



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
 REGION I  
 475 ALLENDALE ROAD  
 KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 29, 2004

Docket No. 03001317  
 Control No. 135047

License No. 08-01738-02

Colonel Thomas M. Fitzpatrick, M.C.  
 Deputy Commander for Clinical Services  
 Department of the Army  
 Walter Reed Army Medical Center  
 6900 Georgia Avenue, NW  
 Washington, DC 20307-5001

**SUBJECT: DEPARTMENT OF THE ARMY, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 135047**

Dear Colonel Fitzpatrick:

This is in reference to your application dated May 21, 2004 requesting to renew Nuclear Regulatory Commission License No. 08-01738-02. In order to continue our review, we need the following additional information:

- Items #5 and #6 of your application list several sealed sources without the identity of the source manufacturer and model number. Please identify the manufacturer and model number of the following sealed sources:

<u>Subitem #</u>	<u>Radioisotope</u>	<u>Maximum Activity</u>
O	strontium 90	500 millicuries
P	cesium 137	
Q	gadolinium 153	
R	iodine 125	500 millicuries
S	cesium 137	

Ex. 2

- Your current license, Amendment No. 77, authorizes the possession and use of the following sealed sources/foils that were not identified in Items #5 and #6 of your renewal application:

<u>Authorization</u>	<u>Listing in Amendment No. 77</u>
Iodine 125 sealed sources	Item 6.R.
Cobalt 60 sealed sources	Item 6.T.
Nickel 63 sealed sources and foils	Item 6.W.
Iodine 129 sealed sources	Item 6.X.
Americium 241 sealed sources	Item 6.BB.
Iridium 192 sealed sources	Item 6.DD.

For each one of these sealed sources/foils, please identify which of the following applies:

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 FOIA-2006-0228

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- (a) You wish to continue to be authorized to possess and use these sealed sources/foils;
- (b) You wish to continue to be authorized to possess and use these sealed sources/foils but the quantity you possess is small enough to allow possession under your current broad scope authorization (any byproduct material with atomic number 3-83 in any form with a possession limit of 400 millicuries of each radionuclide with a total possession limit of 26 curies) or under the proposed expansion of this broad scope authorization (any byproduct material with atomic number 84 to 96 in any form with a possession limit of 100 millicuries of each radionuclide with a total possession limit of 1 curie);
- (c) These sealed sources/foils have never been possessed; or
- (d) These sealed sources/foils have been possessed previously but are not now in use. For each sealed source/foil to which this statement applies, confirm they have been transferred or disposed of so the sealed sources/foils can be removed from your license.

In addition, for each sealed source/foil to which (a) applies, please identify the sealed source/foil manufacturer and model number.

- 3. Items #5 and #6 of your application, subitem B, requests authorization to possess any byproduct material with atomic number 84-96, in any form, 100 millicuries of each radionuclide, with a total possession limit of 1 curie. This request will result in a significant addition to your current license authorization. In consideration of this request, please review your Decommissioning Funding Plan and advise us as to whether additional funding will be required.
- 4. Your current license authorizes possession of 400 kilograms of plated uranium metal depleted in uranium 235, to be used for shielding in linear accelerators, and Items #5 and #6 of your application, subitem W, request a similar authorization. Please list the linear accelerators currently in your possession that contain depleted uranium shielding. In addition, list any linear accelerators formerly in your possession that contained depleted uranium shielding, and provide the records of transfer or disposal.
- 5. Item #7 of your application, paragraph #2, indicates for human use, licensed material shall be used by or under the supervision of individuals designated by the Walter Reed Army Medical Center (WRAMC) Radiation Safety Committee (RSC) and that the RSC, with Radiation Safety Officer (RSO) approval, may grant case-by-case exceptions. Please describe the criteria the RSC will use to grant these exceptions.
- 6. Item #7 of your application, paragraph #3, indicates for non-human use, Principal Investigators and Co-Investigators who meet the training and experience criteria expressed in NUREG 1556, Volume 7, Section 8.7.2, may be designated as authorized users by the RSO. Item #7, paragraph #4, states that for self-shielded irradiators, personnel who meet the training and experience criteria expressed in NUREG 1556,

Volume 5, Appendix G, will be designated as authorized users by the RSO. As described in 10 CFR 33.11, WRAMC has a Type A specific license of broad scope. 10 CFR 33.13(c)(3)(iii) requires, in part, that the applicant for a Type A specific license of broad scope establish administrative controls and provisions relating to organization and management that are necessary to assure safe operations, including the establishment of appropriate administrative procedures to assure review and approval by the radiation safety committee of safety evaluations of proposed uses prior to use of the byproduct material. While in practice the RSO may approve of some byproduct material users on an interim basis (such as between RSC meetings), final approval of users in a Type A specific program of broad scope is reserved for the RSC. Please confirm that final approval of all users will be by the RSC.

In addition, Item #7 of your application, paragraphs #3 and #4 indicate the RSC, with RSO approval, may grant case-by-case exceptions. Please describe the criteria the RSC will use to grant these exceptions.

7. Please describe the process and specific criteria used by your RSC to review and approve of proposed medical and non-medical uses of byproduct material.
8. Provide the criteria that will be used by the RSC to approve uses, training for authorized personnel, and facilities for emerging technologies licensed under 10 CFR 35.1000. The "Licensing Guidance for 10 CFR 35.1000 Sealed Sources and Devices" on the NRC public website at <http://www.nrc.gov/materials/miau/med-use-toolkit.html> may be useful in developing your criteria.
9. Provide a copy of senior management's written statement of delegation of authority to the RSO. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material. Appendix J of NUREG-1556, Volume 11 contains a model delegation of authority and may be helpful to you in developing your response.
10. Provide a statement delineating the RSO duties and responsibilities for carrying out the radiation safety program. Section 8.7.3 of NUREG-1556, Volume 11 discusses the duties and responsibilities of the RSO and may be helpful in developing your response.
11. Submit a specific and detailed description of the duties and responsibilities of the RSC and the administrative procedures by which these functions are carried out. Section 8.7.2, "Radiation Safety Committee" of NUREG-1556, Volume 11 contains information on the duties and responsibilities of the Radiation Safety Committee and may be helpful to you in developing your response.
12. Item #10 of your application, paragraph #1, discusses what appears to be the annual audit required by 10 CFR 20.1101(c). Please describe the audit mechanism implemented by the RSO on a more routine basis to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC approved permits and good health physics practices.

13. Please describe your administrative procedures to assure control of procurement and use of byproduct material.
14. NRC will provide even greater flexibility to Type A Broad Scope licensees to make program changes and changes to procedures specifically identified in documents which were previously approved by the Commission and incorporated into the license, without prior Commission approval. If you would like authorization for this flexibility, please provide the following statements.
  - a. Changes to your program and procedures will be limited to the following areas: training; audit program; radiation monitoring instruments; material receipt and accountability; safe use of radionuclides and emergency procedures; and radiation surveys. In addition, state that you will apply for, and receive an amendment to your license prior to implementing any other programmatic or procedural changes.
  - b. The proposed revision will be documented, reviewed, and approved by the your Radiation Safety Committee in accordance with established procedures prior to implementation.
  - c. The revised program will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
  - d. Your staff will be trained in the revised procedures prior to implementation.
  - e. Your audit program will evaluate the effectiveness of the change and its implementation.

In accordance with 10 CFR 2.390, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

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. 135047. If you have any technical questions regarding this deficiency letter, please call Sandy Gabriel at (610) 337-5182 or contact her by e-mail at [slg2@nrc.gov](mailto:slg2@nrc.gov).

T. Fitzpatrick  
Department of the Army

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In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. You may fax your response to (610) 337-5269.

Sincerely,

***Original signed by James P. Dwyer***

James P. Dwyer  
Senior Health Physicist  
Nuclear Materials Safety Branch 1  
Division of Nuclear Materials Safety

Enclosures:

1. 10 CFR Parts 19, 20, 30 and 35
2. NUREG-1556, Vol. 11

cc:

LTC John R. Mercier, Ph.D., Radiation Safety Officer

T. Fitzpatrick  
Department of the Army

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