



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

November 8, 2021

Michael A. Levy, R.Ph., Director  
Radiation Compliance & Environmental Health &  
Safety  
Corporate Radiation Safety Officer  
Ionetix Corporation  
3130 Sovereign Dr.  
Lansing, MI 48911

SUBJECT: AMENDMENT NO. 9 TO RADIOACTIVE MATERIALS LICENSE FOR IONETIX  
CORPORATION, NRC LICENSE NO. 04-35412-01

Dear Mr. Levy:

Enclosed is Amendment No. 9 to Ionetix Corporation's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 04-35412-01 in accordance with your November 3, 2021 request to add an authorization for gallium-68. Your letter is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML21307A343.

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 630-829-9892 so that we may provide appropriate corrections and answers.

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

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 NRC Enforcement Policy. 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 that 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 <https://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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," 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 ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Sara A. Forster, M.S.  
Health Physicist  
Materials Licensing Branch  
Division of Nuclear Materials Safety

Docket No.: 030-39033  
License No.: 04-35412-01  
Control No.: 629112

Enclosure: Amendment No. 9 to NRC License No. 04-35412-01