SHINE™
Medical Technologies

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SHINE Medical Technologies, Inc. Comments on Amendments to Material Control and Accounting Regulations and Proposed Guidance for Fuel Cycle Facility Material Control and Accounting Plans and Completing the U.S. Nuclear Regulatory Commission Form 327 (NRC-2009-0096 and NRC-2013-0195)

SHINE Medical Technologies, Inc. (SHINE) appreciates the opportunity to comment on the NRC's proposed amendments to Material Control and Accounting (MC&A) regulations and proposed guidance.

Enclosure 1 provides the SHINE comments on the proposed 10 CFR 74 rule change and NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance," for consideration by the NRC.

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

Very truly yours,

R. V. Bynum

R. Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC

**SUNSI Review Complete**
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**ENCLOSURE 1**

**SHINE MEDICAL TECHNOLOGIES, INC.**

**SHINE MEDICAL TECHNOLOGIES, INC. COMMENTS ON AMENDMENTS TO MATERIAL CONTROL AND ACCOUNTING REGULATIONS AND PROPOSED GUIDANCE FOR FUEL CYCLE FACILITY MATERIAL CONTROL AND ACCOUNTING PLANS AND COMPLETING THE U.S. NUCLEAR REGULATORY COMMISSION FORM 327 (NRC-2009-0096 AND NRC-2013-0195)**

**Comments on the Proposed Rule (Docket ID: NRC-2009-0096)**

1. The proposed revision to 10 CFR 74.41(a)(2) (Reference 1) states that production and utilization facilities licensed under 10 CFR 50 are not subject to the requirements of 10 CFR 74, Subpart D, "Special Nuclear Material of Moderate Strategic Significance." A medical isotope production facility licensed as a production facility under 10 CFR 50 that possesses special nuclear material (SNM) of moderate strategic significance (Category II) would not be subject to Subpart D in the new regulation. Currently, 10 CFR 74.41(a) excludes nuclear reactors licensed pursuant to 10 CFR 50. Therefore, under the current regulations, a medical isotope production facility which is not a nuclear reactor would be subject to 10 CFR 74, Subpart D. Other than 10 CFR 74, Subpart A, "General Provisions," and Subpart B, "General Reporting and Recordkeeping Requirements," there does not appear to be applicable regulation to address a medical isotope production facility in the proposed revision to 10 CFR 74.

   SHINE Medical Technologies, Inc. (SHINE) recommends the NRC clarify the requirements that would be applicable to a production facility licensed under 10 CFR 50 that possesses SNM of moderate strategic significance.

2. Table 1 of Reference (1) states Subparts A and B contain proposed requirements applicable to a 10 CFR 70 license authorizing more than 350 grams. Table 2 of Reference (1) states the proposed revision to 10 CFR 74 is applicable to 10 CFR 70 licensees authorized to possess more than 350 grams of SNM for industrial, academic, and research types of use. According to the proposed rule, the regulations would be applicable to any facility possessing more than 350 grams of SNM.

   SHINE recommends the NRC clarify the requirements that would be applicable to a facility licensed under 10 CFR 50 and authorized to possess more than 350 grams of SNM.

3. Section II of Reference (1) states that in proposed 10 CFR 74.19(d), the NRC is proposing to expand the requirement to establish an item control system to include reactor facilities licensed under 10 CFR 50 or 10 CFR 52, and independent spent fuel storage installations (ISFSIs) licensed under 10 CFR 72. Table 2 of Reference (1) states that the new item control requirement in proposed 10 CFR 74.19(d) is applicable to reactors and ISFSIs. The proposed regulation states that 10 CFR 74.19(d) applies to

production or utilization facilities licensed under 10 CFR 50 or 10 CFR 52 and ISFSIs licensed under 10 CFR 72. Reference (1) is inconsistent in defining the applicability by license type of the proposed 10 CFR 74.19(d).

SHINE recommends the NRC clarify applicability of the proposed 10 CFR 74.19(d) for a facility that is not a reactor but which is licensed under 10 CFR 50.

4. The proposed revision to 10 CFR 74 includes a new General Performance Objective (GPO) in 10 CFR 74.3(e). The GPO states:

*"Control access to MC&A information that might assist adversaries to carry out acts of theft, diversion, misuse, or radiological sabotage involving SNM."*

Reference (1) states that the proposed rule would require information related to material control and accounting (MC&A) be stored in a locked file cabinet or office. Table 3 of Reference (1) indicates that the concern is tampering with completed records. NUREG-2159 (Reference 2), Page 5, briefly discusses this proposed regulation, but the discussion is vague and does not provide the necessary implementation guidance related to the intent of the regulation.

A medical isotope production facility may have multiple material balance areas (MBAs) with numerous people working with SNM in different forms and using different platforms to record and manage MC&A information. The information being managed could be a program description, implementing procedures, work instructions, data sheets, laboratory logs, and completed records. Without additional implementing guidance addressing the expectations and intent of the rule, a licensee will be unable to determine if MC&A information should be treated like confidential company information, have controls similar to safeguards information (SGI), or have something in between.

The following questions illustrate this concern:

1) Would the locked cabinet mentioned in Reference (1) need to be a General Services Administration (GSA) approved cabinet?
2) Would a laboratory technician recording a sample result need to guard the data sheet with the same rigor as if it were SGI?
3) Would the program description and implementing procedures need to have restricted access within the document control system?

SHINE recommends the NRC provide additional information related to the intent of this GPO and additional implementing guidance to enable licensees to implement an acceptable MC&A program.

**Comments on NUREG-2159 (Docket ID: NRC 2013 0195)**

1. NUREG-2159 (Reference 2), Section 7.5, states:

*"Licensees should present a description of the methodology, including cutoff and inventory minimization procedures, and they should identify all measurements (including sampling) sufficient to meet the requirements of 10 CFR 74.43(c)(7)."*

This code section is related to the timing of the inventories, and does not contain any other requirements. Complete requirements for inventory control and physical inventories are contained in 10 CFR 74.43(c).

SHINE recommends revising NUREG-2159, Section 7.5, to state

*"Licensees should present a description of the methodology, including cutoff and inventory minimization procedures, and they should identify all measurements (including sampling) sufficient to meet the requirements of 10 CFR 74.43(c)."*

2. NUREG-2159 (Reference 2), Section 7.7, discusses actions to take if the inventory difference (ID) exceeds three times the standard error of the inventory difference (SEID) and certain other minimal quantities. These actions and quantities are stated in 10 CFR 74.43(c)(8)(iii). The quantities listed in NUREG-2159, Section 7.7, are incomplete. 10 CFR 74.43(c)(8)(iii) also includes 9000 grams of uranium-235 contained in low enriched uranium.

   SHINE recommends that NUREG-2159, Section 7.7, include a complete listing of the minimum quantities from 10 CFR 74.43(c)(8)(iii).

3. NUREG-2159 (Reference 2), Section 8.2, states that containers of solutions in which the plutonium, uranium-233, or uranium-235 concentration is less than five grams per liter can be exempted from item control system coverage. Revised 10 CFR 74.43(b)(6) (Reference 1) states that items in solution with a concentration of less than five grams of uranium-235 per liter may be exempted from an item control system. SHINE believes that solutions containing small quantities of plutonium and uranium-233 should be exempt from item control.

   SHINE recommends that the proposed revision of 10 CFR 74.43(b)(6) be changed to be consistent with Section 8.2 of NUREG-2159.

**References**

(1) U.S. Nuclear Regulatory Commission, "Amendments to Material Control and Accounting Regulations," *Federal Register*, Vol. 78, No. 217, November 8, 2013, pp. 67225-67252

(2) U.S. Nuclear Regulatory Commission, "Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance" (Draft Report for Comment), NUREG-2159, September 2013 (ML13253A310)