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Response to Questions Regarding the New License Application to NRC

Monday, October 27, 2014

Betsy Ullrich Senior Health Physicist US NRC Region I Office 2100 Renaissance Boulevard, Suite 100 King of Prussia, PA 19464 (610) 337-5040

RE: Response to Electronic Correspondence from NRC Dated 14 October 2014.

License No. 32-35165-01 Docket No. 030-38762 Control No. 584579

Ref: (a) NUREG-1556, Consolidated Guidance About Materials Licensees, Volume 18, Program-Specific Guidance about Service Provider Licenses, dated November 2000.

Dear Ms. Ullrich,

Thank you for providing feedback with regard to our NRC License Application, below is Siemens Medical Solutions USA Inc's., responses.

1. NRC Request:

Your license application does not include the names and qualifications for persons who will use, or supervise the use of, licensed materials under this license as requested in NUREG-1556, "Consolidated Guidance About Materials Licensees," Volume 18, "Program-Specific Guidance About Service Provider Licenses" (NUREG-1556, Vol. 18), Section 8.7.2, "Authorized Users". You may either provide the names of proposed authorized users with a description of their training and experience, and/or you may state "Before using licensed material, authorized users will receive the training described in Appendix H in NUREG-1556, "Consolidated Guidance About Materials Licensees," Volume 18, "Program-Specific Guidance About Service Provider Licenses", dated November 2000."

Siemens Response:

Before using licensed material, Authorized Users will receive the training described in reference (a), Appendix H.

2. NRC Request:

Confirm that, in addition to the training described in your license application, all authorized users who use, or supervise the use of, licensed materials under this license, will receive the training described in Appendix H of NUREG-1556, Vol. 18. Please note that the Appendix H outline includes more specific training regarding survey instruments and

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emergency procedures than is described in your course outline, and also requires a practical exam and on-the-job training. Although some of this information is checked on your "Appendix D Checklist for License Application", it is not included in your training description.

Siemens Response:

All authorized users who use, or supervise the use of, licensed materials under this license, will receive the training described in reference (a) Appendix H.

3. NRC Request:

In accordance with NUREG-1556, Vol.18, Section 8.8, "Training for Individuals Working In or Frequenting Restricted Areas...", confirm that the instructor for the training will meet the qualifications for an RSO or an authorized user under this license, and is familiar with your program involving licensed activities. Although this information is checked on your "Appendix D Checklist for License Application", it is not included in your training description.

Siemens Response:

Instructors for Authorized User training will meet the qualifications for a RSO or an Authorized User under this license; additionally they will be familiar with our program involving licensed activities.

4. NRC Request:

NUREG-1556, Vol. 18, Section 8.10.6, "Safe Use of Radionuclides and Emergency Procedures" requires that your operating and emergency procedures include a procedure for obtaining an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility. You provided a copy of a "CX RC-US Memorandum of Understanding Regarding Service Provider Use of Radioactive Materials."

a. Confirm that you will obtain an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility, as stated in NUREG-1556.

Siemens Response:

Siemens will present a letter of understanding to all existing customers that explains Siemens' responsibilities and restrictions with regard to service work. The language of this understanding will be incorporated into new contracts and will represent a signed agreement.

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5. NRC Request:

Item 10 of your "Explanation of Items listed in NRC Form 313" states that all radiation detection instruments used by Siemens employees will be provided and maintained by the licensee. Based on a review of the Appendix D Checklist for License Application" and the CX RC-US Memorandum of Understanding Regarding Service Provider Use of Radioactive Material: submitted with the application, it appears that you intend to use customer's instruments. Please note that the selection and use of survey instruments, used to perform surveys during or as a result of work that Siemens personnel perform under the Siemens license, is the responsibility of Siemens. In accordance with NUREG-1556, Vol. 18, Section 8.10.2, "Radiation Monitoring Instruments", submit 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, "Consolidated Guidance About Materials Licensees," Volume 18, "Program-Specific Guidance About Service Provider Licenses", dated November 2000."

Siemens Response:

Siemens understand that surveys required during service work performed by our personnel are the responsibility of Siemens. Siemens Authorized Users intend to use radiation monitoring equipment belonging to the licensed customer. The licensed customer is expected to maintain radiation monitoring equipment in accordance as required by their NRC license.

6. NRC Request:

In accordance with NUREG-1556, Vol. 18, Section 8.10.4, state that "NVLAP-accredited dosimetry will be processed by a NVLAP-accredited entity." Also, confirm if the "Instadose" dosimeters are NVLAP-accredited.

Siemens Response:

NVLAP-accredited dosimetry will be processed by a NVLAP-accredited entity. The Instadose dosimeter we use are NVLAP-accredited.

7. NRC Request:

Item 10 of your "Explanation of Items listed in NRC Form 313" states that surveys will be performed at the discretion of the customer and that Siemens Customer Service Engineers will not normally perform surveys. Please note that any surveys, necessary during or as a result of work that Siemens personnel perform under this license, are the responsibility of Siemens. In accordance with NUREG-1556, Vol.18, Section 8.10.7, "Surveys" state "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in NUREG-1556 "Consolidated Guidance About Materials Licensees," Volume 18, "Program-Specific Guidance About Service Provider Licenses", dated November 2000." Alternately, you may submit an alternate



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method for evaluating any radiation hazards that may result from work performed under this license.

Siemens Response:

We will survey our work areas and maintain contamination levels in accordance with the survey frequencies and contamination levels published in reference (a).

8. NRC Request:

Confirm if you intended the "Appendix D Checklist for License Application" to contain commitments for your license, or if you included the checklist only for completeness.

Siemens Response:

The checklist submitted with our Radioactive Material Application was included only for completeness.

Thank you once again for your time and efforts with regard to our radioactive material license application. If you have any other questions or concerns please contact me.

With Best Regards,

Matthew D. Daut

Chief Radiation Safety Officer

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