



CONVERSATION RECORD

03/10/2015

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU
David Lutkenhoff, M.S., CIH, CIEC, proposed RSO & Peter Jones, Research Dir./Chief

DATE OF CONTACT
03/10/2015

TYPE OF CONVERSATION

- E-MAIL
- TELEPHONE
- INCOMING
- OUTGOING

E-MAIL ADDRESS
dwlutkenhoff@ftch.com; gwen.oki@vai.org; paula.williamsdeboe@vai.org

TELEPHONE NUMBER
(616) 234-5000

ORGANIZATION
Van Andel *Research Institute*

DOCKET NUMBER(S)
030-38554

LICENSE NUMBER(S)
21-32841-01

CONTROL NUMBER(S)
586205

SUBJECT
Your recent letter requesting to amend your license to list David W. Lutkenhoff as Radiation Safety Officer on the above referenced license.

SUMMARY
We have reviewed your amendment request and find that we are unable to continue this action until we have received additional information from you, as outlined below. Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

Submit requested information within **2** days of this record, referencing your NRC License No., 21-32841-01. 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 as soon as possible. If you are unable to respond by Thursday, March 12, 2015, please contact us and notify us when you may be able to respond.

ADDITIONAL INFORMATION REQUESTED:

1. Please submit a current, dated Memorandum of Understanding/Delegation of Authority document for the proposed RSO, signed by both Mr. Lutkenhoff and a member of senior management. Sample RSO Responsibilities and duties, taken from Appendix I to

NUREG 1556, Vol. 7, "Program-Specific Guidance About Academic, Research and Development, and other Licenses of Limited Scope," to include in the submitted MOU/DOA are attached for your reference. You may provide an update to the MOU/DOA for Paula Williamson DeBoe, submitted with your June 20, 2012, letter, use the NRC template MOU/DOA (taken from NUREG 1556, Vol. 7, rev. 1, Appendix F), or create a new custom document appropriate to your program.

2. Please submit Training & Experience documentation, explicitly providing the scope of the proposed RSO's hands-on experience with radioactive materials, educational credentials, and completion of formal Radiation Safety Officer Training. See the attached annotated page from NUREG 1556, Vol. 7, outlining Training and Experience expected for a proposed RSO. Documentation should include specific dates, radionuclides used, quantities, and other details relevant to the materials and uses authorized on this license.

Continue on Page 3

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

03/10/2015

Please provide a signed MOU/DOA document for Mr. Lutkenhoff. You may use the model MOU/DOA below, taken from the draft NUREG 1556, Vol. 7, rev. 1, volume (available at the NRC website), or create your own custom document, to include relevant responsibilities and duties highlighted below.

Model Delegation of Authority to RSO

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

Radiation Safety Officer Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license; see Figure 8.1. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of byproduct material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301.
- Ensure security of radioactive material.
- Posting of documents as required by 10 CFR Parts 19.11 and 21.6.
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are "ALARA."
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.

- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 30.51 and 10 CFR 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests, inventories, use limited to trained, approved users, etc.), the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 10 CFR 20.1101 and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.

The March 6, 2015 letter lacks sufficient detail to demonstrating that proposed RSO is qualified by training and experience.

CONTENTS OF AN APPLICATION

Please provide training and experience information for Mr. Lutkenhoff, M.S., CIH,, as applicable:

NRC believes that to demonstrate adequate training and experience, the RSO should have (1) as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects: Include date on which University of Michigan M.S. degree, Industrial & Environmental Health/Health Physics was conferred. Include the date, location, and training provider, for Mr. Lutkenhoff's most

- Radiation Protection Principles recent radiation safety training in radiation protection principles, characteristics of ionizing radiation, units of radiation dose and quantities, and biological hazards of exposure to radiation, sufficient to identify and control the anticipated radiation hazards.
- Characteristics of Ionizing Radiation
- Units of Radiation Dose and Quantities
- Radiation Detection Instrumentation
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of byproduct material to be used)
- NRC Regulatory Requirements and Standards For any hands-on experience or direct oversight of NRC
- Hands-on use of radioactive materials. licensed activities, include the radionuclide, radioactive quantity, specific radioactive materials use, and description of Mr. Lutkenhoff's use (e.g., handling radionuclides, conducting surveys, designing shielding, etc.)

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. Include the date, location, and training provider at which the Mr. Lutkenhoff completed a formal course designed for RSOs. This course could have been

Response from Applicant: Provide the following: presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. If the proposed

- Name of the proposed RSO RSO has not completed such a formal training course, please describe additional RSO training, such as specific dates of Health Physics, RSO, and
- Information demonstrating that the proposed RSO is qualified by training and experience. Assistant RSO experience at Grand Valley State University (NRC License No. 21-32172-01), Kellogg Company (include NRC License No., if applicable), and Van Andel Research Institute (NRC License No. 21-32841-01).


Applicants should provide information about the proposed RSO's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

Note: It is important to notify NRC, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to NRC as part of an amendment request.

Attachment 2(a)



Van Andel Institute®

TO: Distribution
FROM: David Van Andel 
DATE: June 11, 2012
SUBJECT: Delegation of Authority and Appointment of Radiation Safety Officer

Federal regulations and licensing requirements governing the research use of radioactive materials place requirements on institutions to name an individual with sufficient standing and training as the Radiation Safety Officer (RSO) and to delegate authority to them on behalf of the Institution.

In this regard, I hereby appoint Paula WilliamsonDeBoe, Manager of Environmental Health and Safety, as the Van Andel Institute Radiation Safety Officer and delegate authority and responsibilities to her accordingly. As RSO, Ms. WilliamsonDeBoe is responsible for ensuring the safe use of licensed or permitted radioactive material within the Institute; managing the Institute's radiation safety program; identifying radiation safety issues; initiating, recommending or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of licensed or permitted radioactive material. Additionally, the RSO has the authority to immediately stop any operations involving the use of licensed or permitted radioactive material within the Institute in which health and safety may be compromised or may result in non-compliance with the U.S. Nuclear Regulatory Commission requirements.

Attachment 2(b)

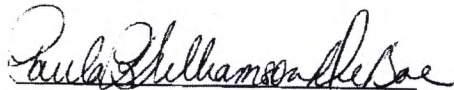
RSO Role/Responsibilities

The Radiation Safety Officer is responsible for overseeing the day-to-day operations of the radiation safety program at Van Andel Research Institute. The RSO will be Paula WilliamsonDeBoe. The responsibilities of the RSO are shown below.

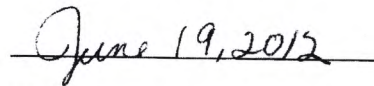
- The day-to-day compliance with the Radiation Safety Program.
- The RSO will communicate with senior management and the Radiation Safety Committee regarding program implementation and compliance status, and will be available to provide advice and assistance on all radiological safety matters.
- The RSO will report directly to the Director of Compliance and secondarily to the Radiation Safety Committee regarding matters pertaining to the Radiation Safety Program.
- The RSO is responsible for radiation protection of all staff and visitors to the laboratories, including general surveillance of overall activities involving radioactive material and personnel monitoring.
- The RSO is responsible for compliance with City of Grand Rapids ordinances, State of Michigan Regulations, and the conditions of the USNRC Materials License
- The RSO is responsible for overseeing the radioactive waste storage and disposal and maintenance of records documenting disposition.
- The RSO will be considered a technical resource on the safe use, storage and disposal of radioactive materials. The RSO will ensure that training will be provided to all staff and visitors appropriate for their use and access to radioisotopes.
- The RSO will review all applications for radioactive material use and ensure that conditions of the USNRC License pertaining to approved radioisotopes and threshold limits.
- The RSO will review new applications and, if found to meet the conditions of the USNRC License, will forward to the Radiation Safety Committee for its consideration of approval before submitting to the USNRC for final approval.
- The RSO may approve minor amendments to existing authorizations for the Radiation Safety Committee, and he/she may suspend any project that is found to be a threat to health or property.
- The RSO will investigate over-exposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, and other deviations from approved radiation safety practices, and implementing corrective actions as necessary.
- The RSO is responsible for implementing all written policies and procedures relating to radiation safety.
- The RSO will oversee proper delivery and receipt, including radiation surveys, of all shipments of radioactive material arriving at or leaving from VAI, as well as packaging and labeling all radioactive materials leaving the Institute.
- The RSO will distribute and process personnel radiation monitoring equipment, determine the need for and evaluation of bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching maximum permissible amounts, and recommend appropriate remedial action.

- The RSO will conduct training, on an as needed basis, of program changes and otherwise instruct personnel in the proper procedures for using radioactive materials.
- The RSO will perform, or arrange for, leak tests on all sealed sources and calibration of radiation survey instruments.
- The RSO will assure that AUs are providing the information to maintain an inventory of all radioisotopes at VARI.
- The RSO will supervise decontamination and recovery operations.
- The RSO will conduct periodic meetings with and provide reports to VARI management and the Radiation Safety Committee (at least annually).
- Maintain in-house Authorization for Use for Authorized Users of radioisotopes.
- Assist the Radiation Safety Committee in the performance of its duties.

I have read and understand these responsibilities of the RSO of the Radiation Safety Program at VARI.



Paula WilliamsonDeBoe



Date

Forster, Sara

From: Forster, Sara
Sent: Tuesday, March 10, 2015 5:11 PM
To: 'dwlutkenhoff@ftch.com'
Subject: Additional Information Request for Van Andel Institute, NRC Lic. No. 21-32841-01
Attachments: 03620.586205.21-32841-01 telecon signed.pdf; VanAndel current MOUDOA.pdf

Dear Mr. Lutkenhoff:

Please the attached file for information needed to complete the review of the amendment request referenced above. Per your request, I have also attached the MOU/DOA from the June 20, 2012, letter. Note that the attached conversation record requests that all information be received in our office on or before the close of business Thursday, March 12, 2015. 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," which may be found at:

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

Submission of your responses 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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