



May 4, 2017

Re. License No. 06-28799-01 **03032976**
Current Amendment No. 19

Br. 2

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, Pa 19406-2713

REC RG1 050517 PM 1154

Dear Sir or Madame,

This is a request to amend the above-referenced license as detailed below:

Condition 9: Authorized Use – Add “Research and Development as defined in 10 CFR 30.4; Animal studies involving small lab animals (e.g. rats and/or mice)”

License Condition	Radioisotope	Requested Proposed Use
9 C	F-18	Research and Development as defined in 10 CFR 30.4; <i>Animal studies involving small lab animals (e.g. rats and/or mice)</i>
9 E	Cu-64	Research and Development as defined in 10 CFR 30.4; <i>Animal studies involving small lab animals (e.g. rats and/or mice)</i>
9 F	Ga-68	Research and Development as defined in 10 CFR 30.4; <i>Animal studies involving small lab animals (e.g. rats and/or mice)</i>

These isotopes shall be used as radioactive tracers during PET CT scans of mice and rats for research purposes in laboratory. All animals will be handled and managed within a vivarium certified by the American Association for Laboratory Animal Science and under the control of Alexion’s Institutional Animal Care and Use Committee. As such, all workers are trained in accordance with NUREG 1556 and its requirements and the requirements of Appendix H, J, and K, Alexion’s Institutional Animal Care and Use Committee (IACUC) Protocols and Alexions’s Radiation Safety Manual.

Sincerely,

Joe Paradiso, CSP
Radiation Safety Office
Director, Environmental Health and Safety
paradisoj@alxn.com

cc. Dr. S. Uden, Institutional Official

594704



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Joseph J. Paradiso Radiation Safety Officer Alexion Pharmaceuticals, Inc. 100 College Street New Haven, Connecticut 06510	Date May 11, 2017
	License Number(s) 06-28799-01
	Mail Control Number(s) 594704
	Licensing and/or Technical Reviewer or Branch Commercial, Industrial, R&D, and Academic Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: May 4, 2017

The initial processing, which included an administrative review, has been performed.
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
 U. S. Nuclear Regulatory Commission
 Division of Nuclear Materials Safety
 2100 Renaissance Boulevard, Suite 100
 King of Prussia, PA 19406-2713
 (610) 337-5260, (610) 337-5313,
 (610) 337-5398, (610) 337-5239