliance with 10 CFR Section 50.34 when evaluating the radiological consequences of postulated design basis accidents (i.e., short-term events) for facility siting and operation.
It is acknowledged there can be a misinterpretation of certain statements found in NUREG-1537, Part 2, Chapter 13, since no explicit percentile χ/Q value is made for accident analysis purposes. However, Chapter 13, *Accident* Analysis, Subsection, *Radiological Consequences,* does refer to Regulatory Guide 1.145 as an acceptable method for demonstrating compliance with the applicable siting criteria. Regulatory Guide 1.145, Section 3, *Determinations of 5% [95th percentile] Overall Site χ/Q Values*, states in part:

> "The χ/Q values that are exceeded no more than 5% of the total time around the exclusion area boundary… … should be determined…"

In other words, the purpose of evaluating the radiological consequences at the 95th-percentile value reasonably assures radiological consequences at the site boundary are not exceed more than 5 percent of the time. Therefore, by applying the long-term 50th-percentile χ/Q values imply the computed radiological consequences at the site boundary are met only 50 percent of the time. Staff experience with both long-term 50th- and short-term 95th percentile χ/Q values has shown non-linearity between the computed radiological consequence results which can range between three-orders-of-magnitude in difference depending on the site location.

Computing radiological consequences of design basis accidents at the 95th-percentile χ/Q value provides reasonable assurance that facilities' licensing bases will not be exceeded by more than 5.0 percent within any given year of operation.

SHINE calculation number 2012-03852 Rev 0, *Short-Term Diffusion Estimates for SHINE*, provides the details of the analysis to calculate atmospheric dispersion factors to be used to assess the consequences of an accidental release of radioactive material. Both the overall bounding long-term and short-term 50th and 95th-percentile χ/Q values are reported to be 3.88E-4 s/m^3 and 5.66E-3 s/m^3 respectively. This difference in χ/Q values would impact the reported SHINE FSAR radiological consequences by about a factor of 15.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

- Provide a postulated set of short-term atmospheric χ/Q values (95th-percentile) at the site boundary based on site-specific meteorological data to be presented in the SHINE FSAR.

- Recompute the radiological consequences of each design basis accident with the short-term atmospheric χ/Q values.

- Provide a matrix listing each design basis accident within rows with subsequent radiological consequences results within subsequent columns applying the original 50th-percentile (before) and 95th-percentile (after) atmospheric χ/Q values.

Audit Topic 4 – Design Basis Accident Verses Beyond Design Basis Accidents

Purpose

The NRC staff seeks to gain alignment on an acceptable approach to perform design basis accidents analyses.

Regulatory Analysis Basis

In 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Section 50.34, *Contents of Applications; Technical Information*, requires that each applicant for a construction permit or operating license provide an analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility. As discussed in Audit Topic 1, it is the staff's understanding that the proposed radiological accident dose criterion serves the purpose of evaluating the suitability of the site from operation of the facility for the purposes of computing radiological consequences.

10 CFR, Section 50.36 requires an applicant for an operating license to include in the application proposed technical specifications as it relates to the evaluations and analysis of the offsite radiological consequences of postulated accidents with fission products.

10 CFR 50.36(c)(3), requires TSs to include items in the category of surveillance requirements, which are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions of operation will be met.

NUREG-1537, *Guidance for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,* Part 2, provides NRC staff guidance on the conduct of reviewing non-power reactor licensing applications, as supplemented by:

- 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, Interim Staff Guidance Augmenting NUREG-1537, Part 1*.

- 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, Interim Staff Guidance Augmenting NUREG-1537*.

Regulatory Guide 1.145, Rev 1, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants*, presents criteria for characterizing atmospheric dispersion conditions for evaluating the consequences of design basis accidents radiological releases at the site boundary as they relate to the applicable siting requirements where short-term atmospheric dispersion factors (χ/Q values) are computed at the 95^{th}-percentile value (i.e., χ/Q value that is equal to or exceeded no more than 5 percent of the total time). Both NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537 refer to Regulatory Guide 1.145 with respect to accident analyses.

Regulatory Guide 2.2, *Development of Technical Specifications for Experiments in Research Reactors*, as it pertains to the development of technical specifications based on the SHINE FSAR for the purposes of crediting natural consequence-limiting features such as solubility, absorption, and dilution and for installed features such as filters may be taken provided each such feature is specifically identified and conservatively justified by specific test or physical data or well-established physical mechanisms. In addition, with respect to installed features credit taken for their effectiveness should depend on the adequacy of the related quality assurance procedures undertaken, including the extent to which surveillance tests simulate the conditions to be met in practice. If assumptions regarding atmospheric dilution are involved, they should not be less conservative than those used in the analysis of design basis accidents.

Technical Analysis Basis

Design basis accidents are postulated accidents that a nuclear facility must be designed and built to withstand without loss to the systems, structures, and components necessary to ensure public health and safety. The design basis accidents are not intended to be actual event sequences, but rather, intended to be surrogates to enable deterministic evaluation of the response of a facility's engineered safety features. These accident analyses are intentionally conservative in order to compensate for known uncertainties in accident progression, fission product transport, and atmospheric dispersion. They can be thought of as loosely defined 'classes' of accidents that bound a number of facility processes, activities, and/or accident sequences identified through a risk-assessment. The quantification of the accidental release of fission products into the atmosphere, or accident radiological "source term," is intended to be representative of a major accident involving significant damage which affects the design of plant systems and is one element used to determine site suitability. The safety margins contained within the design basis accidents are products of specific values and limits contained in the facilities technical specifications, as required by 10 CFR 30.36, *Technical Specifications,* and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

Beyond design basis accident is a term used as a technical way to discuss accident sequences that are possible but were not fully considered in the design process because they were judged to be too unlikely. In that sense, they are considered beyond the scope of design-basis accidents that a nuclear facility must be designed and built to withstand. However, as the regulatory process strives to be as thorough as possible, "beyond design-basis accident" sequences are analyzed to fully understand the capability of a design. Beyond design basis accidents are considered more unlikely than design basis accidents, nonsafety-related systems, structures, and components can be credited for accident mitigation. For example, the 10 CFR 50.62, *Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants*, allows the use of nonsafety-related equipment for accident mitigation. These analyses often include multiple failures beyond those considered for design basis accident analyses, and thus more realistic assumptions are allowed in the analyses.

The staff reviews the radiological consequences of design basis accidents in six parts: (1) review of selected bounding design basis accidents; (2) review of accident source terms; (3) review of the major structures, systems, and components of the facility that are intended to mitigate the radiological consequences of a design basis accident; (4) review of the characteristics of fission product releases from the proposed site to the environment, (5) review

of the meteorological characteristics of the proposed site; and, (6) review of the total calculated radiological consequence dose at the site boundary from the bounding design basis accidents.

The NRC staff generally does not accept design basis accident analyses that credit facility features that:

(a) are not safety-related;

(b) are not covered by technical specifications;

(c) do not meet single-failure criteria, or;

(d) rely on the availability of offsite power. Design basis delays in actuation of these features should be considered, especially for those features that rely on manual operator intervention.

Analysis inputs should be the most restrictive values of plant parameters selected from the range of design values possible during the specific event so that the postulated consequences of the event are maximized. It is generally inappropriate to use values characterized as “best estimates.” Other considerations should include:

(a) The range of values applicable during an accident may vary from accident to accident and will likely differ from the range that applies during normal operations.

(b) The use of different parameter values in different portions of the analyses or to perform a sensitivity analysis to determine the limiting value.

(c) Facility parameters associated with a technical specification limiting condition for operation. If the limiting condition for operation specifies a range, or a value with a tolerance band, the most restrictive value should be used.

(d) Consider situations where and how some parameters may change value during the accident. In these cases, the calculation should either assume the most restrictive value for the entire duration or the calculation should be performed in time steps, with the appropriate parameter values used for each time step.

(e) Parameters based on the results of less frequent surveillance testing, for example, efficiency testing of charcoal filters, the degradation that may occur between periodic tests should be considered in establishing the analysis value.

(f) Analysis parameters which affected by density changes that occur in the process stream. With regards to specified volumetric flow rates as limiting conditions of operations, the density used should be consistent with the density that is assumed in the surveillance procedure that demonstrates compliance with the limiting conditions of operations.

Lastly, a point of discussion regarding the application of the Single Failure Criterion is made when developing design basis accidents. The Single Failure Criterion, as a design and analysis tool, has the direct objective of promoting reliability through the enforced provision of

redundancy in those systems which must perform a safety-related function.[9] As discussed in NUREG-1537, for the purposes of facility design and accident analysis, and the applicable SHINE Design Criteria, a single failure means an occurrence which results in the loss of capability of a component or protection system to perform its intended safety functions. Multiple failures resulting from a single occurrence are considered to be a single failure. Fluid and electric systems are considered to be designed against an assumed single failure if neither (1) a single failure of any active component (assuming passive components function properly) nor (2) a single failure of a passive component (assuming active components function properly), results in a loss of capability of the system to perform its safety functions.

In principle, the Single Failure Criterion as applied in design basis accident analyses is straightforward. Simply stated, it is a requirement that a system which is designed to carry out a defined safety function must be capable of carrying out its mission in spite of the failure of any single active component within the system or in an associated system which supports its operation. Application of the Single Failure Criterion involves a systematic search for potential single failure points and their effects on the system. Such a search is required by the Standard Review Plan and the Standard Format for the Content of Safety Analysis Reports for specified safety systems and components. The objective is to search for design weaknesses which could be overcome by increased redundancy, use of alternate systems or use of alternate procedures. In general, only those systems or components which are judged to have a credible chance of failure are assumed to fail when the Single Failure Criterion is applied. Such failures would include, for example, the failure of a valve to open or close on demand, the failure of an emergency diesel generator to start or the failure of an instrument channel to function.

The SHINE FSAR Chapter 13, *Accident Analysis*, design basis accident analyses are evaluated against the applicant-selected accident dose criterion. As presented by SHINE, the design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. SHINE identified these using the following sources of information:

- NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537;
- Process hazard analysis method within the integrated safety analysis process; and,
- Experience of the hazard analysis team.

The NRC staff has reviewed a sampling for both the irradiation facility and radioisotope production facility design basis accidents with a focus on the two maximum hypothetical accidents. It appears these maximum hypothetical accidents fit the description of beyond design basis accidents where multiple failures are assumed which is beyond typical consideration for licensing purposes. Two examples are provided:

1. Section 13.a.2.1.1.1, *Identification of Causes, Initial Conditions, and Assumptions,* describes the initial conditions, accident sequence and assumptions for the maximum hypothetical accident in the irradiation facility. The defined maximum hypothetical accident is a pressurized release from the primary system boundary through the target solution vessel off-gas system cell. The initial conditions of the irradiation unit are those during its normal operating mode, Mode 2, *Irradiation Mode*. The staff's understanding of the sequence of events is as follows:

[9] ADAMS Accession Number ML060260236

First, the event initiator is a deterministic passive failure of the target solution vessel system pressure boundary causes failure of the target solution vessel off-gas system to function which automatically initiates the safety-related nitrogen purge system. This causes the pressure in the target solution off-gas system cell to increase.

A deterministic active failure assumes the normal nitrogen purge system flow path to be completely blocked, notwithstanding it is designed with redundant valves in parallel to ensure a flow path is available. This results in the over pressurization of the target vessel off-gas system cell which ultimately leaks to the primary confinement boundary and released to the environment.

A deterministic active failure appears to be assumed with no automatic "trip signal" to the nitrogen purge system to prevent over pressurizing the target solution off-gas system cell beyond its design.

Lastly, an active failure due to over pressurization of the target solution off-gas system cell is assumed to release to the environment for a period of thirty days without justification.

The reported irradiation facility public accident dose consequences for the maximum hypothetical accident is 367 mrem TEDE.

It appears multiple single failures have been assumed to define the irradiation facility maximum hypothetical accidents design basis. In addition, with the irradiation unit tripped and the target solution in a safe stable condition, there seems to be little to no motive force available to release radionuclides to the environment once the nitrogen purge system is exhausted.

2. Section 13b, *Radioisotope Production Facility Accident Analyses*, provides a comparison between assumptions made for similar design basis accidents in the radioisotope production facility which highlights the additional conservatisms SHINE is proposing for the maximum hypothetical accidents. They are the (1) the maximum hypothetical accident in the RPF, and (2) the process vessel vent system carbon guard bed fire.

   Section 13b.2.1, *Maximum Hypothetical Accident in the RPF,* describes the maximum hypothetical accident in the radioisotope production facility. It is defined as a fire in a carbon guard bed with degraded carbon delay bed efficiency. It is postulated that 100 percent of the radionuclide inventory is released from the guard bed where it flows downstream into the carbon delay beds and then released to the facility stack. The performance of the carbon delay beds is assumed to be degraded to 95 percent. The staff's understanding of the sequence of events as follows:

   First, the event initiator is an upset or malfunction in the process vessel vent system resulting in high moisture or high temperature flow through the carbon bed.

   An active failure to detect high moisture or high temperature flow through the process vessel vent system results in a fire in a carbon guard bed.

   A passive failure of the downstream carbon delay beds assumes they do not perform at their intended filter efficiency design requirement to adsorb 99 percent of the radioactive material.

An active failure by redundant temperature indications in the guard bed do not identify the incipient fire condition and fails to send an actuation signal to the engineered safety features actuation system. Failure to isolation results in the assumption to not credited limiting the release of radioactive materials from the guard bed.

Lastly, automatic isolation of the guard bed eventually occurs before the gas temperature exiting the bed reaches 180°C to protect the downstream carbon delay beds from damage and release of subsequent radioactive material.

Presumably, the following safety-related components are not credited for mitigation, the:

- process vessel vent system carbon guard bed temperature indicators;
- process vessel vent system carbon guard bed isolation valves;
- engineered safety features actuation system carbon guard bed isolation function;
- process vessel vent system delay bed filtration; and,
- Supercell confinement boundary.

Section 13b.2.6.2, *PVVS Carbon Guard Bed Fire*, describes a similar accident sequence to the maximum hypothetical accidents for the radioisotope production facility but engineered safety features actuation system automatically mitigated release from a credible carbon guard bed fire. The staff's understanding of the sequence of events as follows:

First, ignition of the carbon guard bed occurs due to an upset or malfunction in the process vessel vent system resulting in high moisture or high temperature flow through the carbon bed.

Radioactive material is captured by the downstream carbon delay bed and filtered. One percent of the released radioactive material is released through process vessel vent system and the facility stack to the environment.

Incipient fire conditions are detected by redundant temperature indication in the guard bed, which send an actuation signal to the engineered safety features actuation system.

The engineered safety features actuation system isolates the carbon guard bed using installed isolation valves. Valve closure is accomplished within 30 seconds of detection of elevated temperature above the actuation setpoint.

Following valve closure, the gross release of radioactive material is stopped, and the fire is extinguished. Leakage through the valve occurs at a diminished rate.

The following safety-related components are credited for mitigation, the:

- process vessel vent system carbon guard bed temperature indicators;
- process vessel vent system carbon guard bed isolation valves;
- engineered safety features actuation system carbon guard bed isolation function;
- process vessel vent system delay bed filtration; and,
- Supercell confinement boundary.

The reported radioisotope production facility public accident dose consequences for the maximum hypothetical accident and process vessel vent system delay bed fire accident are 402 mrem TEDE and 39 mrem TEDE respectively.

The assumption defining the sequence of events may be overestimating the release of radioactive material to the environment while the long-term atmospheric dispersion factors computed at the 50th-percentile value are non-conservative – as discussed in Audit Topic 3.

Therefore, the NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

4-A Re-assess the maximum hypothetical accidents considering the discussions above. It may be necessary to redefine the design basis accident source terms and sequence of events to meet the applicable public accident dose criteria.

4-B As discussed above, the DBAs are not intended to represent actual event sequences, but surrogates to enable deterministic evaluations of the response of the facilities engineered safety features. Based on SHINE's use of a risk-assessment to define creditable accident sequences and the substantial operating experience of similar facilities, provide a discussion of the following:

- How SHINE classified and binned the accident sequences from the SHINE safety analysis into each DBA;
- Which technical specifications and limiting conditions of operations were developed from insights gained from the accident sequences identified from the SHINE safety analysis; and
- How the accident sequences, which require workers to take preventive or mitigative actions in order to put the facility in a safe configuration, are reflected in the impacted DBA, including how these actions are controlled through procedures and programmatic controls that may be implemented in the Technical Specifications (Administrative Controls or otherwise).

Audit Topic 5 – Design Basis Accidents Matrix and Accident Methodology

Purpose

The NRC staff seeks to improve the effectiveness and efficiency of the staff's review through the identification of specific design information for each design basis accident.

Regulatory Analysis Basis

10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities*, Section 50.34, *Contents of Applications; Technical Information*, requires that each applicant for a construction permit or operating license provide an analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Technical Analysis Basis

Design Basis Accidents are postulated accidents that a nuclear facility must be designed and built to withstand without loss to the systems, structures, and components necessary to ensure public health and safety. The design basis accidents are not intended to be actual event sequences, but rather, intended to be surrogates to enable deterministic evaluation of the response of a facility's engineered safety features. These accident analyses are intentionally conservative in order to compensate for known uncertainties in accident progression, fission product transport, and atmospheric dispersion. The quantification of the accidental release of fission products into the atmosphere, or accident radiological "source term," is intended to be representative of a major accident involving significant damage which affects the design of plant systems and is one element used to determine site suitability. The safety margins contained within the design basis accidents are products of specific values and limits contained in the facilities technical specifications, as required by 10 CFR 30.36, *Technical Specifications,* and other values, such as assumed accident or transient initial conditions or assumed safety system response times.

The staff reviews the radiological consequences of potential design basis accidents in six parts: (1) review of selected bounding design basis accidents, (2) review of accident source terms, (3) review of the major structures, systems, and components of the facility that are intended to mitigate the radiological consequences of a design basis accidents, (4) review of the characteristics of fission product releases from the proposed site to the environment, (5) review of the meteorological characteristics of the proposed site, and (6) review of the total calculated radiological consequence dose at the site boundary from the bounding design basis accidents.

The SHINE FSAR Chapter 13, *Accident Analysis*, design basis accident analyses are evaluated against the applicant-selected accident dose criterion. As presented by SHINE, the design basis accidents range from anticipated events, such as a loss of electrical power, to a postulated maximum hypothetical accident that exceeds the radiological consequences of any accident considered to be credible. SHINE identified these using the following sources of information:

- NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537;
- Process hazard analysis method within the integrated safety analysis process; and,
- Experience of the hazard analysis team.

The NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

5-A. Because the SHINE modified the application to remove the detailed descriptions of the accident analysis methodology and the results, describe the overall accident analysis methodology (e.g., risk categories, the hazard analysis and its translation into accident sequences with associated consequences and likelihoods). This description should include the following:

- A description of each design basis accident category, including a description of how each category bounds the applicable safety analysis accident sequences (including radiological and chemical[10]), including information on likelihood, consequence level, and risk categories.

5-B In order to improve the effectiveness and efficiency of the staff's review, provide a matrix listing of each design-basis transient or accident within rows with subsequent rows and columns including the following information:

- A description with justification the chosen single-failure assumption.
- Identification of the important analysis inputs and assumptions (listed in sub-rows), including their values (listed in adjacent columns) and reference within the FSAR and Technical Specifications. Typical input parameter values are as follows:
    - A process variable; design feature, or operating restriction that is an initial condition of a design basis accident or transient analysis that either assumes the failure of or presents a challenge to the integrity of a fission product barrier, or criticality limit.
    - A structure, system, component, or manual action that is part of the primary success path and which functions or actuates to prevent or mitigate a design basis accident or transient that either assumes the failure of or presents a challenge to the integrity of a fission product barrier, or criticality limit.
    - Plots of important parameters, where needed.
- Identification of the methodologies and inputs used to perform the analyses (e.g. regulatory guides, approved standards, computational tools), and describe any changes in those methodologies.
- Discussion of the results and acceptance criteria for the analysis.

[10] Hazardous chemicals produced from licensed materials are substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. (See: 10 CFR 70.4, *Definitions*)

Audit Topic 6 – Nuclear Criticality Safety Administrative Controls, Part 1

Purpose

The NRC staff seeks to gain alignment on certain programmatic management features to be placed into a licensee-controlled document within SHINEs Technical Specifications Administrative Controls section.

Regulatory Basis

Paragraph 50.34(b)(4) of 10 CFR Part 50, *Licensing of Production and Utilization Facilities*, requires that each application for an operating license provide a final analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Section 50.36 of 10 CFR Part 50 requires that each such application also include proposed technical specifications derived from the analyses and evaluation performed for the safety analysis report. 50.36(c)(5), *Administrative controls*, states, in part, the following:

> "Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner…"

As applicable, section 70.61(d) of 10 CFR Part 70 requires that the risk of nuclear criticality accidents be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

NUREG-1537, *Guidance for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,* Part 2, provides NRC staff guidance on the conduct of reviewing non-power reactor licensing applications, as supplemented by the following:

- 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, Interim Staff Guidance Augmenting NUREG-1537, Part 1*.

- 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, Interim Staff Guidance Augmenting NUREG-1537*.

NUREGs 1430 through 1434, provide examples of standard technical specifications for Administrative Controls for other Part 50 licensees. While not directly applicable to SHINE,

these NUREGs include descriptions of procedures, programs and manuals, and reporting requirements for Program Management features within licensee-controlled documents.[11]

Technical Basis

As part of an NRC license authorizing the operation of a nuclear facility, technical specifications establish requirements for items such as safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features, and administrative controls. Administrative controls over plant operations to ensure adequate controls are in place to maintain the facility conditions within the safe operating envelope.

As discussed in NUREG-1537 and the ISG to NUREG-1537, The nuclear criticality safety program requires the applicant to establish and maintain NCS safety limits and operating limits for the possession and use of fissile material and to maintain management measures to ensure the availability and reliability of the controls. Criticality control limits and management measures are to be included in the technical specifications as required by 10 CFR 50.36.

The SHINE safety analysis report, Chapter 6, *Engineered Safety Features,* discusses a nuclear criticality safety program in the radioisotope production facility a under section and 6b.3. However, no discussion of a nuclear criticality safety program is discussed in the irradiation facility despite similar hazards being present. The NRC staff acknowledges that the potential consequence of inadvertent criticality to the worker is limited in the irradiation facility by the presence of shielding; however, that does not negate the applicability of certain aspects of the nuclear criticality safety program.

With respect to the design of systems and components intended to be subcritical:

- The design and associated analyses should be performed by trained and qualified nuclear criticality safety staff as described in FSAR Section 6b.3.1.2.

- The design should, where practicable, comply with the double contingency principle as described in FSAR Section 6b.3.1.5.

- The design should ensure subcriticality under normal and all credible abnormal conditions with an approved margin of subcriticality for safety as described in FSAR Section 6b.3.1.4. The presence of shielding does not relax this requirement or provide relief from prevention of inadvertent criticality being the preferred strategy.

[11] For example, Generic Letter 89-01, *Implementation of Programmatic Controls for Radiological Effluent Technical Specifications in the Administrative Controls Section of the Technical Specifications and the Relocation of Procedural Details of RETS to the Offsite Dose Calculation Manual or to the Process Control Program,* discusses how programmatic controls can be implemented in the Administrative Controls section of the Technical Specifications to satisfy existing regulatory requirements. Within NUREGs-1430 through 1434, Section 5, *Administrative Controls*, Subsection, *Programs and Manuals,* provides a list of licensee programs to be established, implemented and maintained. It discusses for instance, the Offsite Dose Calculation Manual (ODCM) which contain the methodologies and parameters applied, how licensee-initiated changes to the ODCM are carried out, who are the approving officials, and applicable reporting requirements.

- The computational methods used to support design and associated analyses are subject to uncertainty and error and should be subject to validation as described in FSAR Section 6b.3.1.5.

- Design should incorporate sufficient subcritical margin to bound calculational uncertainty, bias, and bias uncertainty, and should assess an administrative margin to bound unknown or difficult to quantify (or qualify) uncertainty beyond those identified by the validation as partially described in FSAR Section 6b.3.1.4.
- The design and associated analyses should be consistent with respect to the assumptions and treatment of nuclear criticality safety parameters as described in FSAR Section 6b.3.2.

- Other statements and commitments related to design as described in FSAR Section 6b.3 may be applicable.

With respect to other aspects of the nuclear criticality safety program:

- Program documentation, evaluations, and calculations should be maintained in accordance with the SHINE records management system as described in FSAR Section 6b.3.1.5.

- Equipment characteristics relied on to maintain NCS limits should be identified as NCS controls and be maintained by the SHINE configuration management program as described in FSAR Section 6b.3.1.5.

- Process or design changes that could affect NCS limits or controls should be evaluated using the facility change process as described in FSAR Section 6b.3.1.5.

- NCS oversight activities should be performed as described in FSAR Section 6b.3.1.7.

- The NCS training program, to both NCS staff and fissile material handlers, should be applied as described in FSAR Section 6b.3.1.6.

- Deviations from procedures and unintended alterations in process conditions that affect NCS should be promptly reported to management, investigated promptly, corrected as appropriate, and documented as described in FSAR Section 6b.3.1.8. Other statements and commitments as described in FSAR Section 6b.3 may be applicable.

The SHINE final safety analysis report, Chapter 14, *Technical Specifications*, discusses how the SHINE technical specifications were developed following the format and content guidance using the following sources of information:

- American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.1-2007, *The Development of Technical Specifications for Research Reactors* (ANSI/ANS, 2007); and,

- NUREG-1537 and the Interim Staff Guidance Augmenting NUREG-1537.

Technical Specification 5.5.7, *Nuclear Criticality Safety,* provides a description of the nuclear criticality safety program in the radioisotope production facility.

The NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

6-A. In order to improve the effectiveness and efficiency of the staff's review, provide SHINE's administrative controls in the technical specifications for the nuclear criticality safety program within both the irradiation facility and the radioisotope production facility.

6-B. For any nuclear criticality safety program administrative controls technical specifications identified as being applicable to the radioisotope production facility, but not applicable to the irradiation facility, provide a justification to support inapplicability.

Audit Topic 7 – Nuclear Criticality Safety Administrative Controls, Part 2

Purpose

The NRC staff seeks to gain alignment on how SHINE is satisfying the requirements of 10 CFR 70.24, *Criticality Accident Requirements*.

Regulatory Basis

10 CFR 70.24(a) requires, in part, that each licensee authorized to possess special nuclear material (SNM) in a quantity exceeding 700 grams of contained U-235, 520 grams of U-233, 450 grams of plutonium, 1.5 kilograms of contained U-235 if no uranium enriched to more than 4 wt.% U-235 is present, or 450 grams of any combination thereof, maintain in each area in which such licensed SNM is handled, used, or stored, a criticality accident alarm system.

Technical Basis

The ISG augmenting NUREG-1537, Part 2, Chapter 6b3.2, *Nuclear Criticality Safety in the Radioisotope Production Facility*, states, in part, that the applicant should state clearly how the design of the facility or process provides for criticality control and should identify how the requirements of 10 CFR 70.24 were considered.

FSAR, Section 6b.3.3, *Criticality Accident Alarm System*, states that the SHINE facility provides a criticality accident alarm system (CAAS) to detect a criticality event in the areas *in which non-exempt quantities of fissile material* greater than the limits identified in 10 CFR 70.24(a) are used, handled, or stored outside the irradiation units, where “exempt fissile material” is defined as SNM that meets the requirements from classification as fissile material as specified in 10 CFR 71.15. However, the requirements of 10 CFR 70.24 regarding whether a CAAS is required are based on specific, objective criteria of SNM mass quantities by isotope (or combinations thereof). It does not provide any distinctions as to whether such SNM quantities are, or should be considered, fissile or fissile-exempt, nor does it provide any exceptions for SNM quantities in excess of those limits. As such, SNM quantities greater than the limits established by 10 CFR 70.24 require CAAS coverage regardless of whether they meet the requirements from classification as fissile material as specified in 10 CFR 71.15.

The NRC staff requests that SHINE discuss the following, with the support of any relevant reference calculations or documents, related to information provided in its operating license application:

- Discuss how the SHINE final safety analysis report is consistent with the requirements of 10 CFR 70.24, including whether it is necessary to revise the SHINE safety analysis to be consistent with the requirements of 10 CFR 70.24, or request a specific exemption from the requirements of 10 CFR 70.24 for certain areas of the facility in accordance with 10 CFR 70.17.