



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

August 24, 2022

Cynthia Myers, CIH
Radiation Safety Officer
DDP Specialty Electronic Materials US, LLC
3400 S. Saginaw Rd.
Unit 96
Midland, MI 48640

SUBJECT: AMENDMENT NO. 4 TO RADIOACTIVE MATERIALS LICENSE FOR DDP
SPECIALTY ELECTRONIC MATERIALS US, LLC, U.S. NRC MATERIALS
LICENSE NO. 21-35537-01

Dear Ms. Myers:

Enclosed is Amendment No. 4 to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-35537-01 in accordance with your requests dated May 25, 2022 and August 17, 2022.

Your license has also been amended to reflect the following changes:

- adjust the license authorization for the IUT Medical GmbH Model I-2101 and I-2198 gas analyzers to correct an error in the authorized radionuclide;
- restrict the licensed authorization for the IUT Medical GmbH Model I-2101 and I-2198 gas analyzers to five devices in accordance with your request;
- update the reference to the letter dated February 27, 2019 appearing in Item 9.E. of your license to the letter received February 27, 2020. This aligns with Conditions 10.F. and Condition 26.G., in which this same letter is referenced in your license and this more accurately reflects the timeline of the submission; and
- update the address of the Larkin Laboratory R&D specified in Conditions 10.C. and 10.F.

You requested that license authorization for the Agilent Technologies Model G2397 Electron Capture Detector appearing in Item 8, Subpart C, be modified to reflect continuing authorization for only a single device. Further, you requested that Condition 10.C. be deleted as the Larkin Laboratory no longer serves as an authorized location for this licensed device. In support of your request, you referred to your letters dated May 3, 2019 and October 28, 2019. Following a careful review of these letters, I was unable to locate documentation of the transfer/disposal of the Agilent Technologies Model G2397A electron capture detector or a request for the removal of the Larkin Laboratory as an authorized location of use for the licensed device.

To proceed with your request, please resubmit your request providing documentation of the transfer/disposal of the Agilent Technologies Model G2397A electron capture detector along with an acceptable leak test report for the nickel-63 foil source in the detector cell. If the Gas Chromatograph was received at your facility without the electron capture detector, please clarify that in your request and provide applicable documentation.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

C. Myers

-2-

Please retain records of the transfer/disposal of the IUT Medical GmbH Model I-2101 and I-2198 gas analyzers and associated leak testing performed prior to transfer for disposal for future decommissioning of your licensed facility.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (CFR) Section 51.22(c).

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. NRC Region III office at (630) 829-9887 for needed corrections and answers.

You will be periodically inspected by the U.S. NRC. Failure to conduct your program in accordance with U.S. NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with U.S. 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 U.S. NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with U.S. 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 the U.S. NRC expects of its licensees.

The U.S. 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 the U.S. NRC's safety culture website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. I 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 U.S. NRC-regulated activities.

The U.S. NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the U.S. NRC's electronic document system. Pursuant to the U.S. NRC's RIS 2005-31 and in accordance with 10 CFR §2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the U.S. NRC's website at: <https://www.nrc.gov/docs/ML1619/ML16196A237.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

C. Myers

-3-

In accordance with 10 CFR §2.390 of the U.S. NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the U.S. NRC Public Document Room or from the U.S. NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the U.S. NRC's website at: <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

License No. 21-35537-01
Docket No. 030-39163

Enclosure: Amendment No. 4