

National Institutes of Health
Bethesda, Maryland 20892www.nih.gov
OCT 25 2013

Reply to a Notice of Violation

P-6, Q-4
J-2, J-4Docket No. 03001786
License No. 19-00296-10

2013-001

U.S. Nuclear Regulatory Commission
Washington, DC 20555

REC'D 10 30 13 M 001

Dear Sir or Madam:

This is being submitted in response to a Notice of Violation resulting from an NRC inspection at the National Institutes of Health on June 17-21, 2013. Each violation is summarized in italics, followed by a description of the reason for the violation and what corrective/preventive actions have been implemented.

- A. *The NIH RSC approved an AU and an AMP for the use of a remote afterloader unit under 10 CFR 35.600 based on board certifications that were not recognized by the NRC.*

The RSC was unaware of the nuances affecting which Board certifications are considered acceptable for people applying to become AUs and AMPs. When it was brought to their attention, the approvals for both the AU and the AMP were rescinded. The individuals subsequently re-applied and were approved in July 2013 based on their training and experience. Radiation Safety staff and members of the RSC have been re-trained in requirements for AUs and AMPs and are now aware of the need to review the NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>) to determine which Board certifications are acceptable. Also, to ensure that applications for prospective AUs and AMPs are valid and complete, the applications will be thoroughly reviewed by 2 health physicists before being submitted to the RSC.

- B. *As of June 18, 2013, the RSC did not include an AU representing the use of remote afterloading brachytherapy.*

The RSC mistakenly thought that an Authorized Medical Physicist who is heavily involved in all HDR work would be an appropriate RSC member to represent the Radiation Oncology program. However, during the June 2013 inspection, the NRC pointed out that having an AMP on the RSC is not sufficient because the regulations require the representative to be an AU. Therefore, on June 19, 2013, Dr. Kevin Camphausen, an AU in the Radiation Oncology Branch, agreed to serve on the RSC. Another AU from Radiation

Oncology has been appointed as his backup. In addition, RSC membership in general was reviewed to ensure that all other types of use are represented by appropriately credentialed staff. Full compliance was achieved as of June 19, 2013.

- C. *As of January 15, 2013, the high dose rate remote afterloader unit in use was not the model number specifically listed on the license.*

A request to amend the license to update the model number of the high dose rate remote afterloader was submitted on June 21, 2013. The RSC did not realize that the upgrade in computer software resulted in a change in model number of the unit and thus required the license to be amended. In future, the AU from Radiation Oncology who serves on the RSC will keep the RSC informed of any changes to the HDR program that may require a license amendment. Also, a senior health physicist has been assigned to perform a regulatory audit of the Radiation Oncology program to ensure that all requirements are being met.

- D. *Failure to perform an adequate contamination survey following the use of an unsealed form of radioactive material.*

The contamination was cleaned up as soon as it was identified. Radiation safety staff confirmed that the area had been fully decontaminated as of June 20, 2013. The RSO directed that the researcher undergo re-training on proper contamination control and monitoring procedures. Informal re-training, i.e., one-on-one discussion/demonstration with the researcher, was performed on June 20. In addition, the AU investigated the circumstances of the incident and concluded that the researcher had been distracted from her usual meticulous work because she was attempting to train a summer student in how to perform the complex procedure. The AU decided that when this particular procedure is performed in the future, there will be no instruction or observation by others. On June 24, 2013, the RSO sent an e-mail to all researchers, informing them of the incident and emphasizing the importance of thorough monitoring for contamination, including floor areas, following the use of unsealed forms of radioactive material. Formal re-training of the researcher, her colleague, and her AU was completed on July 29, 2013.

- E. *Failure to monitor the external surfaces for contamination of labeled packages (DOT Yellow II) after they have been transported over public roads from the main campus of NIH to a satellite facility.*

The external surfaces of DOT radioactive labeled packages are monitored for contamination when they arrive at the main campus of NIH. If they are to be used at a satellite facility under NIH's license, they are transported by trained radiation safety staff or contractors. Thus, following the initial inspection at the main campus, the packages remain under the control of the licensee

while being transported to their final destination. Consequently, NIH did not believe re-monitoring of the packages would be required upon their arrival at the satellite facility. However, after the NRC inspectors raised a concern, the delivery of DOT radioactive labeled packages to satellite facilities was immediately suspended. A new policy was subsequently established such that the external surfaces of DOT radioactive labeled packages being delivered to NIH's satellite facilities are monitored for contamination upon arrival at the satellite facility in accordance with 20.1906. Full compliance was achieved as of June 28, 2013.

If you have any additional questions, please contact the NIH Radiation Safety Officer, Nancy Newman, by calling 301-496-2254 or via email to newmann@mail.nih.gov.

Sincerely,

A handwritten signature in black ink that reads "Michael M. Gottesman, M.D." The signature is written in a cursive style with a large initial 'M'.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

cc: NRC Regional Administrator, Region 1