



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

August 30, 2016

J.C. Holland, Complex Warden  
Department of Justice  
Federal Bureau of Prisons  
Federal Medical Center  
P.O. Box 1500  
Butner, NC 27509

**SUBJECT: DEPARTMENT OF JUSTICE, FEDERAL BUREAU OF PRISONS, LICENSE  
AMENDMENT, MAIL CONTROL NO. 591072**

Dear Mr. Holland:

This refers to your license amendment requests dated April 19, 2016. Please find enclosed Amendment No. 8 removing Dr. Hidalgo. Please note that Mr. Jeannette has not been added to the license at this time. We understand from discussions with Mr. Jeannette that the additional information will take some time to collect and Dr. Sprau will continue in the position of Radiation Safety Officer until submission of the additional information. To support a future amendment request to name Mr. Jeannette your Radiation Safety Officer, please submit the following:

1. Please note that the training and experience submitted for Mr. Jeannette does not meet the waiver requirements referenced in your request. Specifically, neither license submitted included "accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses" as referenced in 10 CFR 35.57(a)(3). In addition, the medical use documented for accelerator use is more than 7 years ago and, therefore, does not meet the recentness of training requirements in 10 CFR 35.59. Please submit documentation described in 10 CFR 35.50(a) or (b), along with a preceptor attestation (35.50.d) and training in radiation safety, regulatory issues, and emergency procedures for medical use (35.50.e). You may use the form found at [http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a\(rso\).pdf](http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313a(rso).pdf) to document the above. If relying on a degree to demonstrate the 200 hours of training; please submit a copy of the transcript showing the coursework that applies; along with any recent training.
2. You have requested that Mr. Jeannette be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:
  - a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

- b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
- c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).
- d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
- e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5169 or via electronic mail at penny.lanzisera@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the 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(s) 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 NRC Enforcement Policy. The NRC Enforcement Policy is available at:  
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: [www.nrc.gov](http://www.nrc.gov). Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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/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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

*/RA/*

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

License No. 32-25613-01  
Docket No. 3036175  
Mail Control No. 591072

Enclosure:  
Amendment No. 8

cc: Daniel D. Sprau, Dr.Ph., Radiation Safety Officer

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Thank you for your cooperation.

Sincerely,

*/RA/*

Penny Lanzisera  
Senior Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

License No. 32-25613-01  
Docket No. 3036175  
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Enclosure:  
Amendment No. 8

cc: Daniel D. Sprau, Dr.Ph., Radiation Safety Officer

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**SUNSI Review Complete: PLanzisera**

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