

Sandrik, Lauren

From: Forster, Sara
Sent: Friday, July 13, 2018 2:16 PM
To: Pavon, Sandy; Song, Taehoon
Cc: Sandrik, Lauren
Subject: FW: Additional Information Request for WMU Homer Stryker M.D. School of Medicine, NRC Lic. No. 21-35421-01, CN608855

Please scan in and return to me. There is no attachment. This is a Request for Additional Information. Docket No. is 030-39044.

From: Forster, Sara
Sent: Friday, July 13, 2018 2:15 PM
To: 'leandra.burke@med.wmich.edu' <leandra.burke@med.wmich.edu>
Subject: Additional Information Request for WMU Homer Stryker M.D. School of Medicine, NRC Lic. No. 21-35421-01, CN608855

Dear Ms. Burke:

As noted in my voice message to you on the afternoon of July 13, 2018, we have reviewed your May 17, 2018 letter (NRC Accession No. ML18144A227) requesting changes to the above referenced license including to: (1) remove facilities from facilities located at 4717 Campus Dr., Kalamazoo, MI; (2) list you Leandra H. Burke, M.P.A., as Radiation Safety Officer (RSO), and (3) remove existing Authorized Users (AUs) Benchang Guo, M.D., Ph.D.; and William McDonald, B.S. Upon review, we have noted that this request is lacking specific details as to (1) closeout surveys, use history, and final disposition of materials for the listed facilities; (2) Ms. Burke's dates of training and hands-on experience with tritium and other radionuclides; and (3) iodine-125 radioactive materials use history and replacement AU authorized for use of this radionuclide. Additional information from you is still needed for our office to complete our review of your request.

To remove facilities as listed in your May 17, 2018 letter, the licensee should provide a description of all radionuclides used in the listed areas and final disposition information for material used or stored in each of those areas. The licensee should also provide additional final closeout survey details as requested below.

To list Ms. Burke as the new RSO, as described in NUREG 1556, Volume 7, revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope – Including Electron Capture Devices and X-ray Fluorescence Analyzers," pages 8-13 to 8-16, the licensee should submit additional specific details regarding a proposed RSO's training and experience, commensurate with uses authorized under the license.

To remove William McDonald, B.S. as an AU, the licensee must indicate another qualified AU that will be authorized for the use of iodine-125, under the license. In the alternative, the licensee may request the removal of its authorization for iodine-125 by so stating, and attaching the radioactive materials use history and final disposition of that radionuclide, under the referenced license.

To facilitate our continued review of your request, please provide additional information – via a signed and dated cover letter as noted below:

- 1. Final radioactive materials disposition and closeout survey details for areas of use listed in the licensee's May 17, 2018 letter including:**

- a. History of radioactive materials use in each of the licensee's listed areas of use to be removed (e.g. unsealed and non-volatile carbon-14, iodine-125, etc.).
 - Last date that licensed material was used for research and development use in each area to be removed from the license;
 - Last date that licensed material was stored in each area to be removed from the license;
 - Maximum quantity of each radionuclide used or stored in each area of use to be removed from the license;
 - For any licensed material disposed of via decay-in-storage, confirmation that radioactive materials labels were removed and container surveyed prior to disposal;
 - For any licensed material (sample vials, waste, etc.) transferred to another licensee location or area of use, a statement to that effect, noting the date of the transfer; and
 - For any material dispositioned via return to the manufacturer or transfer to another radioactive materials licensee, a letter confirming receipt.
- b. Final survey results for each area to be released where radioactive material was used or stored under the license including:
 - In addition to date of each survey, the printed names of individual conducting each survey, and survey results. NOTE: Survey results should be reported in mR/hr and wipes should be reported in dpm/100 cm².
 - In addition to instrumentation used to analyze the wipe test results, a description of instrumentation used to conduct the survey including calibration data (e.g. date of calibration, etc.).
 - Resubmitted map of the area for which surveys were provided, including numbered locations keyed to the detailed survey and wipe test results.
- c. For any items (a. and b.) above for which you are unable to respond in full, please provide an explanation as to why the information is unavailable or otherwise cannot be provided with your response.

2. Specific details regarding Ms. Burke's training and experience including:

- a. Date on which she completed the Nevada Technical Associates, Inc. RSO course; and
- b. Detailed description of hands-on experience with hydrogen-3 (from April 2002 – November 2004) and other radionuclides or dates (if any) including, as available:
 - Date(s) of experience;
 - Location(s) of experience;
 - Radionuclide(s) used;
 - Form(s) of radioactive material(s) used;
 - Purpose of use for each radionuclide used; and
 - Quantities of radioactive material(s) used (per experiment and overall possession).

3. Additional AU to be authorized for iodine-125 (with qualifications) or request to remove iodine-125 authorization from the license, including:

- a. Name of AU to be authorized for iodine-125 including:
 - For AUs already listed on the licensee's license, experience with other radionuclides listed on the licensee's license; or
 - For AUs not already listed on the licensee's license, training and experience as outlined in NUREG 1556, Vol. 7, rev. 1, pages 8-16 to 8-17, commensurate with proposed authorization; or

b. Request to remove iodine-125 authorization from Item 6.F. of the licensee's license including:

- Last date that iodine-125 was used for research and development use under the license
- Last date that iodine-125 was used under the license;
- Maximum quantity of iodine-125 used or stored under the license;
- All locations where iodine-125 was used or stored under the license (including street address, room number, and waste containers);
- For any iodine-125 disposed of via decay-in-storage, confirmation that radioactive materials labels were removed and container surveyed prior to disposal and date of final disposition;
- For any iodine-125 dispositioned via return to the manufacturer or transfer to another radioactive materials licensee (including waste broker or storage facility), a letter confirming receipt.

Please provide the requested information within 14 days of this message (on or before July 27, 2018). Include a signed and dated cover letter transmitting your response. 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. Thank you for your prompt attention to this matter.

Sara A. Forster, Health Physicist Licensing Reviewer
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