



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E LAMAR BLVD
ARLINGTON, TX 76011-4511

EMAIL



Name: Jon O'Rullian
Organization: Radiation Solutions, LLC
E-mail Address: jonorullian@msn.com
From: Jacqueline D. Cook
Date: May 18, 2015
Subject: Application dated February 20, 2015 for License Amendment
Pages:

License: 11-35111-01
Docket: 030-38691
Control: 586038

Mr. O'Rullian:

Per your application dated February 20, 2015, the items on the next page are deficiencies (request for additional information) which require your response. **Please respond to this e-mail by Monday, June 1, 2015.** If you are unable to respond by this due date, please don't hesitate to contact me so we can discuss an extension to the date. Our fax number is (817) 200-1263. You may respond by e-mail in pdf format if you'd like. My email address is Jackie.Cook@nrc.gov. When responding to this e-mail, please include the license, docket and control numbers located at the top of this page.

Please note that I used NUREG-1556, Volume 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses", dated October 1998 and NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses", dated November 2000. Please use these guidance documents to assist you in responding to the deficiencies on the next pages. (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v5/>; <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/>).

Thanking you in advance for your cooperation, assistance, and prompt response in this matter.

/RA/
Jacqueline D. Cook
Senior Health Physicist

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer: JAC Date: 5/19/15

1. A. Please note that the type of non-routine maintenance to be performed is specific to gauges.

Please describe the types of non-routine maintenance to be performed on self-shielded irradiators using Appendix I of NUREG-1556, Vol. 5, *Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-shielded Irradiator Licenses*, dated October 1998.

- B. In addition, please describe the types of non-routine maintenance to be performed on gamma stereotactic radiosurgery unit (gamma knife).
2. A. Although you state that before performing non-routine maintenance proposed technicians will have successfully completed the training described in Appendix G.....O'Rullian)", please note that you are requesting to perform non-routine maintenance on self-shielded irradiators and gamma knives. Appendix G is the model training program for authorized users of self-shielded irradiators.

Please clarify this discrepancy.

- B. Please describe the technicians' training and experience which should include the following: 1) previous experience in non-routine maintenance and radiation safety training 2) vendor maintenance certification
3. In Appendix A of your amendment application dated February 20, 2015, you list the services performed on the various makes and models of self-shielded irradiators.

Please expand this list to include the non-routine maintenance, as appropriate.

- A. Please note that we are not familiar with the training given by Foss Therapy Services, Inc. for self-shielded irradiator source reloading/unloading so please submit a course outline including the topics outlined in Appendix G of NUREG-1556, Vol. 5, as appropriate, as guidance with special emphasis on the various types of non-routine maintenance requested.
 - B. Please note that it appears that your International Air Transport Association Dangerous Goods Shipper Re-Certification for Class 7 Materials Air Course as prescribed in DOT 49 CFR 173.1(b) & IATA DGR 1.5 expired March 31, 2015.

Please submit a more recent certification that has not expired.

- A. Please specify the manufacturer and model of the gamma knife specified in Appendix A of your amendment request dated February 20, 2015.
 - B. Although you specified equivalent make and models for the self-shielded irradiators you received training in, please submit documentation from the manufacturer stating that the equivalent make and models are indeed equivalent to the make and model you were trained. If you cannot provide this documentation, please submit evidence of training you received on the specific manufacturer and model you want authorization to perform non-routine maintenance.

- C. In addition, provide submit documentation from the gamma knife manufacturer stating that the equivalent make and models are indeed equivalent to the make and model you were trained. If you cannot provide this documentation, please submit evidence of training you received on the specific manufacturer and model you want authorization to perform non-routine maintenance.
6. A. Please expand your cask to cask irradiator source loading and unloading procedures and emergency procedures to ensure the following:
- doses to members of the public are within regulatory limits and ALARA
 - the source is secured against unauthorized access or removal
 - appropriate labels and signs are used
 - manufacturer's (distributor's) written instructions and recommendations are followed
 - any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g. lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
 - before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised
- B. Please expand your cask to interim cask irradiator source loading and unloading procedures and emergency procedures to ensure the following:
- doses to members of the public are within regulatory limits and ALARA
 - appropriate labels and signs are used
 - manufacturer's (distributor's) written instructions and recommendations are followed
 - any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g. lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
 - before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised
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C. Please expand your gamma knife source loading and unloading procedures and emergency procedures during non-routine maintenance to ensure the following:

- doses to members of the public are within regulatory limits and ALARA
- the source is secured against unauthorized access or removal
- appropriate labels and signs are used
- manufacturer's (distributor's) written instructions and recommendations are followed
- any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g. lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
- before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised

7. Please note that under your section "Steps taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed 10 CFR 20.1301 limits", in paragraph 3 you state the regulation as 10 CFR 20.2013. Please note that there is no 10 CFR 20.2013 in the regulations; however, 10 CFR 20.2103 is the applicable regulations.

Please clarify and correct, as appropriate.

8. Please note that under your request for authorization for leak testing for yourselves and your clients, you state that you will provide leak test kits described in Section 8.9.8 of NUREG-1556, Vol. 18, *Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses*. Please note that the correct reference is Section 8.10.8.

Please clarify and correct, as appropriate.

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Reviewer: JOC Date: 5/19/15