

OFFICE OF NUCLEAR REACTOR REGULATION
REGULATORY AUDIT TOPICS
REGARDING FIRE PROTECTION DESCRIBED IN
OPERATING LICENSE APPLICATION
CONSTRUCTION PERMIT NO. CPMIF-001
SHINE MEDICAL TECHNOLOGIES, LLC
SHINE MEDICAL ISOTOPE PRODUCTION FACILITY
DOCKET NO. 50-608

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

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

Audit Topic 1

The Final Safety Analysis Report (FSAR), Chapter 1, "The Facility," states, in part, that the FSAR generally follows the content and organization of NUREG-1537, Part 1, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content. (ADAMS Accession No. [ML20105A297](#))

Additionally, the FSAR, Chapter 9, "Auxiliary Systems," Section 9a2.3.1, "Fire Protection, Plan and Program," states that the development of the Fire Protection Plan (FPP) is informed by the guidance provided in National Fire Protection Association (NFPA) 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials," and that the structure and content of the FPP are based on the precepts of 10 CFR 50.48(a), "Fire Protection," and NFPA 801. (ADAMS Accession No. [ML20105A305](#))

NUREG-1537, Part 1 states that, "[u]pon receiving an application, the NRC staff will review and evaluate the SAR [Safety Analysis Report] against the standard review plan (NUREG-1537, Part 2) to determine if the SAR contains the information necessary to form the bases for the

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staff findings required for the issuance or renewal of an operating license or granting of a license amendment.”

Based on the information provided in the FSAR Section 9a2.3, the NRC staff was unable to determine how the applicant incorporates the elements of a fire protection plan described in 10 CFR 50.48(a), and follows guidelines in NFPA 801, and NUREG-1537, Parts 1 and 2. Therefore, the NRC staff requests that the applicant provide the following information:

1. Fire Protection Plan (FPP)
2. Fire Hazards Analysis (FHA);
3. Safe Shutdown Analysis;
4. Pre-Fire Plans;
5. Any currently available fire protection administrative control procedures (e.g. welding and cutting, combustible controls, housekeeping, etc.); and
6. Any evaluations that describe the consequences of a radiological release.