UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 12, 2017

GMI OpCo.
(DBA Global Medical Instrumentation
and GMI)
ATTN: Jon Volling, President
6511 Bunker Lake Blvd.
Ramsey, MN 55303

SUBJECT: DISCONTINUATION OF EVALUATION OF GMI OPCO. APPLICATION FOR SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

Dear Mr. Volling:

This letter is in response to your application dated November 14, 2017, requesting a sealed source and device (SSD) registration certificate for Model LSC 8000 liquid scintillator counter. In reviewing your application, we find that it is lacking significant amounts of the required information. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Due to incomplete information, the NRC staff is unable to complete a safety evaluation of your application and has discontinued the evaluation of your application (SSD Case No. 18-07). This action is taken without prejudice to submission of the required information. A new action will be opened once the NRC receives a complete application per the requirements in *Title 10 of the Code of Federal Regulations* (10 CFR) 32.210 and the guidance provided in NUREG-1556, Volume 3, Revision 2.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact me at 301-415-5637, or via e-mail at Hipolito.Gonzalez@nrc.gov.

Sincerely,

/RA/

Hipolito Gonzalez, Chief
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As stated

DISCONTINUATION OF EVALUATION OF GMI OPCO. APPLICATION FOR SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

Date: December 12, 2017

DISTRIBUTION:
SSD 18-07

ADAMS Accession No.: ML17341B184

OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	CValentin-Rodriguez	THerrera	HGonzalez
DATE	12/11/2017	12/11/2017	12/11/2017

OFFICIAL RECORD COPY

GMI OpCo. Application Dated November 14, 2017

The following issues need to be addressed in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32.210 and the information provided in the relevant guidance document NUREG-1556 Volume 3, titled "Applications for Sealed Source and Device Evaluation and Registration."

General

1. Please indicate how the model name for the device should appear in your registration certificate. In your application you used different designations for the device, such as: LSC-8000, LSC8000, LSC 8000, LS 8000.

Description/Construction

2. Please provide detailed design and construction information for the Model LSC 8000. The information should be sufficient to allow us to fully understand the construction and operation of the device. In your response please make sure you include the following:

    - Specific details about the device components and safety features. This should include complete annotated engineering design and/or construction drawings of all safety critical components, such as source holder and shutter assembly. The engineering drawings of safety critical parts and components should be fully dimensioned with tolerances identified, and should indicate the materials of construction.

    - Provide fabrication and assembly methods (e.g., welds, bolts, screws), including size and spacing.

    - Provide engineering drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the device. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the device; how the component is integrated with other components of the device, in addition to helping to determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

    - If the device construction includes dissimilar materials, or materials that will likely be affected by exposure to radiation, provide an explanation for the choice of material.

    - Provide a specific description and location of the device indicators which identify whether the source shielding is in the open or closed position. In addition, please confirm that the indicators clearly state when the shutter is in the open or closed position.

3. In your application you stated that the source model BA516, manufactured by Japan Radioisotope Association, should be registered as part of the device. Please be aware that when requesting that a source by registered as part of a device, you must submit enough information for NRC Staff to perform a complete evaluation of the sealed source.

4. The regulations in 10 CFR 32.51(a)(2)(ii) and (iii) require that design requirements for devices to be used under a general license in 10 CFR 31.5 include dose criteria. Please include dose assessments for both normal use and likely accident conditions. Dose assessments must be consistent with the information submitted about such matters as design, construction, working life, and conditions of use.

Labeling

5. Please provide a copy of the label to be used on the devices to be distributed as specifically licensed devices. In your application you only included the labels for generally licensed devices.

6. Please provide the materials of construction of the label and the method of attachment.

Condition of Use

7. Describe the actions to be taken when the device reaches the end of its working life.

8. Please provide the maximum allowable conditions of use for Model LSC 8000.

Prototype Testing/Historical Use

9. Please provide information that verified that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. The U.S. Nuclear Regulatory Commission (NRC) may accept one of the following methods: (1) testing a prototype of the product, (2) performing an engineering analysis, (3) operational history of the product, or (4) comparison to a similar or equivalent model previously reviewed and registered. Please note that Section 10.5 of Volume 3, Revision 2 of the NUREG-1556 series provides guidance on each of these methods.

Radiation Profiles

10. Please provide the maximum radiation levels around the product when it contains the maximum allowable quantity of Ba-133. You should include the maximum radiation levels on the surface of the product, at 5 cm (2 in), 30 cm (12 in), and 100 cm (39 in) from the product. If applicable, please provide radiation levels when the devices is in the open and closed positions. Measured radiation levels are preferable, but calculated levels are also acceptable. If you submit measured radiation levels, please verify that the conditions under which the measurements were taken and the equipment used-including type, window thickness, sensitivity, and valid calibration-are acceptable for Ba-133. If you submit calculated levels, please show your calculations and any assumptions. Please note that Section 10.6 of Volume 3, Revision 2 of the NUREG-1556 series provides guidance on radiation profiles.

Quality Assurance (QA)

11. Please confirm that your QA Program ensures that: (1) the materials of construction and the final assembly meet the design specifications; (2) the final product is leak tested; (3) a final radiation profile is performed; (4) a test is performed that verifies that the product operates as intended, including all safety functions; and (5) a visual inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.

12. Please confirm that GMI OpCo. will maintain records in the U.S. as required by the provisions set forth by 10 CFR 110.53(b), for future regulatory review.

13. In accordance with the guidance in NUREG-1556, Volume 3, Revision 2, Section10.7 "Quality Assurance and Quality Control," please confirm that GMI OpCo. will evaluate Hitachi-Aloka Medical, Ltd.'s QA program in Japan. Also confirm that GMI OpCo. will perform periodic audits of the facility in Japan. The audits may be conducted by a third party, but the records must be available for review in the U.S.

Accompanying Documentation

14. Please be aware that when distributing to general licensees, you must provide them with specific information as required under 10 CFR 32.51a. This information includes:

    - a copy of the general license contained in 10 CFR 31.5;
    - a copy of 10 CFR 31.2, 30.51, 20.2201, and 20.2202 or a copy of the equivalent Agreement State regulations;
    - a list of services that can only be performed by a specific licensee;
    - information on acceptable disposal options including estimates costs;
    - an indication that NRC's policy is to issue high civil penalties for improper disposal;
    - NRC regional information; and
    - Agreement States contact information.

    Please provide a copy of the information that will be provided to general licensees.