



CONVERSATION RECORD

07/13/2016

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

Stanley D. Hampton, M.S., Corporate Radiation Safety Officer, (317) 276-7862

DATE OF CONTACT

07/13/2016

TYPE OF CONVERSATION

- ☒ E-MAIL (follow-up call by phone on 7/20/16) - sf
☐ TELEPHONE
☐ INCOMING
☒ OUTGOING

E-MAIL ADDRESS

shampton@lilly.com. Also proposed RSO: Trenton L. Mays, M.S., t.mays@lilly.com

TELEPHONE NUMBER

(317) 276-2747

ORGANIZATION

Eli Lilly and Company

DOCKET NUMBER(S)

030-04330

LICENSE NUMBER(S)

13-01133-02

CONTROL NUMBER(S)

590815

SUBJECT

Our review of your April 26, 2016 amendment request and March 10, 2016 response to our February 8, 2016 request for information

SUMMARY

SUMMARY AND ACTION REQUIRED

We have reviewed the above referenced license amendment request to add a new Radiation Safety Officer (RSO) - Trenton L. Mays, M.S., CHP - and response to our recent request for location-of-use information, and find that we are unable to continue this action until we have received additional information noted below.

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

Submit requested information within 14 days of this record, referencing Control No. 590815, 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 cover letter, signed and dated by executive management (i.e. Jan Lundberg, Ph.D., Executive Vice President, Science and Technology President, Lilly Research Laboratories, or other individual with equivalent authority and seniority).

As discussed, we expect to receive your written response on or before July 27, 2016.

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ACTION REQUIRED (IF ANY)

Please provide written responses to each of the following questions:

- (1) A full address is required (e.g. street address, P.O. Box number, etc.) for the mailing address listed in Item 2 to the license. No street number and/or P.O. Box is currently listed on the above-referenced license. What is the street address and/or P.O. Box Number that should be listed in Item 2 (mailing address) to the license?
- (2) A street address is required for each location of use listed in Item 10 to the license. No street address is listed for either the (i) licensee's main research campus (Lilly Corporate Center) or (ii) Lilly Technology Center, both located in Indianapolis, Indiana. What is the street address for each of these locations of use to be listed in Condition No. 10 (locations of use) to the license?

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NAME OF PERSON DOCUMENTING CONVERSATION

Sara A. Forster, Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE

7/13/2016

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

SUMMARY AND ACTION REQUIRED (continued from Page 1)

- (3) The role of Corporate Radiation Safety Officer (CRSO) was discussed in conjunction with the assignment of RSO authority for a new RSO. However, from the application dated December 4, 2012, the CRSO and RSO roles and responsibilities appear to be equivalent. Please define the roles and responsibilities for (i) the RSO and (ii) the CRSO. The response should also confirm that either (iii) the named RSO will review all proposed uses of radioactive materials and provide approval, other than for the use of exempt or generally licensed radioactive sources or devices or (iv) the CRSO will have specific duties, distinct from the RSO, as specified in a signed and dated memorandum of understanding/delegation of authority.
- (4) Please expand upon the description of Mr. Mays' experience with the authorized uses of unsealed materials conducted under your license. Provide dates on which Mr. Mays performed activities related to research & development use - including animal studies, instrument calibrations, and non-commercial transfer of compounds for medical use - of carbon-14, tritium, iodine-125, krypton-85, phosphorus-32, phosphorus-33, sulfur-35, fluorine-18, or similar radionuclides, and for other byproduct material with atomic nos. between 3 through 83. For each type of activity, include the radionuclide(s) and radioactive quantities involved, as applicable. Include specific or estimated details such as numbers of cases reviewed, audits performed, etc., and the level of involvement or responsibility Mr. Mays had for those activities. Details, at a minimum, should be included for Mr. Mays' training and experience relevant to:
 - (i) The review and approval of new authorized users and uses of radioactive material, relevant to the scope of activities conducted under your radioactive materials license;
 - (ii) Conducting audits, monitoring, and area surveys, including contamination surveys, of approved radioactive material uses, use areas, and authorized users, relevant to the scope of activities conducted under your radioactive materials license;
 - (iii) Radioactive materials accounting including ordering, receiving, shipping, and other transportation-related activities, as well as inventory tracking and waste management experience; and
 - (iv) Decommissioning oversight activities.
- (5) Please outline Mr. Mays' experience with the authorized use of sealed sources - including gauging devices, analytical instruments (e.g. gas chromatographs), and static elimination devices registered pursuant to Title 10 of the Code of Federal Regulations Section 32.210. Provide dates on which Ms. Mays performed activities related to the use of sealed sources, including specific details regarding Mr. Mays' experience and training in performing instrument calibrations, as well as safety-related activities associated with fixed gauging devices.

Forster, Sara

From: Forster, Sara
Sent: Wednesday, July 13, 2016 4:33 PM
To: 'shampton@lilly.com'; 't.mays@lilly.com'
Subject: Additional Information Request re Amendment Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN590815
Attachments: 04612.590815.13-01133-02.conversationrecord.pdf

Dear Mr. Hampton and/or Mr. Mays:

In your letter dated April 26, 2016, you requested to remove Mr. Hampton and add Mr. Mays as the Radiation Safety Officer (RSO) for the above listed licensee. In addition, in your letter dated March 10, 2016 regarding NRC's request for information on locations of use, you confirmed that all locations listed on the license are current. We have reviewed your amendment request and submitted location of use information, and require additional information to complete our review. Please see the attached conversation record for our detailed request. I plan to phone you next week (July 18-22) to clarify and discuss this request. If you are able to provide a specific day and/or time that would be most convenient for that call, please let me know. I will do my best to accommodate your schedule.

The attached record requests additional information on or before close of business on Wednesday, July 27, 2016. Additional guidance may be found in NUREG 1556, Vol. 7, "Program Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers," which may be found at:

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

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. Please call or email me to confirm receipt of this email. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
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Division of Nuclear Materials Safety
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