

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

NOV 06 2019



Michael G. Wiese
Radiation Safety Officer
Universal Medical Resources, Inc.
207 Lange Dr.
Washington, MO 63090

Dear Mr. Wiese:

Enclosed is Amendment No. 9 to your NRC Material License No. 24-32189-01 in accordance with your request.

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) 829-9807 so that we can provide appropriate corrections and answers.

This also refers to your letter dated August 16, 2019, the telephone call between you and me on November 5, 2019, and your letter dated November 5, 2019, concerning, in part, your language in the August 16, 2019, letter stating that the new areas of use would be considered "restricted" by you when radioactive materials were in use but that they would be considered "unrestricted" by you when radioactive materials were not in use.

In our telephone call, I explained that this is not possible. The areas where you receive, possess, use and store radioactive materials, sealed and unsealed, are considered "restricted" areas under your license until or unless you request and receive an amendment to your license authorizing their release for "unrestricted" use. They are essentially "permanent" and are incorporated into your license in condition no. 19. In your letter dated November 5, 2019, you retracted the language of concern.

As noted in my letter dated July 18, 2019, please be reminded that 10 CFR 30.33(a)(2) requires, in part, that you request and receive an amendment to your license before making changes to your facilities where radioactive materials are used.

In addition, 10 CFR 30.3 states, "Activities requiring license:

(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter."

Also 10 CFR 30.33 "General requirements for issuance of specific licenses" states:

"(a) An application for a specific license will be approved if:

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;"

These sections establish the regulatory basis for your license and, in part, describe the NRC's duty to determine whether an applicant's equipment and facilities are adequate to protect health and minimize danger to life or property.

Compliance with these sections would be compromised if you used licensed material in a manner other than that authorized in your license, such as by changing restricted areas to unrestricted areas and vice versa. NRC must be able to evaluate your proposed equipment and facilities changes for safety adequacy prior to first use and when your use ends.

What this means is that you must decommission area(s) of use and request and receive an amendment to the license before it/they may be released for unrestricted use.

If you presently have no formerly restricted areas that must come off of your license via the decommissioning and amendment process (and please note that only NRC's Materials Licensing can do that, not a Materials Inspector), then please review the following details for the next time you will need this information.

If you do need to take some areas of use off the license, then please follow this information. If you have questions, please email me at colleen.casey@nrc.gov to arrange a mutually convenient telephone call. My telephone number is 630-829-9841 and my fax number is 630-515-1078.

We cannot authorize licensees to release the "locations/addresses of use" or "areas of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc., including sealed sources and unsealed materials, spills, and contamination.

If sealed sources were transferred or disposed of as part of the close-out of this facility, please provide a copy of the final leak test for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials were transferred or disposed of as part of the close-out of this license, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for

shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; NUREG 1556 Vol. 18, Rev. 1, <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/> and NUREG 1757, Vol. 1, Rev. 2 at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>.

Your complete historical review should specify when and where all licensed materials, were actually possessed under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

If your license historically authorized radioactive materials and/or modalities that you never used, then please so state specifically. Please be mindful that NRC will review your inspection history.

Please respond by stating exactly which licensed materials were used at this location historically and please submit final status survey information covering those radioactive materials.

For licensed materials and waste that were "decayed - in - storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license.

Please be mindful that the condition no. 17 on your license, for DIS, only applies to those materials with a half-life less than or equal to 120 days. Therefore, materials including, but not limited to, cobalt-57, americium-241 and sodium-22 are not subject to DIS.

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present.

Please only submit the last, or final, records for leak tests, DIS disposal, etc.

The final status surveys should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/>

Please submit the following information with your close-out survey:

- a. Always specify each location/address of use (see Condition No. 10 on your license) that corresponds to the areas of use you are requesting to release for unrestricted use.

- b. Diagrams of each facility (area(s) of use and/or locations/addresses of use) with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

Do not submit blueprints or copies of blueprints. The diagrams you used to add the affected areas of use to the license; the diagrams you used for routine exposure rate surveys and wipe tests; and/or diagrams prepared in accordance with NUREG 1556 Vol. 18, Rev. 1.

Submitting diagrams of only certain components/fragments of the areas you are requesting be released for unrestricted use, such as certain walls, hoods, sinks, floors, etc. without the full context of each entire affected area is unacceptable and leads to delays and confusion in processing your request.

Meaningful traditional units (milliroentgen, millirem, dpm, etc.) are best and should be stated, either in addition to SI units or as "stand alone" units. Gross results and/or net results should be identified as such and described appropriately.

- c. The name and position of the person(s) performing the survey.
- d. The last date(s) of use for each radioactive material possessed, used or stored in the areas of use you are requesting to release for unrestricted use. This includes sealed and unsealed materials.
- e. The date(s) when the surveys were performed.
- f. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- g. Background readings and each instruments' efficiency or correction factor. Include the energy level(s) and energy level "windows" you counted for.
- h. The date(s) that the survey instrument(s) were last calibrated. Please do not state when the instrument(s) are "due" to be calibrated in the future. Please do state when the instrument(s) were last calibrated.
- i. The action levels for both exposure rate measurements and wipe tests. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken. Specify whether and where previous spills occurred and how they were remediated.
- j. If sealed sources were used in the affected areas/locations, please include a copy of the most recent inventory and leak test results for each source. These records must include all of the information required by your license conditions for inventories and leak tests.

If sources were transferred please provide the license number (if a current Region III NRC licensee) or a copy of the license for the transferee, or a copy of the license and/or permit for

the broad scope licensee who took possession of the sources. Appropriate acknowledgment(s) of receipt should be submitted for "cradle to grave" accountability.

Also, please always include the telephone number and fax number of at least one person who serves as a point of contact and is knowledgeable in the licensed activities for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.

Please ensure that a senior management representative signs the amendment request. Please ensure that a management representative signs the amendment request, in accordance with 10 CFR 35.12(a), as appropriate, for medical programs.

The NUREG can be found on our website at: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/>. Its full title is "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses, Final Report (NUREG-1556, Volume 18, Revision 1)."

The facility diagrams you submit for new use areas must show compliance with 10 CFR Part 20.1101, "Radiation Protection Programs," 20.1301 and 20.1302, "Radiation Dose Limits for Individual Members of the Public," and 20.1501, "Surveys and Monitoring."

In our telephone call on November 5, 2019, we also discussed the imminent renewal of your license and what that would involve, when it should be received in our offices, the need for a complete refreshment of your license (excluding qualifications for incumbent RSO and authorized users, and the need for an updated RSO "Delegation of Authority."

The NUREG 1556 Vol. 18, Rev.1 should be used to prepare the renewal.

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 cursive script that reads "Colleen Carol Casey".

Colleen Carol Casey
Materials Licensing Branch

License No. 24-32189-01
Docket No. 030-35121

Enclosure:

Amendment No. 9