



CONVERSATION RECORD

10/21/2014

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Stanley D. Hampton, M.S., Radiation Safety Officer		DATE OF CONTACT 10/21/2014	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 shampton@lilly.com		TELEPHONE NUMBER (317) 276-7862	

ORGANIZATION Eli Lilly and Company	DOCKET NUMBER(S) 030-04330
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LICENSE NUMBER(S) 13-01133-02	CONTROL NUMBER(S) 584695
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SUBJECT
Our review of your amendment request dated August 27, 2014

SUMMARY AND ACTION REQUIRED

We have reviewed the above referenced license amendment request 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. 584695, 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 November 4, 2014.

ACTION REQUIRED (IF ANY)

For non-routine maintenance operations (e.g., installation, initial radiation survey, gauge relocation, alignment, and removal of a gauge from service) to be performed by James Natalie, please provide additional information as requested in NUREG 1556, Vol. 4, Appendix N (copy attached for your reference.) At a minimum, information submitted should include:

- (i) a description of the types of work, maintenance, cleaning or repair activities to be performed that involve installation, initial radiation survey, gauge relocation, alignment, and/or removal of a gauge from service;
- (ii) a description of Mr. Natalie's training and experience, consistent with non-routine operations to be performed and training requirements described on page N-2 (attached); and
- (iii) procedures for non-routine operations as noted on pages N-2 to N-3 (attached).

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

SIGNATURE
Sara A. Forster

10/21/2014

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Applicants should review the section in this document on "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

~~Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding), gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding NRC limits. See Figure 8.9.~~

~~Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed, before the unit is returned to routine use.~~

~~If non-routine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes in less than one minute, an unshielded cesium-137 source with an activity of 100 millicuries can deliver 0.05 Sv (5 rems) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 0.05 Sv (5 rems) per year.~~

Thus, applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)).

Accordingly, provide the following information:

Provide additional information as noted:

Describe the types of work, maintenance, cleaning, repair that involve:

- **Installation, relocation, or alignment of the gauge**
- ~~Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)~~
- ~~Replacement and disposal of sealed sources~~
- ~~Removal of a gauge from service~~

- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding NRC limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

~~A licensee may initially mount a gauge, without specific NRC or Agreement State authorization, if the gauge's SSD Certificate explicitly permits mounting of gauges by users and under the following conditions:~~

- ~~• The gauge must be mounted according to written instructions provided by the manufacturer or distributor;~~
- ~~• The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by NRC or an Agreement State;~~
- ~~• The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;~~
- ~~• The gauge must be received in good condition (package was not damaged); and~~
- ~~• The gauge must not require any modification to fit in the proposed location.~~

~~Mounting does not include electrical connection, activation, or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the Commission or an Agreement State to perform such operations.~~

For Mr. Natalie, please provide additional training and experience or description of submitted training

- Identify who will perform non-routine operations and their training and experience. class; i.e., show it is **Acceptable training would include manufacturer's or distributor's courses for non-routine operations or equivalent.** manufacturer's or distributor's course, including hands on experiece.
- **Submit procedures for non-routine operations. These procedures should ensure the following:**
 - doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
 - the source is secured against unauthorized removal or access or under constant surveillance;
 - appropriate labels and signs are used;
 - manufacturer's or distributor's instructions and recommendations are followed;
 - any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the

~~manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and~~

~~— before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.~~

- ~~• Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.~~
- ~~• Verify possession of at least one survey instrument that meets the criteria in "Radiation Safety Program - Instruments in NUREG-1556, Vol. 4, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Fixed Gauges Licenses,' dated October 1998."~~
- ~~• Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed 10 CFR 20.1301 limits. For example, applicants can do the following:
 - ~~— commit to performing surveys with a survey instrument (as described above);~~
 - ~~— specify where and when surveys will be conducted during non-routine operations; and~~
 - ~~— commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.~~~~

Forster, Sara

From: Forster, Sara
Sent: Tuesday, October 21, 2014 2:41 PM
To: 'shampton@lilly.com'
Subject: Additional Information Request for Eli Lilly and Company, NRC Lic. 13-01133-02
Attachments: 03611.584695.13-01133-02 telecon signed.pdf

Dear Mr. Hampton,

See the attached file for additional information needed to complete the review of the request to add non-routine gauge maintenance activities authorization for James Natalie for NRC Lic. No. 13-01133-02. Note that the attached conversation record requests additional information by November 4, 2014. Please call me at your earliest convenience to discuss this request. Additional guidance may be found in NUREG 1556, Vol. 4, "Program Program-Specific Guidance About Fixed Gauge Licenses," which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v4/>.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. 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
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
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