



October 10, 2019

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

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
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www.lilly.com

RE: Response to Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076

Eli Lilly and Company (Lilly) respectfully submits the enclosed response to your email received on October 9, 2019. Please let me know if you have any questions.

Sincerely,

Trenton L. Mays, M.S., CHP
Radiation Safety Officer
Telephone: 317-276-2747
Email: t.mays@lilly.com

enclosure

Eli Lilly and Company (Lilly) response to email re: **Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076**

1. *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.*

Lilly Response: At this time, non-routine maintenance, per NUREG 1556, Volume 4, rev.1, will no longer be conducted by Lilly. If a request to resume such activities arises in the future, an amendment will be submitted in accordance with the NUREG requirements.

2. *Confirm that you wish to remove Thomas Rudolph from the license, as an individual authorized to conduct non-routine maintenance operations.*

Lilly Response: Lilly requests the removal of Thomas Rudolph from the license as an individual authorized to conduct non-routine maintenance operations.

3. *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."*

Lilly Response: 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.

Song, Taehoon

From: Forster, Sara
Sent: Thursday, October 10, 2019 4:04 PM
To: Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: RE: Additional Information Request for Eli Lilly and Company, NRC License No. 13-01133-02, CN614076
Attachments: Response to request for info 9Oct2019 signed.pdf

Hi Sandy and Tae:

Please scan in the document attached to the email. It is additional information to the referenced action.

Thank you very much! Have a nice weekend.

Sara

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
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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

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

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
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