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Docket No. 03038382
Control No. 576289

Date: 01/25/2012 06-32815-01

Subject: Response to letter dated 12/28/11, "General Electric Company dba GE Healthcare, Request for Additional Information Concerning Application for Amendment to License

Dear Ms. Modes/Ms. Kauffman

This is in response to your letter dated 12/28/11 and our telephone conversation on 1/24/12 in which you requested additional information to continue processing our renewal for NRC license 06-32815-01. To facilitate your review, I have answered your questions using the same numbering that you had in your original request, and included your question at the beginning of each item.

1. Your application does not contain all of the information needed to support your request for service provider licensees. Your application did not include instructions/procedures related to leak testing, make and model of survey instrumentation, the safe use of radionuclides (i.e., operating procedures) and emergency procedures for the licensed activities you have requested (e.g., installation, relocation, removal from source, repair, source replacement, calibration, testing and radiation surveys of sealed sources and their devices). Please resubmit your application using the guidance in NURECT-1556, Volume 18, "Program Specific Guidance About Service Provider Licenses", dated November 2000. 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. You may photocopy Appendix C, checkmark the appropriate boxes, and provide the additional information as an attachment.

After clarifying our license needs during our call you stated that you do not want me to resubmit the application, nor use the checklist in Appendix C in the NUREG. Therefore, I am providing the following clarifications regarding your questions about instructions/procedures related to leak testing, make and model of survey instrumentation, the safe use of radionuclides (i.e., operating procedures) and emergency procedures for the licensed activities:

Leak Testing - This license does not authorize possession of any of the radionuclides listed on the license because we only handle the radionuclides at our customer's facilities. I am confirming we do not perform leak test analysis of sealed sources as a service to customers. See answer to Question 6 of this letter for additional clarification.

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Survey Instrument Information – We perform radiation surveys only to support our work of removing and reinstalling sealed sources in the equipment we are servicing. We do not perform radiation surveys as a service to the customer. As requested, the make, model and serial number of the survey meters typically used by our field engineers is included in our response to Question 8 of this letter.

Operating procedures and emergency procedures - GEHC engineers are trained to follow the customer's emergency procedures when working at the customer site. The emergency procedure guideline in the Nuc/PET Radioactive Material Handling Guidelines (issued to service personnel) specifically states:

“In the event of any Radioactive Materials Emergency:

- (1) Notify the customer site RSO and immediately follow the site's emergency procedures.
- (2) Contact your EHS Specialist or Field Service RSO who will assist with incident investigation, customer site follow-up, corrective actions, and determine additional reporting requirements.”

2. Please provide the manufacturer's name and model number(s) for each sealed source. The model numbers are listed on the first page of the Sealed Source and Device Registrations (SSDRs).

As requested, I am providing the manufacture's name and model number(s) for each sealed source and device.

Devices

(A) NR-1032-D-801-S (was NR-1032-D-101-S, but was inactivated in 2009)

(B) NR-1048-D-101-S

Model: PS 96
Manufacturer: SMV International
41 rue Fourny
ZI BP 112
78534 Buc, France

(C) NR-1049-D-801-S (was NR-1049-D-101-S, but was inactivated in 2008)

(D) NR-1049-D-102-S

Model: MG ATC Rod Unit P/N ASM 000415
Manufacturer: ELGEMS Ltd.
P.O. Box 170
Hayozma St. 10
Tirat Hacarmel 30200
Israel

(E) NR-1049-D-108-S (was NR-1049-D-103-S, but was inactivated in 2008)

(F) OH-1048-D-102-S

Model: 67-060006
Manufacturer: SMV America
8380 Darrow Road
Twinsburg, OH 44087

(G) TX-1032-D-103-S

Model: GE Discovery Series (not to include the Discovery LS)
Manufacturer: GE Medical Systems (GE Healthcare)
3000 North Grandview Blvd
Waukesha, WI 53188

(H) WA-1032-D-102-S

Model: Advance Imaging System

- Tilting System Model Number 46-311 000G2
- Non- Tilting System Model Number 46-311 000G3

Discovery TMLS IMAGING SYSTEM

- Discovery TMLS PET System, Model Number 2286326-4

ADVANCE NXi IMAGING SYSTEM

- Model Number 2286326
- Model Number 2286326-2

Manufacturer: GE Medical Systems (GE Healthcare)
3000 North Grandview Blvd
Waukesha, WI 53188

(I) TX-1032-D-104-S

Model: GE Discovery PET/CT 600 and GE Discovery PET/CT 690
Manufacturer: GE Medical Systems (GE Healthcare)
3000 North Grandview Blvd
Waukesha, WI 53188

Sealed Sources

(J) TN-0241-S-101-S

Model: PET-XXX/YY (Variables indicate length and activity – XXX indicates length in millimeter, YY indicates activity in millicuries)
Manufacturer: Sanders Medical Products
2452A Sutherland Avenue
Knoxville, TN 37919

(K) WA-0406-S-202-S

Model: A3407 Series

- "Transmission Source", IPL Product Code HEGL-0019
- "Normalization Source", IPL Product Code HEGL-0020

Manufacturer: Isotope Products Laboratories
1800 North Keystone Street
Burbank, CA 91504

(L) CA0406S204S

Model: NES8412, NES8422 through NES8426, NES8429, NES8497

Manufacturer: Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355

(M) CA0406S185S

Model: A3408, A3418 and A3429
Manufacturer: Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355

(N) CA-0406-S-238-S (Supercedes WA-0406-S-202-S)

Model: 3407, 34aa, HEGL-XXXX Series
Manufacturer: Eckert & Ziegler Isotopes Products
Db a Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
And
1800 N. Keystone St.
Burbank, CA 91504

3. During the last inspection, you informed the inspector that the following SSDRs apply to your radioactive material license:

NR-1032-D-801-S, NR-1048-D-101-S, NR-1048-D-102-S, NR-1049-D-802-S, NR-1049-D-102-S, NR-1049-D-801-S, OH-1048-D-102-S, TX-1032-D-103-S, TX-1032-D104-S, WA-1032-D-102-S

However, in your application dated October 26, 2011, you indicated that the following SSDRs are applicable:

CA-0406-S-185-S, CA-0406-S-204, CA-0406-S-238-S, TN-0241-S-101-S

Please provide a listing of all of the SSDRs that will apply to your licensed activities.

I am confirming that our license activities are for handling sealed sources possessed by the customer (which have been registered pursuant to 10 CFR 30.329(g) or equivalent Agreement State regulations). As requested, the current SSDR's for sealed sources and devices currently used at customer facilities are included in the response to Question 2. New products may come to market that may expand this list.

4. Item 9 on your license included authorization to remove and change the filters. However, in your application dated October 26, 2011, you did not include that activity. Please confirm if you would like this activity included again on your license. If you would like this activity to be authorized on your license, please provide the operating and emergency procedures for this type of activity.

I am confirming that we do not need to include the process of removing and changing the filters on our license. In addition, we do not repair sources. Please amend our Authorized Use to state: "Sealed sources are handled during equipment installation, relocation, repair, calibration and source replacement. These devices have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations as a service to customers at customer facilities.

5. Item 8 in your application dated October 26, 2011 describes your radiation safety training program. However, your radiation safety training outline does not include didactic or practical examinations. Sections 8.7.2 and 8.7.3 from Volume 18 of NUREG-1556, provides you with a model training program. You can provide the following acceptable response: "Before using licensed material, authorized users and ancillary personnel will receive the training described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000."

I am confirming that before beginning work with licensed material, authorized users receive radiation safety training described in Appendix H in NUREG-1556, Vol. 18, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,' dated November 2000.

6. Section 5.1 in your Ionizing Radiation Protection Work Instruction identifies that your field service engineer is responsible for radiation and contamination surveys, but you did not describe the frequency of the surveys and how the surveys will be documented. Section 8.10.7 of NUREG-1556 Volume 18 discusses surveys for use with unsealed radioactive material. Since your application solely deals with sealed sources, a leak test is a primary method for surveying for contamination. You may provide the following statement as your response: "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 state: "Leak testing will follow the model procedure in Appendix O of NUREG-1556, Volume 20."

As stated in Section 10.B of our radioactive materials license application, 'the licensee does not take possession of radioactive material(s) and/or source(s) while at the client's facility.' Therefore, we do not perform leak tests or surveys as a service to our customers, nor are we required to perform them for any activities associated with this license.

7. Section 6.3 of your Ionizing Radiation Protection Work Instruction discusses assessment and control of ionizing radiation dose. However, your instruction allows for your field service engineers to voluntarily decline using dosimetry. On page 4 of SDDR No. TN-0241-S-101-S it states that special attention should be given to hand and extremity monitoring for those performing source installations. Your field service engineers perform source installations. You may provide the following acceptable response in terms of your dosimetry program: "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20," or "we will monitor individuals in accordance with the criteria in the section entitled 'Occupational Dose' in NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses,' dated November 2000.

We will monitor individuals in accordance with the criteria in the section entitled 'Occupational Dose' in NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses' dated November 2000. This would include whole body and extremity monitoring as applicable. Only in cases in which an assessment has been conducted to ensure that personnel dose from ionizing radiation is not likely to exceed the threshold requiring dosimetry, may a badge be eliminated.

8. Section 6.5 of your Ionizing Radiation Protection Work Instruction discusses radiation detection devices, but does not identify the make and model of the survey meters. Please provide a description of the instrumentation that will be used to perform required surveys and a statement that : "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000.' We reserve the right to upgrade our survey instruments as necessary."

The make and model number of survey meters currently used is the Ludlum 2401-EW. We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 18, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,' dated November 2000.' We reserve the right to upgrade or replace our survey instruments as necessary.

9. Your application dated October 26, 2011 indicates that your field service engineers will repair sealed sources and devices. For routine maintenance, please provide a statement such as "We will implement and maintain procedures for routine maintenance of our device according to each manufacturer's (or distributor's) written recommendations and instructions." For non-routine maintenance, please provide detailed operating and emergency procedures that your field service engineers will follow for this licensed activity.

I am confirming that we do not repair sealed sources or devices. We repair customer equipment which may involve the handling (removal, replacement and installation) of sealed sources owned and licensed by the customer.

10. Please remove all references to Agreement States and x-ray devices in your re-submittal because the NRC does not have jurisdiction in these areas. Please note that New Jersey and Maryland are agreement states and would require reciprocity unless you maintain an Agreement State licenses with those States. Also the District of Columbia is not an Agreement State and therefore you will need to use your NRC license for activities in the District. You should revise Section 8.1 in your Ionizing Radiation Protection Work Instruction to reference the NRC's website that accurately lists the current Agreement States. The website address for the list of Agreement States can be found on our website at www.nrc.gov , select about NRC; select State and Tribal Programs; select Agreement State Program or you can go directly using: <http://nrc-stp.ornl.gov/rulemaking.html>.

The GEHC Ionizing Radiation Protection Program is all inclusive for our program. Applicable sections for this license application are 1 through 6.6. Please disregard all references to reciprocity, x-

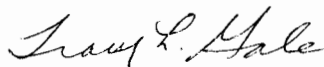
ray equipment and cyclotrons. We are not asking authorization for these activities. Therefore, Section 8.1, does not apply to this license application.

11. In your application dated October 26, 2011, you indicated that personnel will service cyclotrons. On August 8, 2005, the Energy Policy Act of 2005 (EPA) gave NRC new regulatory authority over additional byproduct material. This new byproduct material now also includes naturally occurring materials, such as discrete sources of radium-226 (Ra-226), and accelerator-produced radioactive materials (NARM). NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" provides assistance to applicants in preparing a license application for a specific possession license and should be used for activities that take place once radioactive materials are produced by the accelerator, which include material in the target and associated activation products, to the transfer or distribution of material to another license for preparation of the final product (e.g., radioactive drugs). Please note that the NRC does not regulate the accelerator or its operation. Also, neutron accelerators and other types of accelerators (e.g., linear accelerators) that are used to produce particle beams and not radioactive materials are also not regulated by the NRC. The NRC has regulatory oversight for the activation products and therefore we need to know if your field service engineers will perform licensed activities in these areas under your license and not under your customer's license. If your field engineers will perform service under your customer's license, please remove all references regarding cyclotron service from the re-submittal of your application. Otherwise, provide the applicable information in Appendix C of NUREG-1556, Volume 21.

I am confirming that our field engineers perform cyclotron service under our customer's license and do not take possession of any radioactive material. The GEHC Ionizing Radiation Protection Program is all inclusive for our program. Applicable sections for this application are 1 through 6.6. Please disregard all references to cyclotron service as mentioned in our response to question 10.

Please let me know if you have any other questions or concerns.

Sincerely



Tracy L. Gale
RSO – GEHC Americas Services