



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

JUN 20 2013

Ronald C. Lutsic, D.O.  
Radiation Safety Officer  
Radiation Therapy Associates, P.C.  
6255 North Inkster Road  
Suite 7  
Garden City, MI 48135

Dear Dr. Lutsic:

It has come to our attention that Amendment No. 05 to your NRC Material License No. 21-26536-01 contained an error, in that one digit was wrong in the address in Condition No. 10. Enclosed is a corrected copy reflecting the correct address in bold font. We regret the error and any inconvenience it may have caused you.

However, in reviewing your license to make this correction, we noted that you verbally committed to me, in a telephone conversation at 1:25 p.m. (CT) on January 24, 2005, to providing NRC with some additional information that would complete your license and keep it in compliance with 10 CFR Part 35. You had agreed to provide us with this information within 30 days, or by February 24, 2005, more than eight years ago.

To date, we have not received this information. Therefore, we are requesting it again. Please provide this information within 20 days of the date of this letter or contact me at (630) 829-9841 to make alternative response arrangements. A copy of our original letter to you transmitting Amendment No. 05 is attached. The most relevant excerpt follows:

"This also refers to the telephone discussion between you and me on January 24, 2005, concerning a section of your renewed license that is incomplete, as noted below. You agreed to provide the additional information required to complete your license within 30 days of the date of this letter as I have continued your authorization in Subitem No. 7. B.

Please address your response to my attention and reference control number 313591 to facilitate proper handling.

When my review of your response is final, I will amend your license to authorize the appropriate manufacturers, model numbers and corresponding radionuclide for the material in 10 CFR 35.400 that you wish to use.

Please provide the manufacturer's names and model numbers for all iridium-192 sealed sources you possess or intend to possess under 10 CFR 35.400.

Please note that the information you provide to us must match up exactly with the manufacturer - provided data in the Sealed Source and Device Registry certificates, available from the manufacturers.

The enclosed document contains sensitive security-related information.  
When separated from this cover letter this letter is uncontrolled.

R. Lutsic

Please contact me at one of the telephone numbers below if you need assistance. You may also refer to NUREG 1556, Vol. 9, Final, Section 8.5, Item 5 and Table C.2, Items 5 and 6.

Please refer to NUREG 1556, Vol. 9, Rev. 2 and 10 CFR Part 35 if you have questions about these matters. 10 CFR 35 and NUREG 1556, Vol. 9 Rev. 2 are available on our website at <http://www.nrc.gov>. Then click on the "Nuclear Materials" toolbar key and the "Medical Use Licensing/Part 35" option on the Quick List."

In addition to the information requested originally, we will now also need to adjust the authorization in Subitem No. 8.A. of your license to show one total possession limit, including iodine-131. We can no longer authorize "as needed" amounts for materials in 10 CFR 35.300. Please also provide this information.

You should also have received hard copy originals of NUREG 1556, Vol. 9, Rev. 2 and 10 CFR Part 35 when they were originally published. My original letter to you, attached, refers to the non-revised version of NUREG 1556, Vol. 9, because it was current at the time it was written, January 24, 2005. This volume has been revised twice since 2005 so I inserted the more current information.

Please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions or comments concerning this amendment, please contact me at (630) 829-9841. My fax number is (630) 515-1078 and my email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov).

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

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A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

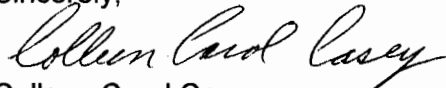
You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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.

Sincerely,



Colleen Carol Casey  
Materials Licensing Branch

License No. 21-26536-01  
Docket No. 030-33353

Enclosures:

1. Corrected Copy of Amendment No. 05
2. Copy of cover letter dated January 24, 2005



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4352

JAN 24 2005

Ronald C. Lutsic, D.O.  
Radiation Safety Officer  
Radiation Therapy Associates, P.C.  
6255 North Inkster Road  
Suite 7  
Garden City, MI 48135

Dear Dr. Lutsic:

Enclosed is Amendment No. 05 renewing your NRC Material License No. 21-26536-01 in accordance with your request. Please note that some of the changes made to your license are printed in **bold** font. Your license has been issued for a ten year term and will not expire until January 31, 2015.

Please be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

- A. This also refers to the telephone discussion between you and me on January 24, 2005, concerning a section of your renewed license that is incomplete, as noted below. You agreed to provide the additional information required to complete your license within 30 days of the date of this letter as I have continued your authorization in subitem No. 7. B. Please address your response to my attention and reference control number 313591 to facilitate proper handling.

When my review of your response is final, I will amend your license to authorize the appropriate manufacturers, model numbers and corresponding radionuclide for the material in 10 CFR 35.400 that you wish to use.

Please provide the manufacturer's names and model numbers for all iridium-192 sealed sources you possess or intend to possess under 10 CFR 35.400. Please note that the information you provide to us must match up exactly with the manufacturer - provided data in the Sealed Source and Device Registry, available from the manufacturers. Please contact me at one of the telephone numbers below if you need assistance. You may also refer to NUREG 1556, Vol. 9, Final, Section 8.5, Item 5 and Table C.2, Items 5 and 6.

Please refer to NUREG 1556, Vol. 9, and 10 CFR Part 35 if you have questions about these matters. 10 CFR 35 and NUREG 1556, Vol. 9 are available on our website at <http://www.nrc.gov>. Then click on the "Nuclear Materials" toolbar key and the "Medical Use Licensing/Part 35" option on the Quick List.

If you have further questions concerning these matters please contact me at (630) 829-9841 or (800) 522-3025.

- B. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your

program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days, pursuant to 10 CFR 35.14:
  - a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
  - b. When the mailing address listed on the license changes.
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers, except as provided in 10 CFR 35.24©);
  - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - c. Add or change the areas of use or the address or addresses of use identified in the license application or on the license, pursuant to 10 CFR 35.13(e), 10 CFR 35.13(f) and 10 CFR 35.14(b)(4); or
  - d. Change ownership of your organization.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for an application for medical use must be the licensee's management, as required by 10 CFR 35.12(a).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for

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review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Colleen Carol Casey  
Materials Licensing Branch

License No. 21-26536-01  
Docket No. 030-33353

Enclosure:

Amendment No. 05