



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

March 11, 2014

Docket No. 03038707
Control No. 582895

License No. 32-31021-02

Michael Guin
Vice President for Service
Siemens Medical Solutions USA, Inc.
221 Gregson Drive
Cary, NC 27511

SUBJECT: SIEMENS MEDICAL SOLUTIONS USA, INC., REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR NEW LICENSE,
CONTROL NO. 582895

Dear Mr. Guin:

This is in reference to your application dated January 17, 2014 (ADAMS Accession No. ML14027A311) requesting a new Nuclear Regulatory Commission License. In order to continue our review, we need the following additional information:

1. Your application does not contain the information needed to support your request for a new service provider license. Please resubmit your application using the guidance in NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." The checklist in Appendix C in NUREG-1556, Volume 18 contains procedures that are acceptable to the NRC and may be used to submit your response.
2. Please confirm that the name of the company is: Siemens Medical Solutions USA, Inc.
3. The possession limits requested in your licensing action require that you submit financial assurance in accordance with the requirements of 10 CFR 30.35. Submit the required financial assurance or modify your licensing request such that financial assurance is not required. You may wish to refer to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance" (ADAMS Accession No. ML12048A683) for assistance in formulating your response.
4. Confirm if you will take possession of licensed material from your clients. If you will not take possession, we will insert a special license condition on your license and change the possession limits to not apply. Therefore, financial assurance is no longer required.
5. For sealed sources:
 - a. Identify each radionuclide (element name and mass number) that will be used in each sealed source.

- b. Provide the manufacturer's (distributor's) name and model number for each sealed source and, if applicable, device requested.
 - c. Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.
 - d. Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State.
- 6. For unsealed material:
 - a. Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit.
 - b. Provide information for *volatile materials*, if known, on the anticipated rate of volatility or dispersion. This information may be obtained from the material vendor, supplier, or manufacturer.
- 7. Only list radioactive material that requires a specific license. Do not provide information regarding exempt radioactive material (Ref.: 10 CFR 30.18).
- 8. Generally-licensed material (Ref.: 10 CFR Part 31) may be listed on a specific license with modifications to the labelling. This process is completed on a case-by-case basis. Please identify any generally licensed material.
- 9. Item 6 in your application dated January 17, 2014, states that you will use the licensed material for calibration of customer's analytical instruments for nuclear medicine and positron emission tomography. But your North Carolina Agreement State license which was attached to your application, indicates that the radioactive material will be used for quality assurance/quality control and testing of nuclear medicine equipment other than dose calibrators. In your "Working with Radioactive Calibration Sources and Radiation Generating Machines SOP," you indicate that radioactive material users handle radioactive material for installation, calibration or repair of imaging or therapy systems. It further states that radioactive material will be used for demonstration, sales, installation and service of machines. In Section 1.4 of this procedure, source replenishment is discussed. Provide all the services you plan to provide to your customers in regards to licensed material.
- 10. Your North Carolina Agreement State license only lists four radionuclides, but you have requested twenty-one radionuclides for your NRC license. Please explain.
- 11. Your North Carolina Agreement State license lists a different mailing address. Please confirm that the correct mailing address is: 221 Gregson Drive, Cary, NC 27511
- 12. You have requested that Dr. Thomas O'Dou serve as Radiation Safety Officer (RSO) during Mr. Marshall's absence. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

- a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.
 - b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
 - c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).
 - d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
 - e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.
13. The training for individuals working in or frequenting restricted areas does not mention hands-on training for all radioactive material workers nor does it indicate that these radworkers will be trained on emergency procedures. Appendix H of NUREG-1556, Volume 18 provides criteria for acceptable training and experience for Authorized Users. Confirm that "Before using licensed material, authorized users and radioactive workers will receive the training described in Appendix H of NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."
14. In your application, you indicated that you will use Instadose badges. Instadose is a new technology that provides instant read-out when connected to any computer with internal access via a USB connector. There are a few issues that need to be resolved before the NRC can authorize this type of dosimetry. You should work with the manufacturer/vendor to support answers to the following questions:
 - a. In terms of cyber security, how secure is this dosimeter? Because the Instadose is a USB connection and the user has to download software to their computer, how secure is this software? Is it possible to lose the data (meaning the official dose of record)? Could the file become corrupted? What is the reliability of this system?
 - b. In terms of manipulation of data, can a user alter or change their dose record?

- c. Confirm that Instadose is accredited with the National Voluntary Laboratory Accreditation Program (NVLAP).
 - d. With the latest technological advances, please indicate if the dose can be traced back to a particular location/job. In other words, can the location where the dose was received be transmitted in the computer-based software program?
 - e. It has come to our attention that when the Instadose badge is stored near electronic devices (e.g., cellphones) there may be an increase in dose. Please confirm and indicate your policy for where to wear the Instadose badge and where to properly store the badge when not in use.
15. If you plan to perform source replenishment (aka source replacement), provide your operating and emergency procedures for this activity.
16. Your application dated January 17, 2014, provided emergency procedures for a radioactive spill and personal skin contamination, but did not address a stuck source, leaking source, unshielded source, damaged source, higher than normal radiation readings, tornado, fire, flood, and other natural disaster. Emergency procedures should be developed for all likely scenarios. Provide your emergency procedures for all likely scenarios.
17. Your application did not address survey instruments. Provide a description of the instrumentation described in Section 8.10.2 of NUREG-1556, Vol. 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," dated November 2000, that will be used to perform required surveys. You can state that you will use instruments that meet the radiation monitoring instrument specifications published in Appendix J of NUREG-1556, Vol. 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," dated November 2000. You can state that you reserve the right to upgrade our survey instruments as necessary.
18. Provide a procedure for obtaining an agreement with customers outlining the roles and responsibilities of both the customer and Siemens, when performing service operations at a customer's facility.
19. Your application did not address leak testing. You can either state:
- "Leak tests, when required by the license, will be performed at intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registration Sheet. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the kit supplier's instructions."

OR

"Leak testing will follow the model procedures in Appendix 0 of NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."

20. Confirm that you will only perform licensed activities on Siemens medical devices and that any replacement part(s) will be original equipment manufacturer (OEM) parts. If non-OEM replacement parts are used, please confirm that a form, fit, and function assessment will be performed and provided to the customer. Note that the source/device must comply with the respective Sealed Source and Device Registration.
21. Please resubmit a new license application in entirety. Do not provide a copy of your North Carolina Agreement State license. Remove all references to radiation generating machines because these are not regulated by the NRC. Do not provide resumes for personnel. The NRC only needs to know the radiation safety training and hands-on experience working with radioactive materials. Do not provide personally identifiable information. NRC issued Information Notice 2013-022 titled "Recent Licensing Submittals Containing Personally Identifiable Information" on November 15, 2013. Information Notices can be found on our Web site.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits**, see our **toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 582895. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5251.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

M. Guin

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If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Kathy Modes

Kathy Modes
Senior Health Physicist
Decommissioning and Technical Support
Division of Nuclear Materials Safety

cc:

Fred Marshall, Jr., Radiation Safety Officer

Jeffrey Roberts, Environmental Health & Safety

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SUNSI Review Complete: KModes

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