

From: [Lynch, Steven](#)
To: ["Jeff.Bartelme@shinemed.com"](mailto:Jeff.Bartelme@shinemed.com)
Subject: SHINE Fire Protection Audit Topic
Date: Monday, June 29, 2020 5:07:00 PM
Attachments: [SHINE Draft Fire Protection Audit Topic.pdf](#)

Jeff,

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 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. As part of its review, the NRC staff has prepared audit topics related to SHINE's fire protection program, which are included as an attachment to this e-mail.

To prevent the inadvertent release of sensitive information, the NRC staff requests that SHINE review this audit topic to ensure that no proprietary information has been included. Should SHINE identify any proprietary information, contact Steven Lynch within the next ten days.

Following the completion of SHINE's review or after ten days, whichever comes first, the document and e-mail correspondence will be added to ADAMS. Proprietary information within these documents will be withheld from public disclosure pursuant to Title 10 of the Code of Federal Regulations 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Documents that do not contain proprietary information will be made publicly available.

The NRC staff also requests that SHINE propose a date or dates to discuss this audit topic, including when specific reference documents may be available.

Please contact me with any questions.

Steve Lynch, Project Manager
Non-Power Production and Utilization Facility Licensing Branch
Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission
Office: O-4H7
MS: O-12D20
Phone: 301-415-1524