



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

April 30, 2023

Eric L. Mollon
Radiation Safety Officer
Ionetix Corporation
3130 Sovereign Dr.
Lansing, MI 48911

Dear Eric L. Mollon:

Enclosed is Amendment No. 11 to your NRC Material License No. 04-35412-01 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) 829-9887 so that we can provide appropriate corrections and answers.

You may also contact me at (630) 829-9841. My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov. The most reliable way to contact me is via email as I am teleworking about half the time.

We noted that the information in your letter dated January 30, 2023, to add Jesse Fogelman as a new authorized user, was minimally adequate.

In order to have a more complete understanding of Mr. Fogelman's qualifications please refer to NUREG 1556 Vol. 21, Rev. 1; NUREG 1556 Vol. 7, Rev. 1; and NUREG 1556 Vol. 18, Rev. 1.

The Table of Contents in each volume will direct you to the "Authorized Users" section 8.7.2 and provide supplementary information and guidance that best enables us to consider a proposed authorized user to your license.

All three volumes are available, respectively, on our website at:

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v21/index.html>

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html>

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/index.html>

Please also refer to the letter dated June 22, 2017, signed by John Vincent, VP Engineering and New Product Development for Ionetix, addressed to the attention of my colleague, Mr. Bryan A.

E. Mollon

Parker. Item No. 5 of this letter corresponds to a request made by Mr. Parker for additional information for the authorized personnel to be named to your "then" initial license.

Mr. Parker requested at that time, and I concur today, that you should not submit resumes or curricula vitae or other "overly detailed" and extraneous information.

The "Statement of Training and Experience" used in your June 22, 2017, letter provided an appropriate level of information. Please use this document/format again for Mr. Fogelman in your written response.

Please also use this document/format in your future requests to change and add new authorized users, Radiation Safety Officers, Alternate Radiation Safety Officers, etc.

Please also always prepare your licensing correspondence in accordance with the three NUREG 1556 Volumes above as your license encompasses all of these in its authorizations. In reviewing your licensing requests to date, it does not appear that you have routinely used the guidance in these documents as completely as intended. Doing so would help minimize our having to request additional information (RFAI) from you and would help the review process proceed more quickly and with fewer impediments.

Within 30 days of the date of this letter (by close of business on May 31, 2023) please provide only one response to the item above.

If additional time is needed to respond, please contact me at colleen.casey@nrc.gov to make alternative arrangements. If you like to schedule a phone call with me to discuss these matters and ask any questions you may have, please email me to set that up.

Please only send us one complete, written, currently dated and legibly signed (by an appropriate senior management official and identify official's position) correspondence document, such as either an NRC Form 313 or a business-style letter containing all the same information as an NRC Form 313.

Please ensure that the requested information is answered completely and accurately.

Please do not send multiple copies of responses and please do not submit any information that is identical to what you have already sent us unless we direct you to do so. If you resubmit such information for the sake of adding context and other details to enhance its meaning, that is acceptable.

Please do not email a PDF document to me, and transmit a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors.

The most reliable and fastest way to respond is to send an emailed PDF of one complete, currently dated and signed copy to R3-DRSSMail.Resource@nrc.gov and please "cc" me as well.

E. Mollon

Please address your written response to my attention as “additional information to control number 634340” to facilitate proper handling in our offices.

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 NRC’s electronic document system.

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.

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>.

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>.

E. Mollon

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,

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 04-35412-01
Docket No. 030-39033
Control No. 634340

Enclosure:

Amendment No. 11