UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISSIONERS:

Stephen G. Burns, Chairman
Kristine L. Svinicki
William C. Ostendorff
Jeff Baran

In the Matter of SHINE MEDICAL TECHNOLOGIES, INC. (Medical Radioisotope Production Facility)	Docket No. 50-608-CP

CLI-16-04

MEMORANDUM AND ORDER

On December 15, 2015, we held a hearing on the application of SHINE Medical Technologies, Inc. for a permit to construct a medical radioisotope production facility in Janesville, Wisconsin.[1] The purpose of the evidentiary hearing was to consider the sufficiency of the NRC Staff's review of SHINE's application. As discussed below, we conclude that the Staff's review was adequate to support the findings set forth in our regulations. We authorize issuance of the construction permit.

[1] *See* SHINE Medical Technologies, Inc.; Notice of Hearing, 80 Fed. Reg. 67,435 (Nov. 2, 2015) (Notice of Hearing); Tr. at 1-220 (attached as Appendix B to Order of the Secretary (Adopting Proposed Transcript Corrections, Admitting Post-Hearing Exhibits, and Closing the Record of the Proceeding) (Jan. 14, 2016) (unpublished) (Transcript Correction Order)).

I. BACKGROUND

A. Proposed Action

SHINE seeks to build a medical radioisotope production facility primarily to produce molybdenum-99. Molybdenum-99 decays to technetium-99m, a radioisotope used in medical diagnostic procedures, including bone scans and cardiac stress tests.[2] SHINE requested and received an exemption to submit its application in two parts.[3] It submitted Part 1 on March 26, 2013, and Part 2 on May 31, 2013.[4]

The Staff has spent approximately 16,000 hours, with an additional 6,000 hours from outside technical experts, reviewing SHINE's application to determine whether it complies with the Atomic Energy Act of 1954, as amended, and the NRC's regulations.[5] The Staff's review included an analysis of the environmental impacts of constructing, operating, and decommissioning the SHINE facility, in accordance with the National Environmental Policy Act of 1969 (NEPA).[6]

Technical reviewers from the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Regulatory Research, and the Office of

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[2] Tr. at 15-16.

[3] *See* SHINE Medical Technologies, Inc.; Exemption, 78 Fed. Reg. 19,537 (Apr. 1, 2013).

[4] *See* SHINE Medical Technologies, Inc., 78 Fed. Reg. 39,342 (July 1, 2013) (docketing Part 1 of the application); SHINE Medical Technologies, Inc., 78 Fed. Reg. 73,897 (Dec. 9, 2013) (docketing Part 2 of the application). *See generally* Ex. NRC-006A to NRC-006H, NRC-006J to NRC-006R, SHINE Medical Technologies, Inc., Construction Permit Application (Construction Permit Application). Staff exhibits NRC-007A to NRC-007D contain the non-public portions of the Construction Permit Application, and as such, they were filed on the non-public docket for this proceeding.

[5] Ex. NRC-014, NRC Staff Responses to Post-Hearing Questions (Dec. 29, 2015), at 2 (unnumbered).

[6] *Id.*

New Reactors contributed to the review of SHINE's application. The Staff also engaged the support of other federal and state agencies and local governments, including the Department of Energy, National Nuclear Security Administration; the Environmental Protection Agency; the U.S. Fish and Wildlife Service; the Advisory Council on Historic Preservation; the Wisconsin Department of Health Services; and the Janesville City Council.[7] The Advisory Committee on Reactor Safeguards (ACRS), a committee of technical experts charged with reviewing and reporting on safety studies and applications for construction permits and facility operating licenses, provided an independent assessment of the safety aspects of the application.[8] The ACRS recommended that the construction permit be issued.[9]

B. Review Standards

The Atomic Energy Act, section 189a., requires that we hold a hearing on an application to construct a commercial production or utilization facility.[10] The Staff published in the *Federal Register* a notice of hearing and provided an opportunity for interested members of the public to

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[7] NRC-010, Construction Permit Application Review, SHINE Medical Technologies, Overview (Dec. 8, 2015), at 5 (Staff Overview Presentation); Tr. at 58-59 (Mr. Dean).

[8] AEA § 182b., 42 U.S.C. § 2232(b); 10 C.F.R. §§ 1.13, 50.58; *see* Letter from John W. Stetkar, Chairman of the ACRS, to Stephen G. Burns, Chairman of the NRC (Oct. 15, 2015) (ADAMS accession no. ML15286A426) (ACRS Letter).

[9] ACRS Letter at 1; *see* Letter from Victor M. McCree, NRC Executive Director for Operations, to John W. Stetkar, Chairman of the ACRS (Nov. 25, 2015) (ML15309A005) (responding to the ACRS Letter).

[10] AEA § 189a., 42 U.S.C. § 2239(a) ("The Commission shall hold a hearing after thirty days' notice and publication once in the Federal Register, on each application under section 103 or 104b. for a construction permit for a facility, and on any application under section 104c. for a construction permit for a testing facility."). Early in the review process, the Staff determined that the proposed SHINE facility qualifies as a section 103 facility because it is intended "primarily for commercial purposes." Ex. NRC-001, "Staff Statement in Support of the Uncontested Hearing for Issuance of Construction Permit for the SHINE Medical Technologies, Inc. Medical Radioisotope Production Facility," Commission Paper SECY-15-0130 (Oct. 22, 2015), at 10-11 (unnumbered) (Staff Information Paper).

petition for leave to intervene.[11] No petitions to intervene were filed. Therefore, there was no separate contested hearing.

We issued a second notice that set the time and place for the uncontested hearing and outlined the standards for our review.[12] The standards track the two major areas of focus for the review of a license application: the Staff's safety and environmental reviews. On the safety side, we must determine whether:

1. the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

2. such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

3. safety features or components, if any, that require research and development have been described by the applicant, and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

4. on the basis of the foregoing, there is reasonable assurance that

    (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

    (ii) taking into consideration the site criteria contained in 10 C.F.R Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.[13]

In making these findings, we are guided by the additional considerations in 10 C.F.R. § 50.40. We consider whether:

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[11] SHINE Medical Technologies, Inc.; Notice of Hearing, Opportunity to Intervene, Order Imposing Procedures, 80 Fed. Reg. 13,036 (Mar. 12, 2015).

[12] Notice of Hearing, 80 Fed. Reg. at 67,436.

[13] 10 C.F.R. § 50.35(a); Notice of Hearing, 80 Fed. Reg. at 67,436.

1. the processes to be performed, the operating procedures, facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with NRC regulations, including the regulations in 10 C.F.R. Part 20, and that the health and safety of the public will not be endangered;

2. the applicant is technically and financially qualified to engage in the proposed activities;

3. the issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public; and

4. any applicable requirements of Subpart A of 10 C.F.R. Part 51 have been satisfied.[14]

Overlapping this last consideration are the environmental findings that we must make to support issuance of the construction permit.[15] The findings reflect our agency's obligations under NEPA, a statute that requires us to consider the impacts of NRC actions on environmental values.[16] To ensure that these obligations are fulfilled for this construction permit proceeding, we must:

1. determine whether the requirements of NEPA section 102(2)(A), (C), and (E), and the applicable regulations in 10 C.F.R. Part 51, have been met;

2. independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

3. determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values; and

[14] 10 C.F.R. § 50.40(a)-(d).

[15] *See, e.g.*, *id.* § 51.105(a).

[16] *See* NEPA § 102(2), 42 U.S.C. § 4332(2); 10 C.F.R. § 51.10.

4. determine whether the NEPA review conducted by the NRC Staff has been adequate.[17]

If we determine that the application meets the standards and requirements of the Atomic Energy Act and the NRC's regulations and that any notifications to other agencies or bodies have been duly made, we will issue a construction permit "in such form and containing such conditions and limitations" that we deem "appropriate and necessary."[18] We do not review SHINE's application *de novo*; rather, we consider the sufficiency of the Staff's review—that is, we determine whether the Staff's review was sufficient to support the required findings.[19]

C. The Hearing Process

The Staff completed its review of the SHINE application in October 2015.[20] At that time, the Staff published its Safety Evaluation Report (SER) and Final Environmental Impact Statement (FEIS), triggering the timeline of activities for the uncontested hearing.[21] We

[17] Notice of Hearing, 80 Fed. Reg. at 67,436 (citing 10 C.F.R. § 51.105).

[18] 10 C.F.R. § 50.50.

[19] *See Exelon Generation Co.* (Early Site Permit for Clinton ESP Site), CLI-05-17, 62 NRC 5, 34-36 (2005).

[20] *See* Ex. NRC-008, Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility (Oct. 2015; revised Dec. 2015) (SER); *infra* note 144 (discussing revisions to the SER); Ex. NRC-009, "Final Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," NUREG-2183 (Oct. 2015) (FEIS).

[21] *See* Staff Requirements—SECY-15-0088—Selection of Presiding Officer for Mandatory Hearings Associated with Early Site Permit Applications and Construction Permit Applications for Medical Isotope Production and Utilization Facilities (Aug. 25, 2015), at 1 (ML15238B093) (directing that the first uncontested hearing on a construction permit for a medical isotope production facility follow the Commission's Internal Procedures for uncontested combined license proceedings); Internal Commission Procedures, ch. IV, "Commission Meetings/Hearings," at IV-12 to IV-21 (ML11269A125).

received the Staff's information paper, which serves as its pre-filed testimony, shortly after issuance of the SER.[22]

1. Pre-hearing Activities

We then set the schedule for the parties to file their lists of witnesses, as well as for SHINE to provide its pre-filed testimony.[23] We issued questions on environmental and safety-related topics for SHINE and the Staff to answer in writing in advance of the hearing.[24] In addition, we invited interested states, local government bodies, and federally recognized Indian Tribes to provide statements for us to consider as part of the uncontested proceeding.[25] We received no responses to our invitation.

2. The Hearing

The scheduling note, issued to the parties before the hearing, set the topics for and the order of presentations at the hearing.[26] In the first panel, witnesses for SHINE and the Staff provided an overview of the construction permit application and the Staff's review. The next two panels focused on safety-related issues, and the final panel focused on environmental issues.

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[22] *See* Ex. NRC-001, Staff Information Paper, at 1. The Staff also provided a Draft Construction Permit and Draft Record of Decision. Ex. NRC-002-R, Draft Construction Permit; Ex. NRC-003, Draft Record of Decision.

[23] Notice of Hearing, 80 Fed. Reg. at 67,436.

[24] *See* Order of the Secretary (Transmitting Pre-Hearing Questions) (Nov. 10, 2015; corrected Nov. 20, 2015) (unpublished) (Pre-Hearing Questions). We also issued three questions that contain sensitive unclassified non-safeguards information and that therefore were filed on the non-public docket for the proceeding. The parties' responses to those questions were likewise filed on the non-public docket.

[25] Notice of Hearing, 80 Fed. Reg. at 67,436.

[26] Memorandum from Annette Vietti-Cook, Secretary of the Commission, to Counsel for SHINE and the Staff (Dec. 3, 2015) (ML16028A336) (Scheduling Note).

The Staff made available forty-four witnesses at the hearing.[27] Twelve of these witnesses were scheduled panelists; the remainder stood by to answer questions on topics relating to their expertise.[28] A total of twenty-two witnesses offered testimony on behalf of SHINE on panels at the hearing and in pre-filed written testimony.[29]

a. Summary of the Overview Panels

Greg Piefer, SHINE Chief Executive Officer, Jim Costedio, SHINE Licensing Manager, Bill Hennessy, SHINE Engineering Manager, Eric Van Abel, SHINE Engineering Supervisor, and Katrina Pitas, SHINE Vice President for Business Development, represented SHINE on the overview panel.[30] Dr. Piefer provided background on the company and its mission.[31] Mr. Costedio provided background on the location and general design of the facility, and Mr. Van Abel described SHINE's production process.[32] Mr. Hennessy answered questions relating to the facility's design, and Ms. Pitas answered questions regarding public engagement during the site-selection process.[33]

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[27] *See NRC Staff Revised Exhibit List and Witness List* (Dec. 11, 2015); *NRC Staff Proposed Transcript Corrections and Notification of Additional Sworn Witness* (Dec. 28, 2015); Tr. at 11.

[28] Scheduling Note at 1-5; Tr. at 11.

[29] *See Revised List of Anticipated Witnesses for SHINE Medical Technologies, Inc. for the Hearing on Uncontested Issues* (Dec. 8, 2015); Tr. at 9; Ex. SHN-001, *Applicant's Pre-Filed Testimony of James Costedio for the Mandatory Hearing on Uncontested Issues for the SHINE Medical Technologies, Inc.'s Medical Radioisotope Production Facility* (Nov. 24, 2015) (SHINE Pre-Filed Testimony).

[30] Tr. at 13, 37; Scheduling Note at 1.

[31] Tr. at 14.

[32] *Id.* at 23-36.

[33] *Id.* at 37-38, 39-40, 47-48.

William Dean, Director of the Office of Nuclear Reactor Regulation, Mirela Gavrilas, Deputy Director of the Division of Policy and Rulemaking in the Office of Nuclear Reactor Regulation, Jane Marshall, Deputy Director of the Division of License Renewal in the Office of Nuclear Reactor Regulation, and Marissa Bailey, Director of the Division of Fuel Cycle Safety, Safeguards, and Environmental Review in the Office of Nuclear Material Safety and Safeguards, provided background on the Staff's review of the construction permit application.[34] Mr. Dean described the purpose of the facility and the Staff's efforts to prepare for its review of the application.[35] Dr. Gavrilas discussed the Staff's safety review and the regulatory standards by which the Staff conducted its review, and Ms. Marshall discussed the Staff's environmental analysis.[36] Ms. Bailey provided the Staff's findings in support of issuance of the construction permit.[37]

b. Summary of the Safety Panels

The first safety panel focused on the proposed design of the SHINE facility and the unique regulatory challenges that the Staff faced during its review of the construction permit application, as detailed in chapters 1 and 4 of the SER.[38] Eric Van Abel testified for SHINE.[39] With him on the panel were Bill Hennessy and Catherine Kolb, SHINE Engineering

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[34] Scheduling Note at 2; Tr. at 54-55.

[35] Tr. at 55-58.

[36] *Id.* at 58-66.

[37] *Id.* at 66-70.

[38] *See* Scheduling Note at 2; Ex. SHN-027, Commission Mandatory Hearing, SHINE Construction Permit Application, Safety—Panel 1, Facility (Dec. 8, 2015); Ex. NRC-011, Construction Permit Application Review, SHINE Medical Technologies, Safety Panel 1 (Dec. 8, 2015) (Staff Safety Panel 1 Presentation).

[39] Tr. at 99-103.

Supervisor.[40] Alexander Adams, Chief of the Research and Test Reactors Licensing Branch in the Office of Nuclear Reactor Regulation, Steven Lynch, Project Manager, Research and Test Reactors Licensing Branch, Office of Nuclear Reactor Regulation, and Mary Adams, Senior Environmental Engineer, Enrichment and Conversion Branch, Office of Nuclear Material Safety and Safeguards, provided testimony for the Staff.[41] In addition to chapters 1 and 4, SER chapters 2, 3, 5, 6, and 7 were subject to our examination during the first safety panel.[42]

The second safety panel focused on chapter 13 of the SER, which addressed the applicant's analyses for radiological and chemical exposure accidents.[43] In particular, the discussion centered on the novel application of accident analysis methodologies from 10 C.F.R. Parts 50 and 70.[44] Eric Van Abel again testified for SHINE, with Bill Hennessy, Jim Costedio, and Catherine Kolb on the panel.[45] Steven Lynch, Joseph Staudenmeier, Senior Reactor Systems Engineer, Reactor Systems Code Development Branch, Office of Nuclear Regulatory Research, and Kevin Morrissey, Project Manager, Fuel Manufacturing Branch, Office of Nuclear Material Safety and Safeguards, provided testimony for the Staff.[46] Chapters 8, 9, 11, 12, 14, and 15 also were subject to our examination during the second safety panel.[47]

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[40] Scheduling Note at 2.

[41] Tr. at 103-10; Scheduling Note at 2.

[42] Scheduling Note at 3.

[43] *Id.*

[44] *Id.*

[45] Tr. at 133-37.

[46] *Id.* at 137-44.

[47] Scheduling Note at 3.

c. Summary of the Environmental Panel

The environmental panel discussed the Staff's decision to prepare an environmental impact statement (EIS) for the SHINE facility; the Staff's consultation with other agencies on the EIS, as well as its interaction with the Department of Energy as a cooperating agency; the Staff's consideration of environmental impacts; and the Staff's analysis of alternatives to the proposed action.[48] Katrina Pitas testified for SHINE, with Bill Hennessy, Catherine Kolb, and Tim Krause, an Environmental Specialist from Sargent and Lundy, on the panel.[49] Jane Marshall, David Wrona, Chief of the Environmental Review and Guidance Update Branch in the Office of Nuclear Reactor Regulation, and Michelle Moser, Project Manager and Biologist in the Office of Nuclear Reactor Regulation, provided testimony for the Staff.[50]

3. Post-hearing Questions

After the hearing, we issued additional questions for written answers from SHINE and the Staff.[51] We admitted SHINE's and the Staff's responses as exhibits, and we adopted corrections to the hearing transcript.[52] We also admitted a revised Staff exhibit and then closed the evidentiary record for the uncontested hearing.[53]

II. DISCUSSION

Before we begin our discussion of the SHINE application, we emphasize what this decision does *not* do. First, although we authorize issuance of the construction permit, our

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[48] *Id.* at 4.

[49] Tr. at 160-68; Scheduling Note at 4.

[50] Tr. at 168-87; Scheduling Note at 4.

[51] Order of the Secretary (Transmitting Post-Hearing Questions) (Dec. 21, 2015) (unpublished).

[52] Transcript Correction Order at 1.

[53] *Id.* at 1-2.

decision does not constitute approval of the design.[54] SHINE has represented that it will apply for an operating license and submit with that application a Final Safety Analysis Report, which will contain the final detailed design.[55] And second, this decision does not discuss all of the aspects of SHINE's construction permit application, the Staff's review, or our sufficiency review. Rather, we provide here a survey of the key facts that support our findings. We base our decision, however, on the record in its entirety.

A. The Proposed Design

1. Principal Features of SHINE's Medical Radioisotope Production Facility

SHINE's proposed design is first-of-a-kind.[56] Although some of the general concepts underlying SHINE's proposed approach to medical isotope production have individually been used in other applications, SHINE's facility would be the first to bring them together in its production process.[57] There are two "facilities," housed within the same 55,000 square foot building, that would make up the SHINE Medical Radioisotope Production Facility: the "Irradiation Facility" and the "Radioisotope Production Facility."[58] The SHINE facility would be

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[54] *See* 10 C.F.R. § 50.35(b) ("A construction permit will constitute authorization to the applicant to proceed with construction but will not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit.").

[55] *See id.* § 50.35(c); Tr. at 39-40 (Mr. Hennessy), 46 (Mr. Costedio).

[56] *See* Ex. NRC-006C, Construction Permit Application, Preliminary Safety Analysis Report (PSAR), at 1-1; Ex. NRC-011, Staff Safety Panel 1 Presentation, at 5-7.

[57] *See* Ex. NRC-010, Construction Permit Application Review, SHINE Medical Technologies, Overview (Dec. 8, 2015), at 8 (Staff Overview Panel Presentation); Ex. NRC-011, Staff Safety Panel 1 Presentation, at 5-7; Ex. NRC-006C, Construction Permit Application, PSAR, at 1-14 to 1-17.

[58] Ex. SHN-026, Commission Mandatory Hearing, SHINE Construction Permit Application Overview (Dec. 8, 2015), at 7-8 (SHINE Overview Panel Presentation); Tr. at 23 (Mr. Costedio).

located in the center of an undeveloped, 91-acre (36.8-hectare) agricultural parcel in Janesville, Wisconsin.[59]

SHINE would generate the molybdenum-99 in the Irradiation Facility, using a neutron driver to induce fission in a vessel that contains a solution of low-enriched uranium and sulfuric acid (uranyl sulfate)—the "Target Solution Vessel."[60] The neutron driver uses a deuterium accelerator and tritium gas target to create neutrons through a fusion reaction. The neutrons then drive the fission reaction inside the Target Solution Vessel.[61] The fission process would continue for about 5.5 days, after which time the irradiated solution in the Target Solution Vessel would be drained and stored for a short period of decay before it is piped to supercells in the Radioisotope Production Facility to separate the molybdenum-99 from other isotopes in the solution.[62]

The Target Solution Vessel and a neutron multiplier, which aids the fission reaction, sit within the "Subcritical Assembly Support Structure."[63] This structure would serve to contain any leaks from the Target Solution Vessel.[64] An annular dump tank, the "Target Solution Vessel Dump Tank," surrounds the bottom of the structure, with fail-open valves that would open to allow the target solution to drain passively (via gravity) out of the Target Solution Vessel.[65]

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[59] Ex. SHN-026, SHINE Overview Panel Presentation, at 7; Tr. at 23 (Mr. Costedio).

[60] Tr. at 26-27 (Mr. Van Abel).

[61] Ex. NRC-006C, Construction Permit Application, PSAR, at 1-9.

[62] Tr. at 27 (Mr. Van Abel); Ex. SHN-026, SHINE Overview Panel Presentation, at 20.

[63] Ex. SHN-026, SHINE Overview Panel Presentation, at 16; Tr. at 29-30 (Mr. Van Abel).

[64] Tr. at 30 (Mr. Van Abel).

[65] Ex. SHN-026, SHINE Overview Panel Presentation, at 15-16.

Together these components comprise the "Subcritical Assembly," which would be submerged in a light water pool to provide cooling and radiation shielding.[66]

The Subcritical Assembly and the neutron driver, along with other supporting systems, make up an "Irradiation Unit."[67] SHINE proposes to operate up to eight Irradiation Units at a time.[68] The other supporting systems include the "Target Solution Vessel Off-Gas System," which would sit adjacent to the accelerator and the Subcritical Assembly and remove gases generated during the irradiation process; the light water pool; the primary closed loop cooling system, which cools the Target Solution Vessel during the irradiation process; and the tritium purification system, which supplies clean gases to the neutron driver.[69]

Key to SHINE's proposed design, the Irradiation Units would remain subcritical at all times.[70] To ensure that they remain subcritical, SHINE will determine the appropriate uranium concentration and corresponding maximum allowable fill height of the Target Solution Vessels using startup physics tests and computer models.[71] The vessels would then be "filled to a level five percent by volume below the predicted critical volume."[72] Moreover, during the irradiation

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[66] *Id.*; Tr. at 31 (Mr. Van Abel).

[67] Ex. SHN-026, SHINE Overview Panel Presentation, at 15.

[68] *Id.*; Tr. at 23-24 (Mr. Costedio), 36 (Mr. Van Abel).

[69] Ex. SHN-026, SHINE Overview Panel Presentation, at 15; Tr. at 28-29 (Mr. Van Abel). The deuterium and tritium gases are mixed in the fusion process; the purification system separates the gases and supplies purified tritium back to the neutron driver. Tr. at 28, 30-31 (Mr. Van Abel).

[70] *See* Tr. at 22 (Dr. Piefer), 23-24 (Mr. Costedio).

[71] Ex. SHN-002, *SHINE Medical Technologies, Inc.'s Responses to Commission's Public Pre-Hearing Questions* (Dec. 8, 2015), at 27-28 (SHINE Responses to Pre-Hearing Questions); Tr. at 31-32 (Mr. Van Abel).

[72] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 29; *see also* Tr. at 32 (Mr. Van Abel).

process, fission in the target solution would increase temperature and void fraction, which also would cause a decrease in reactivity and drive the system further subcritical.[73] Other, automatic safety features would ensure that criticality is not reached: the system would be designed to shut down under certain conditions, such as high neutron flux or high primary coolant temperature.[74] Under these conditions, the driver would shut down to stop generating source neutrons and the solution would drain to the Target Solution Vessel Dump Tank, which itself would be geometrically designed to prevent criticality.[75]

Once irradiated, the target solution would be piped to a separate area of the building, the "Radioisotope Production Facility," where the molybdenum-99 would then be extracted, purified, packaged, and shipped to customers.[76] After the molybdenum-99 is separated, the uranium solution would return to the Irradiation Facility for reuse in another irradiation cycle.[77] SHINE plans to clean the recycled solution periodically to remove other fission products.[78]

In the Radioisotope Production Facility, criticality safety is treated much like it would be in a fuel cycle facility and is focused on the "detection and annunciation" of criticality accidents.[79]

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[73] Tr. at 32-33 (Mr. Van Abel). The increasing void fraction during the irradiation process is due to radiolytic bubble formation from a mixture of gas species, including hydrogen and noble gases. *See* Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 21.

[74] Tr. at 32 (Mr. Van Abel).

[75] Ex. NRC-004-R, *NRC Staff Responses to Commission Pre-Hearing Questions* (Dec. 8, 2015), at 16 (Staff Responses to Pre-Hearing Questions).

[76] Tr. at 24 (Mr. Costedio), 33 (Mr. Van Abel). The Radioisotope Production Facility is also where the uranium solution would be created in the first instance. Ex. SHN-026, SHINE Overview Panel Presentation, at 10.

[77] Tr. at 27 (Mr. Van Abel).

[78] *Id.* at 27-28 (Mr. Van Abel).

[79] *See* Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 14-15.

In the Radioisotope Production Facility, the piping, vessels, and components would be designed in criticality-safe geometries.[80] SHINE would employ a "Criticality Accident and Alarm System" to detect and alert operators in the event of a criticality accident.[81] To determine the likelihood of such an event, SHINE analyzed various scenarios that might result in a possible inadvertent criticality.[82] For example, SHINE looked at the supercell area where the molybdenum-99 would be extracted and determined that an inadvertent criticality could result either from "[l]eaks in the piping resulting in target solution collecting in the sump and/or trenches" leading to "a criticality unsafe accumulation of fissile material," or "[c]hanges in piping design or valve alignment that may result in misdirection to a tank that is not designed to be criticality-safe."[83] For all of the analyzed scenarios, however, SHINE determined that a criticality accident in the Radioisotope Production Facility would be highly unlikely.[84]

In addition to its criticality safety analyses, SHINE evaluated other accident initiating events and scenarios.[85] One such analysis considered the "Maximum Hypothetical Accident" for both the Irradiation Facility and the Radioisotope Production Facility.[86] The Maximum Hypothetical Accident analysis was used to establish an upper limit to the radiation doses to

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[80] *See* Ex. NRC-006G, Construction Permit Application, PSAR, at 3-106.

[81] *See* Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 14; Ex. NRC-006G, Construction Permit Application, PSAR, at 6b-15, 7b-37.

[82] Ex. NRC-006G, Construction Permit Application, PSAR, at 13b-25 to 13b-29.

[83] *Id.* at 13b-26.

[84] *Id.* at 13b-27.

[85] *See* Ex. SHN-028, Commission Mandatory Hearing, SHINE Construction Permit Application, Safety—Panel 2, Accident Analysis (Dec. 8, 2015) (SHINE Safety Panel 2 Presentation); Ex. NRC-006G, Construction Permit Application, PSAR, ch. 13.

[86] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 2; Tr. at 134-37 (Mr. Van Abel).

workers and the public for all credible accidents at the facility.[87] The Maximum Hypothetical Accident itself is considered not credible, and non-mechanistic—that is, its hypothetical cause, whatever it may be, is not taken into account.[88]

For the Irradiation Facility, SHINE hypothesized that one of the Target Solution Vessels and its surrounding Subcritical Assembly Support Structure would be breached, releasing the maximum inventory of target solution for that vessel.[89] The presence of the light water pool, which surrounds the Subcritical Assembly Support Structure, was ignored, but SHINE assumed that the high radiation would be detected, initiating alarms and mechanisms to confine the material.[90]

In the Maximum Hypothetical Accident, the Irradiation Unit cell would remain intact, and other safety features, including high efficiency particulate air (HEPA) filters and charcoal absorbers would further limit the release of radioactive material.[91] SHINE calculated the dose consequences of such an accident to be 3.1 rem total effective dose equivalent (TEDE) for a worker, and 0.017 rem (17 millirem) TEDE to a member of the public at the site boundary.[92]

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[87] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 2; Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-2.

[88] *See* NRC-006G, Construction Permit Application, PSAR, at 13a2-2 to 13a2-3.

[89] *Id.* at 13a2-3; Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 3.

[90] Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-3 to 13a2-4; Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 3.

[91] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 3; Tr. at 135 (Mr. Van Abel); Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-3 to 13a2-4.

[92] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 3.

For the Radioisotope Production Facility, SHINE assumed the simultaneous rupture of the five tanks that would be used to store noble gases removed during the irradiation process.[93] These tanks would contain their maximum inventory, and their contents would be instantly released.[94] The high radiation detection alarms would be initiated, and redundant isolation dampers would close.[95] The concrete walls surrounding the storage tanks also would remain intact and confine a majority of the release.[96] For this hypothetical accident, SHINE calculated the dose consequences to be 3.6 rem TEDE for a worker and 0.082 rem (82 millirem) TEDE for a member of the public at the site boundary.[97] As this scenario provided higher dose consequences, the Radioisotope Production Facility Maximum Hypothetical Accident is considered the bounding scenario for the entire SHINE facility.[98] SHINE's dose consequence estimates from this accident scenario would be within the dose limits for normal operation in 10 C.F.R. Part 20.[99]

Because of the conservatisms included in the analysis, however, SHINE expects that any accident doses would be lower than those calculated.[100] The proposed design incorporates several engineered safety features to protect the public health and safety in the event of an

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[93] *Id.* at 4; Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-4.

[94] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 4.

[95] *Id.*

[96] Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-4.

[97] Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 5.

[98] *See id.* at 4-5; Tr. at 135 (Mr. Van Abel).

[99] *See* 10 C.F.R. §§ 20.1201, 20.1301 (governing maximum dose to workers and members of the public during normal operation).

[100] *See* Ex. SHN-028, SHINE Safety Panel 2 Presentation, at 5.

accident, some of which SHINE did not credit in its Maximum Hypothetical Accident scenarios.[101] Principal among the proposed design's safety features are biological shielding—heavy concrete—surrounding the Irradiation Units and the supercells, isolation valves on piping systems, and ventilation systems, all of which would confine radiological releases.[102] Moreover, the SHINE facility would have a low radionuclide inventory—up to 10,000 times less than a power reactor—and it would be operating at low temperature and pressure, and therefore dispersion forces are expected to be lower than those calculated in the event of an accident.[103]

SHINE also analyzed design-basis accidents initiated by external events, including flooding, aircraft impacts, tornadoes, and rain and snow load on the roof of the facility.[104] Once in operation, the facility also will house a number of chemical hazards, including the acids that will be used to prepare the target solution. SHINE identified twenty-four "chemicals of concern," eleven of which were studied closely due to their toxicity, dispersibility, or inventory.[105]

2. The Staff's Review Methodology

The Staff began preparing for SHINE's construction permit application in 2009, several years in advance of its submittal.[106] The Staff created an interoffice working group, gathering personnel with expertise in a number of technical areas to ensure an efficient review process.[107]

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[101] *See id.* at 3, 5; Ex. SHN-026, SHINE Overview Panel Presentation, at 22.

[102] Tr. at 34-35 (Mr. Van Abel).

[103] Tr. at 34 (Mr. Van Abel); Ex. SHN-026, SHINE Overview Panel Presentation, at 22.

[104] Tr. at 149 (Ms. Kolb), 150 (Mr. Lynch); Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-15.

[105] Tr. at 151 (Mr. Van Abel); *see also* Ex. NRC-006G, Construction Permit Application, PSAR, at 13b-37 to 13b-51.

[106] Ex. NRC-010, Staff Overview Panel Presentation, at 5; Tr. at 57 (Mr. Dean).

[107] Ex. NRC-010, Staff Overview Panel Presentation, at 5; Tr. at 57 (Mr. Dean).

Based on an early understanding of the design, the Staff believed that both the Irradiation Facility and the Radioisotope Production Facility fit the "production facility" definition in 10 C.F.R. § 50.2 and therefore could be licensed under Part 50.[108] When it received SHINE's application, however, the Staff determined that only the Radioisotope Production Facility qualified as a production facility under our rules.[109] The Irradiation Facility did not fit the definition of a "production facility."[110] Because they would remain subcritical, the Irradiation Units also did not fit the definition of a "utilization facility" in 10 C.F.R. § 50.2.[111] The Staff reasoned, however, that the units otherwise would be designed with several features of a nuclear reactor, with a power level similar to non-power reactors that are licensed as utilization facilities under Part 50.[112] Accordingly, with our approval, the Staff issued a direct final rule to amend the definition of a "utilization facility" in 10 C.F.R. § 50.2 to include the SHINE Irradiation Facility.[113] The rule became effective on December 31, 2014, thus enabling the entire SHINE facility to be licensed under Part 50.[114]

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[108] Direct Final Rule, Definition of a Utilization Facility, 79 Fed. Reg. 62,329, 62,330 (Oct. 17, 2014) (Direct Final Rule).

[109] *Id.* at 62,331.

[110] *Id.* at 62,331-32.

[111] *Id.* at 62,332.

[112] *Id.*; *see also* Tr. at 107-08 (Mr. Lynch).

[113] Direct Final Rule, 79 Fed. Reg. at 62,335. That section now states: "Utilization facility means: (1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233; *or (2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608*." 10 C.F.R. § 50.2 (2015) (emphasis added).

[114] Direct Final Rule, 79 Fed. Reg. at 62,329.

The Staff also updated its guidance documents to support its review of SHINE's application.[115] Because of the similarity of SHINE's proposed design to a non-power reactor, the Staff used the Standard Review Plan for Non-Power Reactors, NUREG-1537.[116] In addition, the Staff created interim guidance to supplement NUREG-1537 that specifically addresses applications for medical radioisotope production facilities, including SHINE's.[117] The interim staff guidance incorporates relevant guidance from NUREG-1520, the Standard Review Plan for applications for fuel cycle facilities.[118] SHINE followed the guidance in these documents when it prepared its application.[119]

Because of the uniqueness of SHINE's proposed design, we focused part of the hearing on the Staff's review methodology.[120] The Staff also had identified its licensing process as a novel issue in its pre-filed testimony.[121] We asked the parties to discuss the application of Part 50 to the SHINE application and to discuss SHINE's use of the General Design Criteria in

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[115] *See* Tr. at 57-58 (Mr. Dean).

[116] *See id.* (Mr. Dean); "Guidelines for Preparing and Reviewing Applications for Licensing Non-Power Reactors: Standard Review Plan and Acceptance Criteria," NUREG-1537, Parts 1 and 2 (Feb. 1996) (ML12251A353 (package)) (NUREG-1537).

[117] Tr. at 57-58 (Mr. Dean); Final Interim Staff Guidance Augmenting NUREG-1537, "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 Homogenous Reactors, Parts 1 and 2 (ML12156A069 and ML12156A075) (Oct. 2012) (Interim Staff Guidance Augmenting NUREG-1537). A notice of its issuance was published in the *Federal Register*. 77 Fed. Reg. 65,728 (Oct. 30, 2012).

[118] *See* Interim Staff Guidance Augmenting NUREG-1537, Part 1, at v (explaining that the Staff borrowed extensively from NUREG-1520 in the areas of facility description and accident analyses).

[119] Ex. SHN-026, SHINE Overview Panel Presentation, at 12; Tr. at 25 (Mr. Costedio).

[120] *See, e.g.*, Pre-Hearing Questions at 2-3.

[121] Ex. NRC-001, Staff Information Paper, at 10-13.

10 C.F.R. Part 50, Appendix A, for the proposed design.[122] In particular, we explored with the parties their technical judgment in determining the regulatory scheme to apply and whether any exemptions from our regulations were necessary to license the SHINE facility.[123] SHINE stated that it prepared its application to "fully address the requirements in 10 [C.F.R.] Part 50 that apply to Construction Permits, and that are applicable to the SHINE facility."[124] SHINE represented that because its facility is not a power reactor, it applied all of the regulations necessary for a construction permit application except those that expressly apply only to "power reactors" or "nuclear power plants," consistent with the guidance in NUREG-1537, Part 1, Appendix A.[125] The Staff took the same approach. It reviewed SHINE's construction permit application "under every applicable section of . . . [Part 50]."[126] The Staff did not apply regulations that pertained only to reactors or power reactors.[127] The Staff explained that because SHINE addressed all of the applicable regulations and because SHINE did not separately request any exemptions from those requirements, the Staff did not find it necessary to issue any exemptions from Part 50.[128]

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[122] Prehearing Questions at 2.

[123] *Id.* at 2-3.

[124] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 2.

[125] *Id.*

[126] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 2.

[127] *Id.* For example, in response to a pre-hearing question regarding the applicability of the definition of "safety-related structures, systems, and components" in 10 C.F.R. § 50.2, the Staff explained that SHINE complied with only those portions that did not expressly apply to power reactors, which is consistent with the Staff's practice when licensing non-power reactors. *Id.* at 4-5.

[128] *Id.* at 2. The Staff represented that the only exemption issued for the SHINE application was an exemption from 10 C.F.R. § 2.101(a)(5), which allowed SHINE to submit its application in two parts. *See* Ex. NRC-001, Staff Information Paper, at 9-10.

With regard to the General Design Criteria in Part 50, Appendix A, SHINE explained that it "undertook a systematic process to identify potentially applicable [General Design Criteria]" to address the requirement that its construction permit application include the principal design criteria for the proposed facility.[129] Even though these criteria apply to the design of nuclear power plants and therefore do not expressly apply to SHINE's application, SHINE considered the General Design Criteria to "provide a proven basis with which to develop an initial assessment of the safety of the design of the SHINE facility."[130] SHINE's process is documented in sections 3.5a and 3.5b of its Preliminary Safety Analysis Report.[131] Using the General Design Criteria to inform its review, the Staff independently assessed the adequacy of SHINE's principal design criteria.[132]

We also asked the Staff to discuss any challenges it encountered during its review and to explain how it determined which aspects of the design were necessary for the issuance of a construction permit and which could be left to the operating license stage.[133] As noted above, the Staff based its review on the criteria in 10 C.F.R. § 50.34 and the guidance in NUREG-1537 and the Staff's interim guidance document.[134] In addition, the Staff noted that the findings for issuance of a construction permit contemplate that the design might be preliminary in nature (as

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[129] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 3. *See generally* 10 C.F.R. § 50.34(a)(3)(i).

[130] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 3.

[131] Ex. NRC-006G, Construction Permit Application, PSAR, §§ 3.5a, 3.5b, at 3-57 to 3-106.

[132] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 3.

[133] Pre-Hearing Questions at 2.

[134] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 1-2.

it is here) and that issuance of the permit would not constitute approval of the final design.[135] With these considerations in mind, the Staff reviewed the application to ensure that SHINE adequately described its preliminary design, including the principal design criteria, design bases, general arrangement, and approximate dimensions; that SHINE provided a preliminary analysis of structures, systems, and components, including the ability to prevent and mitigate accidents; and that SHINE identified ongoing research and development.[136]

According to the Staff, when determining the amount of design detail necessary for SHINE's construction permit application, the issue of criticality safety in the Radioisotope Production Facility proved particularly challenging.[137] And the Staff found that the "most challenging aspect of the criticality review was ensuring a properly benchmarked criticality code with sufficient margin to ensure subcriticality."[138]

Using the applicable guidance, the Staff ensured that SHINE had addressed all of the design criteria for criticality safety.[139] The Staff focused on particular passive engineered features of SHINE's proposed facility and processes "that could not readily be changed" after construction.[140] The Staff examined whether SHINE had provided a "validated criticality code, an acceptable minimum margin of subcriticality, and [sufficient] conservative margin, to ensure the facility and process[es] will be designed to be subcritical under normal and credible

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[135] *Id.* at 1.

[136] *Id.*

[137] *Id.* at 2.

[138] *Id.*

[139] *See id.* at 2; Ex. NRC-008, SER, at 6-30 to 6-31.

[140] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 2.

abnormal conditions," and "commitments to ensure compliance with the double contingency principle."[141] The Staff also evaluated SHINE's proposed criticality accident alarm system.[142]

The Staff requested additional information from SHINE, and based on SHINE's responses, the Staff determined that SHINE had provided sufficient information for the construction permit stage of the proceeding but that SHINE would need to provide additional information before completing construction.[143] The Staff proposed four criticality-safety permit conditions that would require SHINE to submit periodic reports with additional information on: (1) the basis for the design of the criticality safety accident alarm system; (2) the basis for SHINE's determination that a criticality event in the Radioisotope Production Facility is not credible; (3) summaries of criticality safety analyses demonstrating that all processes in the Radioisotope Production Facility will remain subcritical under all normal and credible abnormal conditions and will satisfy the double contingency principle; and (4) nuclear criticality safety evaluations for all fissile isotopes or application of additional subcritical margin to account for these isotopes, either of which shall demonstrate that all processes in the Radioisotope Production Facility will remain subcritical under all normal and credible abnormal conditions.[144]

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[141] *Id.* The "double contingency principle" states that the "'design should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.'" Ex. NRC-008, SER, at 6-34 (quoting a report from the American National Standards Institute/American Nuclear Society, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," ANSI/ANS-8.1-1998 (2007)).

[142] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 2.

[143] *See* Ex. NRC-008, SER, at 6-31 to 6-32. The requests for additional information "covered topics such as SHINE's treatment of controlled parameters, application of the [double contingency principle], and [SHINE's] ability to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical." *Id.* at 6-31.

[144] *See id.* at 6-32 to 6-41; Ex. NRC-011, Staff Safety Panel 1 Presentation, at 8; Ex. NRC-002-R, Draft Construction Permit, at 2-3. A fifth permit condition, relating to radiation protection, would require SHINE to provide periodic information on components within the Radioisotope

In addition to exploring the scope of the Staff's review, we asked several questions directed to the adequacy of the Staff's review of SHINE's accident analyses. With regard to the Maximum Hypothetical Accident for the Irradiation Facility, we asked the Staff to explain why it found sufficient SHINE's consideration of the failure of one Target Solution Vessel, rather than multiple vessels.[145] The Staff stated that the facility would be designed to withstand any event that might cause multiple vessel failures, and the Target Solution Vessels would be isolated from one another under robust concrete shielding, without a way for the failure of one unit to trigger the failure of others.[146] SHINE responded that it looked at potential events that might involve multiple units but found that none of them would be worse than what was hypothesized for the Maximum Hypothetical Accident analysis.[147]

We also asked the parties to address their consideration of accidents initiated by external events, including aircraft impacts.[148] The SHINE facility would be located directly

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Production Facility, demonstrating that shielding and occupancy times are "consistent with as low as is reasonably achievable practices" and 10 C.F.R. Part 20 dose requirements. Ex. NRC-002-R, Draft Construction Permit, at 3.

Another permit condition would have established a screening process for construction changes that would require pre-approval from the NRC. A similar process was developed for combined licenses (the preliminary amendment request, or "PAR," process). After responding to our pre-hearing questions, however, the Staff revised its pre-filed testimony, SER, and Draft Construction Permit to remove this condition, finding on further reflection that such a process would not be appropriate with respect to a construction permit where, as here, the applicant has not sought approval of a final design. *See NRC Exhibit List and Notice of Revisions* (Dec. 8, 2015); Pre-Hearing Questions at 21-22; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 45-47.

[145] Tr. at 145 (Commissioner Baran). This question was a follow-up from the Staff's response to our pre-hearing question on the same topic. *See* Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 6-7.

[146] Tr. at 145 (Dr. Staudenmeier).

[147] *Id.* at 147 (Mr. Van Abel).

[148] *See, e.g.*, *id.* at 121 (Commissioner Baran); Pre-Hearing Questions at 6.

adjacent to a small airport, the Southern Wisconsin Regional Airport.[149] Although SHINE's proximity to the airport would allow timely shipment of its finished product—molybdenum-99 has a sixty-six-hour half-life[150]—it also places the facility in a location where aircraft impacts might be an issue of heightened concern. During its review the ACRS also identified aircraft impacts as an area of concern.[151]

SHINE's application included an aircraft impact analysis on the proposed facility's safety-related structures, which evaluated the types of aircraft expected near the SHINE facility and the ability of the facility to withstand impacts from those aircraft.[152] At the hearing, the Staff explained that its review accounted for the probability of an aircraft landing or taking off at the Southern Wisconsin Regional Airport or flying in the vicinity of the SHINE facility, no matter its size.[153] If the probability was below a certain threshold, it was excluded from further examination.[154] Based on the probabilities, SHINE considered two types of aircraft: the Challenger 605 and the Hawker 400.[155] The Staff reviewed SHINE's analysis as well as SHINE's responses to the Staff's requests for additional information and determined that

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[149] *See* Ex. NRC-006G, Construction Permit Application, PSAR, at 3-34; Ex. SHN-029, Commission Mandatory Hearing, SHINE Construction Permit Application, Environmental Overview (Dec. 8, 2015), at 5 (SHINE Environmental Panel Presentation) (showing bird's-eye view of airport and SHINE facility).

[150] *See* Tr. at 15 (Dr. Piefer), 46 (Mr. Hennessy).

[151] *See* ACRS Letter at 3.

[152] *See* Ex. NRC-006G, Construction Permit Application, PSAR, § 3.4.5.1; Tr. at 121-23 (Mr. Marschke).

[153] Tr. at 207 (Mr. Lynch).

[154] *Id.* (Mr. Lynch).

[155] *Id.* (Mr. Lynch); Ex. NRC-006G, Construction Permit Application, PSAR, at 3-35, 3-43 to 3-44.

SHINE's analysis was satisfactory.[156] The ACRS also was satisfied that "[a]ll areas of the . . . [facility] that contain safety-related systems and equipment . . . [would be] protected against damage from the identified design-basis aircraft impacts."[157]

B. Technical and Design Information for Later Consideration

SHINE has described the principal design features and the technology that it plans to use, but additional detail, some of which will be obtained after further research and development, will be supplied when SHINE submits its operating license application.[158] In particular, SHINE identified two ongoing research and development activities.[159] Oak Ridge National Laboratory will conduct irradiation and corrosion testing to study the mechanical performance of SHINE's systems.[160] And Argonne National Laboratory will conduct studies to ensure that uranyl peroxide will not precipitate out of the target solution.[161] The Staff will be "tracking these activities and will verify their resolution prior to the completion of construction."[162] SHINE represented that it expects to complete construction of its Medical Radioisotope Production Facility by December 2022.[163]

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[156] *See* Ex. NRC-008, SER, at 2-12 to 2-14.

[157] ACRS Letter at 3.

[158] *See, e.g.*, Tr. at 39-40 (Mr. Hennessy).

[159] Ex. NRC-008, SER, at 1-8.

[160] *Id.*

[161] *Id.*

[162] *Id.*; *see also id.* at A-36.

[163] *Id.* at 1-8.

SHINE also has planned additional work on the computer codes that will be used to model the thermal-hydraulics behavior of SHINE's Subcritical Assembly.[164] Los Alamos National Laboratory "is writing a transient systems modeling code to analyze the coupled nuclear and thermal-hydraulics behavior of solution systems," including SHINE's Subcritical Assembly.[165] And Los Alamos is validating the code to ensure that it "matches the behavior of aqueous systems," like SHINE's, "under a wide range of conditions."[166] SHINE plans to use this code to perform part of its transient modeling for accident and normal operating conditions for its operating license application.[167]

Other code validation will be performed using data from experiments that have been conducted on systems comparable to what will be used in SHINE's irradiation process.[168] Thermal-hydraulic experiments were performed at the University of Wisconsin—Madison on an assembly designed to simulate the design of the Target Solution Vessel.[169] The experiments used "[e]lectric heaters and bubble injection . . . to replicate the power generation and gas production in the SHINE facility" in a rectangular assembly, with two of the walls of the assembly cooled by cooling water.[170] The experiments "were used to determine the heat transfer coefficients and void fractions expected for this system over a range of power conditions."[171] An

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[164] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 45-46.

[165] *Id.* at 46.

[166] *Id.*

[167] *Id.*

[168] *See id.* at 46-47.

[169] *Id.* at 47.

[170] *Id.*

[171] *Id.*

experiment was performed at Argonne National Laboratory to simulate conditions in the Target Solution Vessel, using a scanned electron beam to irradiate a uranyl sulfate solution in a rectangular vessel with cooled walls.[172] The temperature distributions were recorded throughout the vessel, and these temperatures, along with the properties of the solution and the power distribution of the electron beam, will be used for code validation.[173] In addition to the data obtained from the University of Wisconsin and Argonne experiments, data from previous studies also will be used to validate the thermal-hydraulics codes.[174] The Staff will review the adequacy of SHINE's code validation efforts at the operating license stage.[175]

The Staff will be tracking several other items, listed as regulatory commitments in Appendix A of the SER, that SHINE must include in its Final Safety Analysis Report with its operating license application.[176] For its part, SHINE will track these items in its Corrective Action Program.[177] We list only some of these commitments here.

For example, SHINE committed to provide a seismic qualification for components used in the SHINE facility, either by analytical methods, tests, or combined methods.[178] SHINE also committed to installing a "non-safety-related seismic monitoring system to help establish the acceptability of continued operation of the plant following a seismic event."[179] The monitoring

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[172] *Id.*

[173] *Id.*

[174] *Id.* at 46-48.

[175] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 22.

[176] Ex. NRC-008, SER, app. A.

[177] *See id.* at A-3, A-35; Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 5-6.

[178] Ex. NRC-008, SER, at A-3.

[179] *Id.*

system "will provide acceleration time histories or response spectra experienced at the facility to assist in verifying that structures, systems, and components (SSCs) important to safety at the SHINE facility can continue to perform their safety functions."[180] As another example, SHINE will provide the locations of the isolation valves, which, as discussed above, are part of the planned confinement system for the Irradiation Facility, and which would be actuated under certain accident conditions, including a tritium leak from the neutron driver system.[181] And SHINE will provide a complete list of parameters that will trigger an automatic trip to shut down an Irradiation Unit and ensure safe operation of the facility.[182] These parameters will be determined using the results of SHINE's planned transient system modeling, which will in turn affect the layout and position of sensors within the Irradiation Units.[183] SHINE currently expects the parameters to include "primary system pressure, sweep gas flow, and hydrogen concentration measurements."[184]

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[180] *Id.*; *see also* Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 44-45.

[181] *See* Ex. NRC-008, SER, at 6-8, 13-23, A-5 to A-6. SHINE considered a tritium leak from the tritium purification system as one of its design basis accidents. *See* Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-59; Ex. NRC-008, SER at 13-23 to 13-25. The isolation valves are just one of the components that would be used to confine tritium in the event of a release. *See* Ex. NRC-006G, Construction Permit Application, PSAR, at 13a2-60. In addition, the piping for the tritium purification system and the neutron driver system would be double-walled, and isolation dampers would close in the event of a high-radiation alarm or other actuation signal. *See id.* at 13a2-59 to 13a2-60; *see also id.* at 13a2-17 (describing the double-walled piping for the neutron driver system).

[182] *See* Ex. NRC-008, SER, at A-4 to A-5; Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 39-40.

[183] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 39-40.

[184] *Id.* at 40; Ex. NRC-008, SER, at A-5.

Additionally, SHINE provided a Preliminary Emergency Plan that discusses provisions for coping with radiological emergencies and minimizing accident consequences.[185] Among other things, the Preliminary Emergency Plan describes the roles and responsibilities of the Emergency Response Organization, the emergency classification system, and facilities and equipment necessary for responding to emergencies.[186] Appendix A of the SER contains several commitments for SHINE to provide detailed emergency planning information when it submits its Final Safety Analysis Report.[187]

In meeting with the Staff, the ACRS identified items that also should be included in SHINE's Final Safety Analysis Report, and the Staff's list of tracked commitments includes these items.[188] To fulfill these commitments, SHINE will provide a strategy for addressing an extended shutdown of the SHINE facility, and SHINE will provide a definition of safety-related activities to be used in its Quality Assurance Program Description in its operating license application.[189] In its letter, the ACRS noted that it had additional questions that it expected would be addressed at the operating license stage concerning "criticality control and margin, adequacy of confinement, systems that provide support to safety-related systems, partial losses of electrical power, hydrogen generation and control, underwater maintenance issues, and possible 'red oil' and acetohydroxamic acid reactions."[190] We asked the parties to explain their

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[185] Ex. NRC-008, SER, at 12-2. The emergency plan contains non-public information and was filed on the non-public docket for this proceeding.

[186] *Id.* at 12-3.

[187] *Id.* at A-10 to A-14.

[188] *See id.* at A-35.

[189] *Id.*

[190] ACRS Letter at 4. The ACRS identified red oil and acetohydroxamic acid as compounds that have been implicated in industrial accidents and may be present in the SHINE facility. *Id.*

plans to address these items.[191] SHINE stated that although these items are not tracked as commitments in the SER, SHINE will track these topics along with its regulatory commitments in its Corrective Action Program.[192] The Staff stated that it intends to follow up on all issues raised by the ACRS at the operating license stage.[193]

C. The Proposed Site

SHINE plans to build its Medical Radioisotope Production Facility on a 91-acre (36.8-hectare) agricultural parcel that lies just south of the corporate boundaries of the City of Janesville in Rock County, Wisconsin.[194] The area surrounding the site is rural and is used primarily for agriculture.[195] The population within 5 miles (8 kilometers) of the SHINE site, based on 2010 estimates, is approximately 43,000.[196] The nearest permanent residence is about half a mile (a little less than 1 kilometer) northwest of the center of the site.[197] Several industrial facilities and the Southern Wisconsin Regional Airport are located within 5 miles (8 kilometers) of the SHINE site.[198]

The findings for the issuance of a construction permit require that we "tak[e] into consideration" the site criteria in 10 C.F.R. Part 100 to ensure that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of

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[191] Pre-Hearing Questions at 3.

[192] Ex. SHN-002, SHINE Responses to Pre-Hearing Questions, at 6; Tr. at 53 (Mr. Costedio).

[193] Tr. at 85-86 (Dr. Gavrilas), 105-06 (Mr. Adams).

[194] Ex. NRC-008, SER, at 2-2.

[195] *Id.*

[196] *Id.*; Ex. NRC-006C, Construction Permit Application, PSAR, at 2.1-7.

[197] Ex. NRC-008, SER, at 2-2.

[198] *Id.* at 2-5; Ex. NRC-006C, Construction Permit Application, PSAR, at 2.2-1 to 2.2-2.

the public.[199] The site criteria in Part 100 apply to nuclear reactors, and therefore do not expressly apply to the SHINE facility, but the Staff considered conditions similar to those in Part 100 in its review of the suitability of the proposed site.[200] The Staff reviewed SHINE's analyses of the geography and demography of the site; the proposed facility's interaction with nearby industrial, transportation, and military facilities; and site-specific issues relating to meteorology, hydrology, geology, seismology, and geotechnical engineering.[201] This review also included SHINE's analyses of structures, systems, and components and "equipment designed to ensure safe operation, performance, and shutdown when subjected to extreme weather, floods, seismic events, missiles (including aircraft impacts), chemical and radiological releases, and loss of offsite power."[202] After reviewing SHINE's analyses, the Staff concluded that there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.[203]

At the hearing, we asked SHINE to describe its seismic hazard evaluation.[204] Dr. Alan Hull, a seismic hazard specialist with Golder Associates, testified for SHINE.[205] Dr. Hull explained that the proposed facility is located in a low seismic hazard zone.[206] SHINE's analysis

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[199] 10 C.F.R. § 50.35(a)(4)(ii).

[200] Ex. NRC-001, Staff Information Paper, at 20; Ex. NRC-008, SER, at 2-1.

[201] Ex. NRC-001, Staff Information Paper, at 20; Ex. NRC-008, SER, at 2-1; *cf.* 10 C.F.R. § 100.10 (listing factors to be considered when selecting sites for nuclear reactors, including population density, seismology, meteorology, geology, and hydrology).

[202] Ex. NRC-001, Staff Information Paper, at 20.

[203] *Id.*

[204] Tr. at 126 (Chairman Burns).

[205] *Id.* (Dr. Hull).

[206] *Id.* at 126-27 (Dr. Hull).

used the Central Eastern United States-Seismic Source Characterization catalog, among other references, to establish the design basis earthquake for the SHINE facility—a 5.8 magnitude earthquake.[207]

We also asked SHINE to describe its flooding hazard analysis.[208] SHINE looked at the probable maximum precipitation event and the probable maximum flood at the proposed site.[209] The Rock River is about 2 miles (3.2 kilometers) from the site, but even in the event of the probable maximum flood, the water would be about 50 feet (15.2 meters) below the elevation of the site; therefore SHINE determined that flooding would not pose a hazard to the facility.[210] The probable maximum precipitation event would come up to the facility elevation, but SHINE determined that it would not flood the structure.[211] Berms would be constructed around the perimeter of the plant to prevent flooding due to off-site runoff.[212]

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[207] Ex. NRC-006C, Construction Permit Application, PSAR, at 2.5-14, 2.5-17; Tr. at 127 (Dr. Hull).

[208] Tr. at 128 (Chairman Burns).

[209] *Id.* (Ms. Kolb). The probable maximum precipitation event "is defined as the theoretical greatest depth of precipitation for a given duration that is physically possible over a particular drainage area at a certain time of year." Ex. NRC-006C, Construction Permit Application, PSAR, at 2.4-13. The probable maximum flood is estimated using NRC Regulatory Guides 1.59 and 3.40 and data from the U.S. Army Corps of Engineers. *Id.* at 2.4-11. *See generally* Regulatory Guide 1.59, "Design Basis Floods for Nuclear Power Plants," Rev. 2 (Aug. 1977) (ML003740388); Regulatory Guide 3.40, "Design Basis Floods for Fuel Reprocessing Plants and for Plutonium Processing and Fuel Fabrication Plants," Rev. 1 (Dec. 1977) (ML003739400).

[210] Tr. at 128 (Ms. Kolb); *see also* Ex. NRC-006C, Construction Permit Application, PSAR, at 2.4-9, 2.4-11 to 2.4-13 (noting the difference between site elevation and the probable maximum flood at 51 feet (15.5 meters)).

[211] Tr. at 128 (Ms. Kolb); *see also* Ex. NRC-006C, Construction Permit Application, PSAR, at 2.4-6 to 2.4-9; Ex. NRC-008, SER, at 2-16 to 2-20 (finding acceptable SHINE's consideration of hydrologic events for the proposed site).

[212] Ex. NRC-006C, Construction Permit Application, PSAR, at 2.4-9.

D. Additional Safety Considerations

SHINE also must demonstrate that it is financially qualified to construct the proposed Medical Radioisotope Production Facility.[213] SHINE provided information on the estimated costs of constructing the facility and related fuel cycle costs, and it described the sources of funding that it would use to cover those costs.[214] It explained that it has obtained funding from various sources of financing, including equity, debt, and government grants.[215] Among these sources, SHINE has received funding commitments to date totaling $58 million; a cost-sharing agreement with the Department of Energy, National Nuclear Security Administration would provide $25 million of that amount.[216] SHINE is in the process of obtaining equity investment financing.[217] SHINE also expects to enter into a short-term lease, a debt agreement, or some combination of the two, but expects that it would fully own the facility within five years of startup.[218] Although not required at the construction permit stage, SHINE also provided information on the costs and expected sources of funds during facility operation and

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[213] *See* 10 C.F.R. §§ 50.33(f)(1), 50.40(b); *see also* 10 C.F.R. pt. 50, app. C.

[214] Ex. NRC-006G, Construction Permit Application, PSAR, at 15-1; *see* 10 C.F.R. § 50.33(f)(1) (requiring an applicant for a construction permit to demonstrate that it "possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs").

[215] Ex. NRC-006G, Construction Permit Application, PSAR, at 15-2.

[216] *Id.*

[217] *Id.*

[218] *Id.*

decommissioning, which the Staff will consider when SHINE submits its operating license application.[219]

The Staff reviewed SHINE's financial qualifications information, including SHINE's responses to requests for additional information.[220] The Staff requested itemized information on SHINE's construction costs and requested that SHINE provide the basis for each estimated cost in its application.[221] The Staff found reasonable SHINE's construction estimates, which were prepared by an established construction company with experience across a variety of industries.[222] The Staff also found reasonable SHINE's estimated fuel cycle costs, which were based on information obtained from the Department of Energy, National Nuclear Security Administration for the cost of a one-year supply of low enriched uranium.[223] After reviewing SHINE's cost and funding information, the Staff concluded that SHINE had met the financial qualifications requirements for the issuance of a construction permit.[224]

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[219] *Id.* at 15-3 to 15-5; Ex. NRC-008, SER, at 15-1. The expected construction costs and anticipated revenue from operating the SHINE facility are proprietary and are not included in the public version of the application.

SHINE also provided information on nuclear insurance and indemnity pursuant to the Price-Anderson Act. *See* AEA § 170, 42 U.S.C. § 2210; 10 C.F.R. pt. 140. But because SHINE has not applied to possess special nuclear material, the Staff determined that this information was outside the scope of the construction permit application. Ex. NRC-006G, Construction Permit Application, PSAR, at 15-7; Ex. NRC-008, SER, at 15-6 to 15-7. The Staff stated that it will review this information when SHINE submits its operating license application or applies for a Part 70 license to possess special nuclear material. Ex. NRC-008, SER, at 15-6 to 15-7.

[220] Ex. NRC-008, SER, at 15-3 to 15-4.

[221] *Id.* at 15-4.

[222] *Id.*

[223] *Id.*

[224] *Id.* at 15-4 to 15-5.

SHINE also provided information on whether it would be subject to foreign ownership, control, or domination.[225] SHINE explained that it is a private corporation that has approximately 25 shareholders.[226] SHINE employees also participate in a stock options plan. SHINE stated that "[t]o the best of [its] knowledge, all of [its] current shareholders holding 1 percent or more of SHINE's stock are U.S. citizens or entities owned or controlled by U.S. citizens" and "[a]ll of [its] current employees holding stock options are U.S. citizens."[227] SHINE further represented that six of the seven directors on SHINE's Board are U.S. citizens.[228] Based on its review, the Staff found that SHINE had provided sufficient information to demonstrate that it "is not owned, controlled, or dominated by an alien, foreign corporation, or foreign government."[229]

E. The Staff's Environmental Review

The Staff prepared an EIS given "the potential for . . . significant impacts and unique considerations . . . [for] a first-of-a-kind application for a medical radioisotope production facility."[230] After publishing a notice of its intent to prepare an EIS, the Staff held two public scoping meetings in Janesville to gather input on issues to consider in its environmental

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[225] Ex. NRC-006G, Construction Permit Application, PSAR, at 15-6; *see* 10 C.F.R. § 50.33(d)(iii) (requiring an applicant that is a corporation to state "[w]hether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details").

[226] Ex. NRC-006G, Construction Permit Application, PSAR, at 15-6.

[227] *Id.*

[228] *Id.* One of the directors is a Canadian citizen with U.S. permanent resident status. *Id.*

[229] Ex. NRC-008, SER, at 15-6.

[230] Tr. at 171 (Mr. Wrona).

review.[231] The Staff received comments on a variety of topics, including impacts to groundwater, nearby agricultural land, impacts from potential aircraft accidents, and alternative sites and technologies.[232] The Staff responded to the scoping comments in the draft EIS (DEIS).[233] The DEIS was itself put out for public comment, and those comments received were addressed in the FEIS.[234]

In its preparation of the EIS, the Staff worked with the Department of Energy as a cooperating agency. The Department of Energy itself was obliged under NEPA to conduct an environmental review due to its financial support of the project, and the American Medical Isotopes Production Act of 2012 requires the NRC and the Department of Energy to ensure that their "environmental reviews of facilities to produce medical radioisotopes are [complementary] and not duplicative."[235] To that end, the Staff and the Department of Energy entered into a Memorandum of Agreement, which designated the NRC as the lead agency with the primary role in preparing the EIS; the Department of Energy provided assistance as the cooperating agency.[236]

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[231] SHINE Medical Technologies, Inc., 78 Fed. Reg. 39,343 (July 1, 2013); Tr. at 172 (Mr. Wrona); Ex. NRC-009, FEIS, at xvii.

[232] Tr. at 172-73 (Mr. Wrona).

[233] *Id.* at 173 (Mr. Wrona).

[234] *See* Construction Permit Application for the SHINE Medical Radioisotope Production Facility, 80 Fed. Reg. 27,710 (May 14, 2015); Ex. NRC-009, FEIS, app. A.

[235] Tr. at 173-74 (Mr. Wrona); *see* 42 U.S.C. § 2065(d) ("The Department and the Nuclear Regulatory Commission shall ensure to the maximum extent practicable that environmental reviews for the production of the medical isotopes shall complement and not duplicate each review.").

[236] Tr. at 174 (Mr. Wrona); Ex. NRC-009, FEIS, at 1-5; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 40-41.

The Staff evaluated the environmental impacts of constructing, operating, and decommissioning the SHINE facility across a variety of resource areas, including ecological resources, water resources, and socioeconomic conditions.[237] The Staff concluded that the potential impacts of the proposed action would be small for all resource areas, except for traffic, where impacts could range from small to moderate due to increased vehicle traffic to and from the site.[238] The Staff's review also considered the environmental impacts of waste generated from operating the SHINE facility, a topic that we explored with the parties in pre-hearing questions and at the hearing.[239] In addition to other waste streams, we asked the parties to address plans for disposal of any Greater-Than-Class-C (GTCC) waste generated during SHINE's production process.[240] SHINE stated that it has been in discussions with facilities that are licensed to accept GTCC waste for storage.[241] Further, SHINE explained that a provision in the American Medical Isotopes Production Act requires the Department of Energy to take back and dispose of waste without a disposal path.[242] SHINE also raised the possibility that its finalized design might limit or eliminate any GTCC waste stream.[243]

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[237] Tr. at 175 (Ms. Moser); *see also* Ex. NRC-009, FEIS, ch. 4.

[238] Tr. at 175 (Ms. Moser); Ex. NRC-009, FEIS, at 6-1, 6-4.

[239] *See* Tr. at 154-55 (Commissioner Svinicki), 202 (Commissioner Baran); Pre-Hearing Questions at 20; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 42.

[240] *See* Tr. at 154-55 (Commissioner Svinicki), 202 (Commissioner Baran); Pre-Hearing Questions at 20.

[241] Tr. at 155 (Ms. Kolb).

[242] *Id.* at 155-56 (Ms. Kolb), 203 (Dr. Vann Bynum); *see* 42 U.S.C. § 2065(c)(3)(A)(ii) (requiring that the uranium lease contracts must require the Secretary of Energy "to take title to and be responsible for the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased under this section for which the Secretary determines the producer does not have access to a disposal path").

[243] Tr. at 155 (Ms. Kolb). The Environmental Protection Agency commented on this issue in the DEIS. *See* Ex. NRC-009, FEIS, at A-36 to A-37. After the Secretary closed the record for this

The Staff also evaluated whether any threatened or endangered species were present onsite that could be affected by the project. Section 7 of the Endangered Species Act of 1973 requires an agency, in consultation with and with the assistance of the Secretary of the Interior or the Secretary of Commerce (as appropriate), to ensure that "any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species."[244] The U.S. Fish and Wildlife Service (under the Department of the Interior) and the National Marine Fisheries Service (under the Department of Commerce) jointly administer the Act.

SHINE conducted ecological surveys of the proposed site and the offsite area where construction of the sewer line would occur.[245] The Staff reviewed this information, as well as information obtained from the U.S. Fish and Wildlife database and concluded that no endangered species were present in this area.[246] The Staff also contacted the U.S. Fish and Wildlife Service, which stated that no federally listed, proposed, or candidate species would be expected within the project area and that no critical habitat is present.[247] The Staff conducted a

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proceeding, the Staff informed us that the Environmental Protection Agency had again raised this issue in comments on the FEIS. The Staff attached its response, which explained that the Environmental Protection Agency had based its comments on a non-public draft of the FEIS that did not include the Staff's finalized discussion of the GTCC issue. The Staff provided to the Environmental Protection Agency the response from the published FEIS and supplemented that response with testimony from the hearing. *See Notification of Correspondence Between the NRC Staff and the Environmental Protection Agency Regarding the Final Environmental Impact Statement* (Jan. 15, 2016).

[244] Endangered Species Act § 7(a)(2), 16 U.S.C. § 1536(a)(2).

[245] Ex. NRC-009, FEIS, at 3-35.

[246] *Id.*

[247] *Id.* The Staff determined that because the site does not contain any surface water features and the nearby Rock River "does not contain marine or anadromous fish species," there would

similar review for state-listed species and determined that none would be present at the proposed site or nearby adjacent areas.[248] The Wisconsin Department of Natural Resources also determined that the site would not provide a suitable habitat for state-listed species, therefore there would be no potential for them to exist on the site.[249]

In accordance with the National Historic Preservation Act of 1966, the Staff reviewed whether the proposed action would have any effect on historic and cultural resources.[250] SHINE commissioned an archeological survey of the site, but "did not identify any archaeological sites or evidence of cultural resources within the survey area."[251] The Staff contacted the Advisory Council on Historic Preservation and the Wisconsin Historical Society.[252] The Staff also visited the Wisconsin Historical Society and reviewed listings of archeological resources.[253] Based on the information it gathered, the Staff concluded that there were no historic properties or historic and cultural resources on the proposed site.[254] The Wisconsin Historical Society confirmed that no historic properties would be affected by the proposed action.[255]

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be no federally listed species within the action area under the jurisdiction of the National Marine Fisheries Service. *Id.*

[248] *Id.* at 3-35 to 3-36.

[249] *Id.* at 3-36.

[250] *Id.* at 3-40, 4-28 to 4-29.

[251] *Id.* at 3-40; *see also* Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 43.

[252] Ex. NRC-009, FEIS, at 4-28 to 4-29.

[253] *Id.*; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 43.

[254] Ex. NRC-009, FEIS at 4-28 to 4-29; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 43.

[255] Ex. NRC-009, FEIS, at 4-29.

Also as part of this review, the Staff initiated consultation with 13 federally recognized Indian Tribes with historic ties to southern Wisconsin.[256] The Staff received scoping comments from one tribe, the Forest County Potawatomi, which stated that the proposed project would be located on Potawatomi ancestral land, expressed concern for any impacts to historic and cultural properties in that area, and requested to receive the results of the historic and cultural investigation.[257] The Staff attempted to contact the Tribe to share information about its review.[258] It also provided copies of the DEIS and FEIS to the Forest County Potawatomi, along with the other affected Tribes.[259] The Peoria Tribe of Indians of Oklahoma commented on the DEIS and stated that the proposed action would not appear to affect items of cultural significance to the Tribe but requested immediate notification and consultation if items covered under the Native American Graves Protection and Repatriation Act are discovered onsite.[260]

The Staff also analyzed alternatives to the proposed action.[261] This review included consideration of the no-action alternative, alternative sites, and alternative technologies.[262] For the no-action alternative, i.e., if the construction permit were to be denied, the Staff found that no changes would occur on the site, but that alternative also would not meet the purpose of the

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[256] *Id.*

[257] *Id.*; Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 31-33.

[258] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 32. The Staff represented that it provided information about the availability of SHINE's archeological survey report to the Potawatomi Tribe in March 2015. *Id.*

[259] *Id.*

[260] *Id.*

[261] *See* Ex. NRC-009, FEIS, ch. 5.

[262] *Id.* at 5-1.

proposed action—to provide a domestic supply of molybdenum-99.[263] After reviewing the applicant's systematic site-selection process, the Staff examined two alternative sites, both in the State of Wisconsin—one in Chippewa Falls, and one in Stevens Point.[264] The Staff compared the environmental costs and benefits of the proposed action at these alternative sites with the costs and benefits of the proposed action at the Janesville site.[265] The Staff found that impacts at the Chippewa Falls site would be small for all resource areas except for noise and traffic.[266] It found that impacts at the Stevens Point site would be small for all resource areas except for traffic, noise, and visual impacts to the surrounding landscape.[267] With "small to moderate impacts" in fewer resource areas, the Staff concluded that the Janesville site was the environmentally preferable alternative site.[268]

The Staff considered three technologies for the production of medical isotopes that it found to be feasible: neutron capture technology, aqueous homogenous reactor technology, and linear-accelerator-based technology.[269] The Staff selected these technologies because at the time the Staff was preparing the EIS, they had been selected to receive funding from the National Nuclear Security Administration.[270] The Staff further narrowed its review of these

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[263] *Id.* at 5-1 to 5-2.

[264] *Id.* at 5-2 to 5-6.

[265] *Id.* at 5-103 to 5-105.

[266] Ex. NRC-013, Construction Permit Application Review, SHINE Medical Technologies, Environmental Panel (Dec. 8, 2015), at 12 (Staff Environmental Panel Presentation).

[267] *Id.*

[268] Tr. at 181 (Ms. Moser).

[269] Ex. NRC-009, FEIS, at 5-92.

[270] *Id.* at 5-92 to 5-93.

alternatives, however, to one technology—the linear accelerator—because sufficient information was not available to review the other alternatives.[271] The Staff concluded that the linear accelerator technology, if constructed, operated, and decommissioned at the Janesville site, would have similar impacts to SHINE's proposed technology—small impacts in all resource areas except for traffic, which would be small to moderate.[272]

Considering the results of its environmental review the Staff recommended the issuance of the construction permit to SHINE.[273] At the operating license stage, the Staff will prepare a supplement to the FEIS to address any new and significant information that was not available during its review of the construction permit application.[274]

F. Findings

We have conducted an independent review of the sufficiency of the Staff's safety findings, with particular attention to the topics discussed above. Our findings, however, are based on the record as a whole. Based on the evidence presented in the uncontested hearing, including the Staff's review documents and the testimony provided, we find that SHINE has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified major features or components incorporated therein for the protection of the health and safety of the public. Further technical or design information as may be required to complete the safety analysis has reasonably been left for later consideration and will be supplied in the Final Safety Analysis Report. SHINE has described the safety features or components that require research and

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[271] *Id.* at 5-93 to 5-94; Tr. at 179-80 (Ms. Moser).

[272] Ex. NRC-009, FEIS, at 5-104 to 5-105.

[273] *Id.* at 6-13.

[274] Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 40.

development and has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with these features or components. On the basis of the foregoing, we find that there is reasonable assurance that open safety questions will be resolved satisfactorily at or before the latest date stated in the application for completion of construction of the proposed facility, and that, taking into consideration the site criteria in 10 C.F.R. Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

In making these findings, we also conclude that: there is reasonable assurance that construction of the facility will not endanger the health and safety of the public, and that the authorized activities can be conducted in compliance with the NRC's regulations, including the requirements in 10 C.F.R. Part 20; SHINE is technically and financially qualified to engage in the activities authorized; issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public; and SHINE's application meets the standards and requirements of the Atomic Energy Act and the NRC's regulations, and the required notifications to other agencies or bodies have been duly made.[275] Additionally, we find that the Staff's proposed permit conditions are appropriately drawn and sufficient to provide reasonable assurance of adequate protection of public health and safety.[276]

We also conducted an independent review of the Staff's environmental analysis in the FEIS, taking into account the particular requirements of NEPA. NEPA section 102(2)(A) requires agencies to use "a systematic, interdisciplinary approach which will insure the

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[275] *See, e.g.*, 10 C.F.R. § 2.104(a); Ex. NRC-009, FEIS, at 1-6 to 1-7.

[276] *See* 10 C.F.R. §§ 50.35(b), 50.50; Ex. NRC-002-R, Draft Construction Permit, at 2-3. We agree with the Staff's decision to remove the proposed permit condition that would have set forth criteria for SHINE to obtain pre-approval for certain construction changes. *See* Ex. NRC-004-R, Staff Responses to Pre-Hearing Questions, at 45-47; *see also supra* note 144.

integrated use of the natural and social sciences and the environmental design arts" in decision-making that may impact the environment.[277] We find that the environmental review team used the systematic, interdisciplinary approach that NEPA requires.[278] The environmental review team consisted of over twenty individuals with expertise in disciplines including ecology, geology, hydrology, human health, socioeconomics, and cultural resources.[279]

NEPA section 102(2)(E) calls for agencies to study, develop, and describe appropriate alternatives.[280] The alternatives analysis is the "heart of the environmental impact statement."[281] Based on the Staff's testimony at the hearing, as well as the discussion in the FEIS, we find that the environmental review identified an appropriate range of alternatives with respect to the no-action alternative, alternative technologies, and alternative sites and adequately described the environmental impacts of each alternative.[282] We find reasonable the Staff's conclusion that none of the alternatives considered is environmentally preferable to the proposed action.[283]

NEPA section 102(2)(C) requires us to assess the relationship between local short-term uses and long-term productivity of the environment, to consider alternatives, and to describe the unavoidable adverse environmental impacts and the irreversible and irretrievable commitments

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[277] NEPA § 102(2)(A), 42 U.S.C. § 4332(2)(A).

[278] *See, e.g.*, Tr. at 170-87 (providing an overview of the Staff's environmental review methodology and findings); Ex. NRC-013, Staff Environmental Panel Presentation, at 5-16.

[279] Ex. NRC-009, FEIS, at 7-1 (listing contributors from the NRC; Department of Energy, National Nuclear Security Administration; Los Alamos Technical Associates; and Idoneous Consulting).

[280] NEPA § 102(2)(E), 42 U.S.C. § 4332(2)(E).

[281] 10 C.F.R. pt. 51, subpt. A, app. A, § 5.

[282] *See, e.g.*, Tr. at 176-82, 188-89 (Ms. Moser); Ex. NRC-009, FEIS, ch. 5.

[283] *See, e.g.*, Tr. at 181-83 (Ms. Moser); Ex. NRC-009, FEIS, at 6-4.

of resources associated with the proposed action.[284] The discussion of alternatives is in Chapter 5 of the FEIS; the other items are discussed in Chapter 6.[285] The environmental review team found that the short-term uses of the environment—construction, operation, and decommissioning of the SHINE facility—would commit land and energy indefinitely or permanently.[286] After the facility is decommissioned, the land could return to productive use, but it may not be suitable for farming, depending on the condition of the soil, and would be further limited if the land is used to meet waste disposal needs.[287] Also in the short term, however, the project would bring increased employment, expenditures, and tax revenues that would directly benefit local, regional, and state economies.[288] Additionally, there could be long-term benefits from "[l]ocal governments investing project-generated tax revenues into infrastructure and other required services," which would enhance economic productivity; and the additional infrastructure resulting from the SHINE facility (e.g., connection to water and sewer systems) "would be available and beneficial for any future use of the proposed SHINE facility after its decommissioning."[289]

Chapter 6 of the FEIS includes a chart of the unavoidable adverse environmental impacts during construction, operation, and decommissioning, along with actions to mitigate those impacts.[290] The environmental review team found that the unavoidable adverse impacts

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[284] NEPA § 102(2)(C)(ii)-(v), 42 U.S.C. § 4332(2)(C)(ii)-(v).

[285] Ex. NRC-009, FEIS, chs. 5-6.

[286] *Id.* at 6-11 to 6-12.

[287] *Id.* at 6-12.

[288] *Id.*

[289] *Id.*

[290] *Id.* tbl. 6-2.

of the project would be small for all resource areas, except for increased traffic during construction and decommissioning, which could be small to moderate.[291] To mitigate traffic impacts, "SHINE would stagger construction work-shift schedules to reduce the hourly traffic flow . . . and schedule truck deliveries early in the day to help reduce traffic congestion."[292] SHINE also would follow delivery routes and avoid residential areas.[293]

Finally, with regard to irreversible and irretrievable commitments of resources, the environmental review team concluded that construction of the SHINE facility would irretrievably consume construction materials, unless SHINE recycles them after decommissioning.[294] The soils on the property could be irreversibly damaged, such that they would no longer be suitable for farming.[295] During operation, the uranium used in the production of molybdenum-99 "would be the main resource that would be irreversibly and irretrievably committed."[296] The Staff also found that electricity, fuel, and water would be expended, but that the amounts used for constructing, operating, and decommissioning the SHINE facility would not be expected "to deplete available supplies or exceed available system capacities."[297]

We must weigh these unavoidable adverse environmental impacts and resource commitments—the environmental "costs" of the project—against the project's benefits.[298]

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[291] *Id.* at 6-5, 6-9; Tr. at 65-66 (Ms. Marshall).

[292] Ex. NRC-009, FEIS, at 6-9.

[293] *Id.*

[294] *Id.* at 6-12.

[295] *Id.*

[296] *Id.*

[297] *Id.* at 6-13.

[298] *Cf.* 10 C.F.R. § 51.105(a).

Considering the need for a reliable supply of medical isotopes in the United States and the expected increase in jobs and tax revenue described during the hearing and in the FEIS, we find that the benefits of the project outweigh the costs described above. Moreover, we have considered each of the requirements of NEPA section 102(2)(C) and find nothing in the record that would lead us to disturb the Staff's conclusions on those requirements.

In sum, for each of the topics discussed at the hearing and in today's decision, we find that the Staff's review was reasonably supported in logic and fact and sufficient to support the Staff's conclusions. Based on our review of the FEIS, we also find that the remainder of the FEIS was reasonably supported and sufficient to support the Staff's conclusions. Therefore, as a result of our review of the FEIS, and in accordance with the Notice of Hearing for this uncontested proceeding, we find that the requirements of NEPA section 102(2)(A), (C), and (E), and the applicable regulations in 10 C.F.R. Part 51, have been satisfied with respect to the construction permit application. We independently considered the final balance among conflicting factors contained in the record of this proceeding. We find, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, that the construction permit should be issued.

III. CONCLUSION

We find that, with respect to the safety and environmental issues before us, the Staff's review of SHINE's construction permit application was sufficient to support issuance of the construction permit. We *authorize* the Director of the Office of Nuclear Reactor Regulation to issue the permit for the construction of the SHINE Medical Radioisotope Production Facility. Additionally, we *authorize* the Staff to issue the record of decision, subject to its revision as necessary to reflect the findings in this decision.

IT IS SO ORDERED.

For the Commission

NRC Seal

/RA/

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Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 25th day of February, 2016.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
SHINE Medical Technologies, Inc.	)	Docket No. 50-608-CP
	)	
(Mandatory Hearing)	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **COMMISSION MEMORANDUM AND ORDER (CLI-16-04)** have been served upon the following persons by the Electronic Information Exchange.

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[Original signed by Clara Sola]
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