



8/2/2016

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Re: Reply to a Notice of Violation, License 50-29349-01

Dear Sir or Madam:

This letter is a "Reply to a Notice of Violation" for license number 50-29349-01, docket number 030-38049, for Rehabilitation Medicine Associates, PC, in Anchorage, Alaska.

The violation specified that we released patients that were administered radioactive iodine-131 and failed to follow procedures in accordance with Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials." Specifically, there was no record of the basis for release of these individuals.

The reason for the violation was lack of familiarity with the release conditions and record requirements specified in Appendix U.

Upon notification of the violation on the date of the visit, we immediately suspended our use of sodium iodine-131 with activities greater than Column 1 of Table U.1. No activities greater than 33 mCi of iodine-131 were administered. Our intent is to achieve full compliance with Appendix U prior to any further administrations of iodine-131 greater than 33 mCi.

Our corrective action to achieve full compliance with Appendix U is as follows:

1. Establish written policies and procedures that meet the conditions of Appendix U for releasing patients with activities greater than those noted in Column 1 of Table U.1.
2. The policy and procedures, including associated forms, will be reviewed and approved by our consultant health physicist.
3. The RSO, authorized users and nuclear medicine technologists will review Appendix U and will review the new written policies and procedures.

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4. Training on the above policies and procedures will be performed on August 11, 2016, by our consultant health physicist. Training will include hands-on completion of required records for sample cases.
 5. Once the above is completed, we will recommence our iodine-131 program as follows:
 - a. For the next 5 cases of administration of iodine-131 greater than 33 mCi, the planned record of release will be reviewed by the RSO and by the consultant health physics consultant prior to administering the radioactive material and releasing the patient to ensure compliance with Appendix U.
 - b. After the first five cases of administration of iodine-131 greater than 33 mCi, the health physics consultant will review the records of release on a monthly basis until July 2017.
 - c. The health physics consultant will review the records of release on an annual basis, beginning August 2017.
 - d. The health physics consultant will provide refresher training on Appendix U and associated policies and procedures on an annual basis to the nuclear medicine technologist.
 - e. Any new authorized user for iodine-131 and any new nuclear medicine technologist will receive training on this program prior to their involvement in any administration of iodine-131 greater than 33 mCi.

I may be contacted at (907)677-4700

A handwritten signature in black ink that reads "John J. McCormick, M.D." The signature is fluid and cursive.

John J. McCormick, M.D.
Radiation Safety Officer

CF:

US NRC, Regional Administrator, Region IV, 1600 E. Lamar Blvd, Arlington, Texas 76011-4511