



June 9, 2017

SMT-2017-025

Secretary
U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

References: (1) U.S. Nuclear Regulatory Commission, "Non-Power Production or Utilization Facility License Renewal (10 CFR Parts 2, 50, and 51)," *Federal Register*, Vol. 82, No. 60, March 30, 2017, pp. 15643-15660

SHINE Medical Technologies, Inc. Comments on Proposed Rulemaking Related to Non-Power Production or Utilization Facility License Renewal (Docket ID NRC-2011-0087)

SHINE Medical Technologies, Inc. (SHINE) appreciates the opportunity to comment on the proposed rulemaking related to non-power production or utilization facility license renewal (Reference 1).

Enclosure 1 provides the SHINE comments on Reference (1).

If you have any questions, please contact me at 608/210-1735.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Jeff M. Bartelme', with a stylized flourish at the end.

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Steven T. Lynch, Project Manager, USNRC

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. COMMENTS ON PROPOSED RULEMAKING RELATED TO NON-POWER PRODUCTION OR UTILIZATION FACILITY LICENSE RENEWAL (DOCKET ID NRC-2011-0087)

The proposed rulemaking related to non-power production or utilization facility license renewal (Reference 1), in part, amends 10 CFR 50.2 to include a definition for “non-power production or utilization facility,” of “NPUF.” As described in Reference (1), the creation of a definition for NPUF is intended to address inconsistencies in definitions and terminology associated with NPUFs, which result in challenges in determining the applicability of certain regulations. The existing definitions for non-power facilities do not include new entities like SHINE Medical Technologies, Inc. (SHINE).

Although the proposed rule is intended to ensure clarity and consistency in the applicability of the associated regulations for NPUFs, the scope of the proposed rulemaking leaves uncertainty in the applicability of certain regulations within Title 10 of the Code of Federal Regulations to SHINE and other future entities. Reactor-specific regulations are not applicable to SHINE, despite the classification of the SHINE facility as an NPUF along with non-power reactors, research reactors, and testing facilities. Specific examples of such regulations, applicable to certain NPUFs but not applicable to SHINE, are provided below. This is not intended to be an all-inclusive listing.

- 10 CFR 171.15, *“Annual fees: Reactor licenses and independent spent fuel storage licenses.”*

10 CFR 171.15(f) provides the annual fees for licensees authorized to operate a non-power reactor licensed under 10 CFR Part 50. Annual fees applicable to each a research reactor and a test reactor are provided in 10 CFR 171.15(f); however, the subject annual fees are not applicable to the SHINE facility.

- 10 CFR 140.11, *“Amounts of financial protection for certain reactors.”*

The SHINE Construction Permit (Reference 2) is conditioned such that the Commission will not issue a license authorizing operation of the SHINE facility unless SHINE executes an indemnity agreement as required by Section 170 of the Atomic Energy Act of 1954, as amended (the Act). 10 CFR 140.11 provides the amount of financial protection required of licensees to satisfy the requirements of the indemnification agreement, based on the nuclear reactor’s thermal power level. As the requirements of 10 CFR 140.11 are reactor-specific, they are not applicable to SHINE. The financial protection requirements provided in 10 CFR 140.12, *“Amount of financial protection required for other reactors.”*, intended to cover facilities for which the amount of financial protection is not determined in 10 CFR 140.11, is also written as reactor-specific, and not applicable to SHINE.

SHINE recommends expanding the scope of the proposed rulemaking to provide clarity and consistency in the applicability of associated regulations for NPUFs within the entirety of Title 10, Chapter I, of the Code of Federal Regulations.

References

- (1) U.S. Nuclear Regulatory Commission, "Non-Power Production or Utilization Facility License Renewal (10 CFR Parts 2, 50, and 51)," *Federal Register*, Vol. 82, No. 60, March 30, 2017, pp. 15643-15660
- (2) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. – Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)