

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

DEC 19 2013



James C. Hatten  
Radiation Safety Officer  
EMD Millipore  
15 Research Park Drive  
St. Charles, MO 63304

Dear Mr. Hatten:

Enclosed is Amendment No. 22 renewing your NRC Material License No. 24-26445-01 in accordance with your request. Your license has been issued for a ten year term and will not expire until December 31, 2023. Please note that the major changes made to your license may appear in **bold font**.

***Your renewal application dated June 25, 2013, was unclear and incomplete in several respects. Therefore we temporarily continued all of the previously accepted documents in Condition No. 19 of your license.***

***The following discrepancies were noted in your renewal application and should be addressed in accordance with the instructions below and submitted to us in writing within 30 days of the date of this letter, in order to complete your renewal application in its entirety.***

***When all open items related to your renewal are responded to, reviewed and accepted, we may then update Condition No. 19 to remove all documents that pre-date the June 25, 2013 renewal application.***

***Please be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."***

- 1. We noted that your renewal application dated June 25, 2013, made reference to an "Assistant RSO" in several sections. Also, no current "Delegation of Authority" for your current, incumbent RSO, James C. Hatten, was signed, dated and enclosed with your application.***

***No name or qualifications for an "Assistant RSO" were included in your application, so we were unable to accept this designation as it was too vague and unsupported.***

**Please note that we excluded all references to an "Assistant RSO" from Condition No. 19. A. at this time. If you wish to pursue adding an additional RSO to your license, please call me at (630) 829-9841 to discuss the types of information that we will require to consider such a request.**

**Please also submit a currently signed and dated "Delegation of Authority" for your current incumbent RSO. This should be signed by Mr. Hatten and by a senior management representative. There was an unsigned and undated "Delegation of Authority" included in your application, which was not acceptable.**

- 2. Please explain why only NUREG 1556 Vol. 12 was used to prepare your license renewal application. NUREG 1556 Vol. 12 is intended to be used in conjunction with at least one other NUREG 1556 document, as appropriate.**

**For your type of program, NUREG 1556 Vol. 7 should also have been used. Please submit appropriate responses to NUREG 1556 Vol. 7. Appendix C in this document may help you.**

- 3. We noted that reference was made to NUREG 1556 Vol. 11 in your renewal application in the "Emergency Procedures" section on page 37. However, your license is not a broad scope, which is addressed in NUREG 1556 Vol. 11. Please explain and correct this commitment.**
- 4. Item 10 in your application, subitem no. 3, and references on pages 32 and 34, state that packages will be "surveyed with the specification of 10 CFR 20.205." However, there is no "10 CFR 20.205." Please explain and correct these commitments.**
- 5. On page 36 of your application, item O. makes reference to "10 CFR 20.203(f)(1)." However, there is no "10 CFR 20.203(f)(1)." Please explain and correct this commitment.**
- 6. In your description of facilities and equipment in the renewal application:**
  - a. There is no mention made of any forms of shielding. Yet this license authorizes millicurie quantities of iodine-125, phosphorus-32 and phosphorus-33. Please explain and submit appropriate radiation safety commitments addressing the forms of shielding materials you will employ, where and how they will be used, what they will consist of, etc.**
  - b. There is very minimal mention of airborne radioactivity operating and emergency procedures, ventilation systems employed, and composition of facilities in your laboratories, etc. Please refer to NUREG 1556 Vol. 7, Item 8.10.7 and Appendix K. Please provide appropriate descriptions of your facilities and equipment, including, but not limited to, airborne radioactive material potential hazards, ventilation and bioassay commitments, composition of facilities in your laboratories, etc.**

- 7. Item 10 of your application, on page 6, shows "Monitor Key Personnel" written in. Please explain what this means as it does not constitute an adequate commitment for the license.**

**Please provide this information within 30 days of the date of this letter, in writing, addressed to my attention at the address above. Please reference it as "additional information to control number 581164." Please contact me if you have further questions about this matter. Upon receipt of your written response, we will then continue our review.**

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is [colleen.casey@nrc.gov](mailto:colleen.casey@nrc.gov).

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

You will be periodically inspected by 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 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 General Statement of Policy and Procedure for NRC Enforcement Actions.

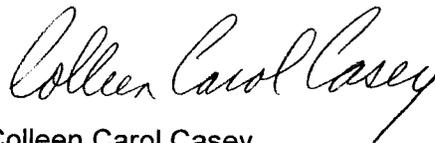
Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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/regulatory/enforcement/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.

Sincerely,

A handwritten signature in black ink that reads "Colleen Carol Casey". The signature is written in a cursive style with a large, prominent "C" at the beginning.

Colleen Carol Casey  
Materials Licensing Branch

License No. 24-26445-01

Docket No. 030-32903

Enclosure:  
Amendment No. 22