



September 28, 2015

SMT-2015-052
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

- References: (1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
(2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A361)

SHINE Medical Technologies, Inc. Application for Construction Permit
SHINE-Definition of "Safety-Related Activities"

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI (References 1 and 2).

SHINE has determined it is appropriate to define "safety-related activities," as follows:

safety-related activities – those activities affecting the safety-related functions of structures, systems, and components, including siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

SHINE will update Section 1.3 of the Quality Assurance Program Description (QAPD) to include the above definition of "safety-related activities," and provide the updated QAPD as part of the SHINE Operating License (OL) Application. An Issues Management Report (IMR) has been initiated to track the inclusion of the SHINE-definition of "safety-related activity" in the QAPD.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on September 28, 2015.

Very truly yours,

A handwritten signature in blue ink, appearing to read "Piefer", with a stylized flourish at the end.

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, Inc.
Docket No. 50-608

cc: Administrator, Region III, USNRC
Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health