



CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU		DATE OF CONTACT	TYPE OF CONVERSATION	
Trenton L. Mays, M.S., CHP, Radiation Safety Officer		11/20/2019	<input type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input type="checkbox"/> OUTGOING	
E-MAIL ADDRESS		TELEPHONE NUMBER		
t.mays@lilly.com		317-276-2747		
ORGANIZATION		DOCKET NUMBER(S)		
Eli Lilly and Company		030-04330		
LICENSE NAME AND NUMBER(S)		MAIL CONTROL NUMBER(S)		
13-01133-02		614076		

SUBJECT
Additional Information Request re your August 29, 2019 letter (ML19242B527)

SUMMARY AND ACTION REQUIRED (IF ANY)
We have reviewed the referenced request to remove your Clinton Laboratories and Materials Center locations of use from the referenced radioactive materials license. Upon review, we have found that we are unable to remove the Materials Center location of use until we receive additional information regarding the radioactive materials use history and closeout information for that facility.

The application referenced a historical site assessment (HSA) of the Materials Center, including a generally licensed nickel-63 source, sealed waste drum storage, and shipments of solid/biological waste. However, no copy of the HSA report, confirmation of receipt of radioactive waste, or other information supporting the decommissioning of the Materials Center location at 1249 White River Pkwy., Indianapolis, IN 46221. Please refer to pages 2-3 of this record for additional information needed to complete this review.

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

Please submit requested information within 7 days of this record, referencing the License, Docket, and Mail Control Number listed above. If you are unable to respond by that time, or are unable to respond to all questions completely, please contact me as soon as possible to discuss.

NAME OF PERSON DOCUMENTING CONVERSATION
Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch, Division of Nuclear Materials Safety, RIII

SIGNATURE <i>Sara A Forster</i>	DATE OF SIGNATURE 11/20/2019
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CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

13-01133-02

MAIL CONTROL NUMBER(S)

614076

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

T. Mays

Request for Additional Information and/or Clarification, regarding Historical Site Assessment, Final Status Surveys, and Disposition of licensed radioactive materials used or stored at the Materials Center, 1249 White River Pkwy., Indianapolis, IN 46221:

- History of radioactive materials used and stored at the referenced location including:
 - List of all radionuclides used (other at the facility, if any
 - List of all radionuclides possessed at the facility, if any
 - Clarification as to whether only radioactive waste stored in sealed drums was used or stored at the facility, or if other forms of material was used or stored there
 - Last date on which unsealed material was used at the facility, for each radionuclide used
 - Last date on which unsealed material was stored at the facility, including as radioactive waste
 - Maximum quantity used or stored, for any given container or operation, per radionuclide
 - Maximum total possession - at any given time - for each radionuclide

- Final Status surveys for radioactive materials used and stored at the referenced location including:
 - Diagram of all areas where unsealed material was used or stored
 - For each room where waste drums were stored, final area surveys and wipe test results of the area, including of waste drums disposed of as radioactive waste, and including a diagram keyed to the survey and wipe test results
 - Descriptions of solid/biologic waste shipped from this location on June 28, 1994, and of mixed hazardous waste shipped from this location on May 1, 1997, including radionuclides, whether the waste was shipped as radioactive, and the entity to which the waste was transferred
 - Confirmation that no waste was disposed of via sewerage or air release, from the referenced location, or, if applicable, a description of any such disposals including radionuclides, dates of disposal, and total quantities disposed

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)

13-01133-02

MAIL CONTROL NUMBER(S)

614076

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

T. Mays

RFAI, continued:

- Final disposition of radioactive materials disposed of from the referenced location of use including:
 - Confirmation that no radioactive materials - including waste - remain at the location
 - Name of the entity to which materials were transferred
 - Copy of the Agreement State license showing that the receiving entity was authorized to receive the transferred material or the License Number for the Radioactive Materials licensee receiving the material
 - Confirmation of receipt of the material from the entity receiving the material

Song, Taehoon

From: Forster, Sara
Sent: Wednesday, November 20, 2019 11:12 AM
To: Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: Additional Information Request No. 2 for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076
Attachments: 03611.614076.13-01133-02 NRC 699a.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Good morning, Tae...

Could you please have this message and the attachment scanned in? It is a request for additional information/conversation record that will eventually be profiled as publicly available.

Thank you,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892
Facsimile: (630) 515-1078



From: Forster, Sara
Sent: Wednesday, November 20, 2019 11:09 AM
To: Trenton L. Mays <t.mays@lilly.com>
Subject: Additional Information Request No. 2 for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Dear Mr. Mays:

Thank you for the update about the Clinton facilities. We were able to find the decommissioning reviews associated with Amendment No. 62 and there are no additional questions about removing that facility. However, I have prepared a detailed request for information related to the Materials Center Historical Site Assessment, Final Status Surveys, and Final disposition of materials. Please see attached for the detailed questions.

I am not available today to discuss the request. However, if you are available tomorrow or on Friday, a phone call may help to clarify the types and level of information that is needed and/or available for us to complete our review. Please do not hesitate to call or email me with any questions you may have, or to schedule a time for a call.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892
Facsimile: (630) 515-1078



From: Trenton L. Mays <t.mays@lilly.com>
Sent: Friday, November 15, 2019 1:45 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: RE: RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Sara,

Yes, no problem. I believe the NRC release and visit following unsealed material use was reviewed (with inspection, I believe) previously as noted in amendment #62 to the license.

We are available on Monday and can discuss. Two potential openings are 9am EST or 11am EST – would either of these work? Otherwise we can find a different time later in the day.

Thanks,
Trent

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Friday, November 15, 2019 1:59 PM
To: Trenton L. Mays <t.mays@lilly.com>
Subject: [EXTERNAL] RE: RE: RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Thank you for the inquiry, Mr. Mays.

We are in the process of finalizing the review. However, we may have some additional questions about historical use of radioactive materials at the referenced facilities. Do you know whether the NRC did a decommissioning review and/or inspection associated with those past uses of the longer-lived, unsealed materials. I am reviewing NRC's records but was wondering if you had any recollection of that history.

If you are available on Monday 11/18/2019 or later next week in case we have questions, that would be appreciated.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
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From: Trenton L. Mays <t.mays@lilly.com>
Sent: Friday, November 15, 2019 12:08 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Sara,

Thanks again for working with us on this amendment. I wanted to touch base to see if there were any additional questions you were anticipating or if the amendment is just being processed/finalized at this point.

I realize we are still within 90 days of our original submission, I just want to keep our colleagues in each organization (Lilly and the company that has become independent) informed of the current status.

Thanks, have a great weekend!

Trent

Trenton L. Mays, M.S., CHP
Radiation Safety Officer
Manager, Radiation Safety, Env Risk Assessment and Global Hazcom
Eli Lilly and Company
Lilly Corporate Center, Indianapolis IN 46285 U.S.A.
+1 317.276.2747 (office) | +1 317.601.8998 (mobile)
t.mays@lilly.com | www.lilly.com

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Thursday, October 10, 2019 5:05 PM
To: Trenton L. Mays <t.mays@lilly.com>
Subject: [EXTERNAL] RE: RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Thank you for the additional information, Mr. Mays. We will let you know if anything else is needed to complete our review.

Sincerely,

Sara A. Forster
U.S. NRC

From: Trenton L. Mays <t.mays@lilly.com>
Sent: Thursday, October 10, 2019 3:20 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Trenton L. Mays <t.mays@lilly.com>
Subject: [External_Sender] RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Ms. Forster,

Thank you for your review. Please find enclosed the responses to the requests for confirmation noted below.

Let me know if you need additional information or the attached format is not sufficient.

Sincerely,

Trenton L. Mays, M.S., CHP
Radiation Safety Officer
Manager, Radiation Safety, Env Risk Assessment and Global Hazcom
Eli Lilly and Company
Lilly Corporate Center, Indianapolis IN 46285 U.S.A.
+1 317.276.2747 (office) | +1 317.601.8998 (mobile)
t.mays@lilly.com | www.lilly.com

The Lilly logo is a stylized, cursive script of the word "Lilly" in a dark color.

From: Forster, Sara <Sara.Forster@nrc.gov>
Sent: Wednesday, October 9, 2019 8:46 AM
To: Trenton L. Mays <t.mays@lilly.com>
Subject: [EXTERNAL] Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Dear Mr. Mays,

Our office has reviewed your August 29, 2019 letter requesting to remove two locations of use from the referenced license. As we discussed via phone on Monday, October 7, 2019, please note that additional information is needed to complete our review. Accordingly, we are sending this email request to confirm that – combined with the removal of the fixed gauges at the Clinton Laboratories location of use – non-routine maintenance activities associated with fixed gauging devices will no longer be conducted under the license.

In accordance with this change, as discussed, please:

- **Confirm that the licensee will no longer conduct non-routine maintenance – as described in NUREG 1556, Volume 4, rev. 1, “Consolidated Guidance About Materials Licenses: Program-**

Specific Guidance About Fixed Gauge Licenses, Section 8.10.8 - Maintenance, pp. 8-29 through 8-30 – of fixed gauging devices;

- **Confirm that you wish to remove Thomas Rudolph from the license, as an individual authorized to conduct non-routine maintenance operations; and**
- **Confirm the statement: “The gauge manufacturer, distributor, or other person licensed by the NRC or an Agreement State will perform nonroutine operations such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources.”**

Please provide the requested information within 14 days of this message (on or before October 23, 2019). Include a signed and dated cover letter transmitting your resubmitted application. Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Please call or email me with any questions you may have, or if you are unable to respond by the date suggested above. Please also contact me as soon as possible to let me know that you have received this message and are working on a response.

Please do not hesitate to contact me if you have any questions concerning this message.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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