



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
1600 E. LAMAR BLVD  
ARLINGTON TX 76011-4511

October 30, 2023

Jefferson Fairbanks, Ph.D.  
Radiation Safety Officer  
St. James Healthcare  
400 South Clark Street  
P.O. Box 3300  
Butte, MT 59702

SUBJECT: AMENDMENT NO. 58 TO RADIOACTIVE MATERIALS LICENSE FOR  
ST. JAMES HEALTHCARE, NRC LICENSE NO. 25-13173-02

Please find enclosed Amendment No. 58 to NRC License No. 25-13173-02 removing four authorized users as requested in letter dated October 27, 2023. Please note that you requested in letters dated July 18, 2023, and October 27, 2023, to add to this license Jeffrey Gilroy, M.D., as an authorized user for 10 CFR 35.300, Use of unsealed byproduct material for which a written directive is required, and provided State of Colorado license CO 1261-01 as supporting documentation. You further stated that Colorado authorization 7.36.5 granted to Dr. Gilroy is equivalent to the NRC regulation 10 CFR 35.300, Use of unsealed byproduct material for which a written directive is required, and this statement is incorrect as previously explained to you in email dated October 18, 2023. You were offered an opportunity to submit NRC Form 313A(AUT) to document training and experience for Dr. Gilroy to qualify him as an authorized user for 10 CFR 35.300, Use of unsealed byproduct material for which a written directive is required, but you did not provide this information in your letter dated October 27, 2023. Colorado license CO 1261-01 limits Dr. Gilroy's authorization to parenteral administration of unsealed byproduct material requiring a written directive and this authorization is equivalent to NRC regulation 10 CFR 35.396, Training for the parenteral administration of unsealed byproduct material requiring a written directive. Your request to authorize Jeffrey Gilroy, M.D., as an authorized user for 35.300, Use of unsealed byproduct material for which a written directive is required, cannot be approved at this time. Instead, Amendment No. 58, approved Jeffrey Gilroy, M.D., for parenteral administration of unsealed byproduct material requiring a written directive, which is in alignment with Dr. Gilroy's authorization in the State of Colorado license. You can submit a separate amendment request using NRC Form 313A(AUT) to document Jeffrey Gilroy, M.D., training and experience in oral administration of sodium iodide I-131, in order to qualify him as an authorized user for 10 CFR 35.300, Use of unsealed byproduct material for which a written directive is required.

An environmental assessment for this licensing action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-200-1189 if you have any questions about this license.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.
3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
  - b. If you decide not to acquire or possess and use authorized material; or
  - c. When no principal activities under the license have been conducted for a period of 24 months.
4. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
  - a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
  - b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
  - c. The licensee's mailing address changes;
  - d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
  - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.
5. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officers;
  - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;

- c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
  - d. Change the name or ownership of your organization.
6. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by 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 the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; 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: [www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html).

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 [www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html).

Thank you for your cooperation.

Sincerely,

Roberto J. Torres, M.S., Senior Health Physicist  
Materials Licensing Branch

Docket No.: 030-12143  
License No.: 25-13173-02  
Control No.: 637700

Enclosure: As stated