



CONVERSATION RECORD

08/27/2013

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Maha Srinivasan, M.S., Radiation Safety Officer (RSO)		DATE OF CONTACT 08/27/2013	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS msriniva@wayne.edu		TELEPHONE NUMBER (313) 577-1200	

ORGANIZATION Wayne State University, Health Physics Department	DOCKET NUMBER(S) 030-01995
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LICENSE NUMBER(S) 21-00741-08	CONTROL NUMBER(S) 581015
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SUBJECT
Our review of your license amendment request dated June 5, 2013, revised request dated August 5, 2013, and additional information dated August 14, 2013

SUMMARY

We have reviewed your amendment request and find that we are unable to continue this action until we have received additional information outlined on page 2 of this conversation record.

Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

Submit requested information within 2 days of this record, referencing Control No. 581015, as listed at the top of this memo. Please FAX your response to my attention at (630) 515-1078. You may also scan your response and send to me via email, as a pdf file. Include a signed and dated cover letter with your response.

As discussed, we expect to receive your written response on or before August 29, 2013.

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ACTION REQUIRED (IF ANY)

We have requested that the licensee provide additional information as follows:

- Purpose of use for F-18 and C-11
- Radiation Safety Committee criteria for approving new or increased possession limits for facilities using PET isotopes (e.g. F-18)

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A.B. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE
Sara A.B. Forster 8/27/13

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

M. Srinivasan

1. In the June 5, 2013, letter, the purpose of radionuclide use is listed to include teaching, while the current license limits radionuclide use to research and development. Please indicate whether teaching is included in the use of fluorine-18 and carbon-11.
2. For Radiation Safety Committee (RSC) approval of new or increased possession limits for PET radionuclide use (e.g. fluorine-18) facilities, please indicate facility approval requirements. For example, is a specific industry standard applied to the review or does the RSC otherwise evaluate adequacy of the shielding to assure that radiation levels in any unrestricted areas do not exceed levels outlined in Title 10 Code of Regulations (CFR) Part 20? The response outlined in the August 14, 2013, letter is unclear as it generally references NUREG 1556, Volumes 1-11, but does not identify specific volumes/revisions that may be applicable. NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," (Jan. 2008) pp. 8-40 to 8-59, found at <http://www.nrc.gov/reading-rm/doc-staff/sr1556/v9/r2/>, contains information relevant to applications to use PET radionuclides. A suggested response to our request for your confirmation that the RSC will review shielding adequacy for PET radionuclide use areas is provided below. Please resubmit your response to this item, following the suggested format or clearly identifying RSC review criteria to be applied.

SUGGESTED RESPONSE:

For PET radionuclide use, the Radiation Safety Committee will require the following, in accordance with the requirements outlined in NUREG 1556, Vol. 9, Rev. 2, sufficient to ensure that occupational and public exposures do not exceed the limits identified in 10 CFR Part 20:

- Written description of PET radionuclide use facilities and equipment
- Review and evaluation of shielding for proposed PET radionuclide use areas
- Surveys for external radiation exposure levels in both restricted and unrestricted areas adjacent to and within PET radionuclide use areas