

November 25, 2015

Mr. John W. Stetkar, Chairman
Advisory Committee on Reactor Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: RESPONSE TO REPORT ON THE SAFETY ASPECTS OF THE
CONSTRUCTION PERMIT APPLICATION FOR SHINE MEDICAL
TECHNOLOGIES, INC. MEDICAL ISOTOPE PRODUCTION FACILITY

Dear Mr. Stetkar:

By letter dated October 15, 2015 (Agencywide Documents Access and Management System Accession No. ML15286A426), the Advisory Committee on Reactor Safeguards (ACRS) reported on its review of the staff's safety evaluation report for the SHINE Medical Technologies, Inc. (SHINE) construction permit application. This construction permit application describes the preliminary design and analysis of SHINE's proposed commercial medical isotope production facility, to be located in Janesville, Wisconsin. The proposed SHINE facility would comprise an irradiation facility and radioisotope production facility for the irradiation and processing of special nuclear material to produce medical radioisotopes, such as molybdenum-99. The ACRS undertook this review to fulfill the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards," which mandate the ACRS' review and report on construction permits for facilities of the type described in 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities."

In its letter, the ACRS recommended that the SHINE construction permit should be approved. During its discussions with SHINE and the U.S. Nuclear Regulatory Commission (NRC) staff, the ACRS identified two safety concerns that could impact the operation of the SHINE facility if not sufficiently addressed during construction. To address these concerns, the ACRS requested that additional information be provided on (1) the facility's layout capability and (2) the facility's ability to withstand potential aircraft impact. During the ACRS subcommittee and full committee meetings, SHINE and the NRC staff (1) provided information addressing the provisions made to address facility layout and (2) clarified the analysis of the SHINE facility's ability to withstand aircraft impacts. Based on discussions during the subcommittee and full committee meetings, the ACRS determined that SHINE and the NRC staff provided sufficient information to address facility layout and potential aircraft impact such that it could recommend the issuance of a construction permit.

Additionally, SHINE clarified the relationship between safety-related structures, systems, and components (SSCs) and safety-related activities by defining safety-related activities as those affecting the safety-related functions of SSCs, including siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

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SHINE has committed to providing procedures for facility layout and an updated quality assurance program description that includes its definition of safety-related activities in its final safety analysis report. The staff is tracking these commitments in Appendix A of its safety evaluation report related to the SHINE construction permit application.

The staff appreciates the Committee's efforts on this matter. We thank the ACRS for its valuable input, and we look forward to working with the Committee in the future.

Sincerely,

/RA Michael R. Johnson Acting for/

Victor M. McCree
Executive Director
for Operations

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
SECY

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SHINE has committed to providing procedures for facility layup and an updated quality assurance program description that includes its definition of safety-related activities in its final safety analysis report. The staff is tracking these commitments in Appendix A of its safety evaluation report related to the SHINE construction permit application.

The staff appreciates the Committee's efforts on this matter. We thank the ACRS for its valuable input, and we look forward to working with the Committee in the future.

Sincerely,

/RA Michael R. Johnson Acting for/

Victor M. McCree
Executive Director
for Operations

cc: Chairman Burns
Commissioner Svinicki
Commissioner Ostendorff
Commissioner Baran
SECY

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