



CONVERSATION RECORD

04/10/2015

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Alan Schaffer, Chemistry Unit Manager and proposed Radiation Safety Officer		DATE OF CONTACT 04/06/2015	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 alan.schaffer@health.mo.gov		TELEPHONE NUMBER (573) 751-3334	

ORGANIZATION Missouri Public Health Laboratory	DOCKET NUMBER(S) 030-38804
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LICENSE NUMBER(S) N/A	CONTROL NUMBER(S) 585831
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SUBJECT
Our review of your new license application dated January 5, 2015.
Additional information requested below is requested on or before the close of business on April 20, 2015.

SUMMARY AND ACTION REQUIRED:

To complete your new license application, please submit additional information as noted below. Refer to NUREG 1556, Vol. 7, "Program-Specific Guidance About Academic, Research and Development, Licenses of Limited Scope," found at the website, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v1/r1/sr1556v7.pdf>.
For your convenience, applicable guidance volume pages are attached.

PLEASE NOTE THE FOLLOWING WHEN PREPARING YOUR RESPONSE:

- Submit requested information within 14 days of our conversation, as listed at the top of this memo.
- * (IF YOU ARE UNABLE TO RESPOND BY APRIL 20th, PLEASE CALL OR EMAIL AS SOON AS POSSIBLE) *
- Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.
- Provide your response on typed 8.5" x 11" sheets, or by completing the applicable portions of the Appendix C checklist.
- Include a signed and dated cover letter with your response; reference Control No. 585831 in that response.
- Please FAX your response to my attention at (630) 515-1078 OR scan your response and send to me via email, as a pdf file.

ADDITIONAL INFORMATION NEEDED:

1. Concerning authorized materials, as discussed, please update Item 6, "Purpose for which licensed material will be used," to clarify that the requested overall possession limits, form, and radionuclides listed in Item 5, apply to both purposes - as calibration sources and as contaminated samples. In the alternative, provide separate Item 5 responses for each purpose of use listed on the license.
2. Concerning the requested Radiation Safety Officer, please submit a current, dated Memorandum of Understanding/Delegation of Authority document for the proposed RSO, signed by both Mr. Schaffer and a member of senior management. Sample RSO Responsibilities and duties, taken from Appendix I to NUREG-1556, Vol. 7, are attached for your reference. You may use the

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 04/10/2015

CONVERSATION RECORD (continued)

A. Schaffer

C/N 585831

SUMMARY AND ACTION REQUIRED - ADDITIONAL INFORMATION NEEDED (Continued from page 1):

NRC template MOU/DOA (taken from NUREG 1556, Vol. 7, rev. 1, Appendix F), or create a new custom document appropriate to your program.

3. 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. Please also include the course completion certificate for the Nevada Technical Associates course, including a course outline and evaluation criteria.
4. Please list all Authorized Users (AUs) for this license. For each AU, please submit Training & Experience documentation, explicitly providing the scope of the proposed AU's hands-on experience with radioactive materials, and educational credentials. See the attached annotated page from NUREG 1556, Vol. 7, outlining Training and Experience expected for a proposed AU. Documentation should include specific dates, radionuclides used, quantities, and other details relevant to the materials and uses authorized on this license.
5. Concerning Item 9, "Facilities and equipment," please provide a facility diagram for the area of use where the radioactive materials testing sample reception, preparation, and analysis will take place. The diagram should include room numbers, as applicable, and be drawn to scale (or otherwise indicate dimensions). An architectural diagram is neither needed or requested; however, the diagram should show any radioactive materials work, waste, or storage area - including refrigerator/freezers and fume hoods. For any radioactive materials receiving, shipping, or waste storage areas, please provide room numbers and a "work-flow" description of how licensed material will be transferred - safely and securely - between rooms, while under the licensee's control. Please refer to the attached Appendix K to NUREG 1556, Vol. 7, for sample Facilities and Equipment Considerations that may be considered in your response.

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.

APPENDIX I

- 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.

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

The January 5, 2015 application 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. Schaffer, 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

Include date on which undergraduate degree in biology was conferred. Include the date, location, and training provider, for Mr. Schaffer's most recent radiation safety training in radiation protection principles, characteristics of ionizing radiation, units of radiation dose and quantities,

- Radiation Protection Principles 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 licensed activities, include the radionuclide, radioactive quantity, specific radioactive materials use, and description of Mr. Schaffer'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 training certificate for the formal 40-hour RSO training course Mr. Schaffer completed at Nevada Technical Associates, as indicated in Item 7 to the application.

Response from Applicant: Provide the following:

- Name of the proposed RSO

* **Information demonstrating that the proposed RSO is qualified by training and experience.** *

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.

NRC believes that to demonstrate adequate training and experience the AU should have (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles
 - Characteristics of Ionizing Radiation
 - Units of Radiation Dose and Quantities
 - Radiation Detection Instrumentation
 - Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used)
 - Hands-on Use of Radioactive Materials.
- The January 5, 2015, application did not list any AUs. It is our understanding that Mr. Schaffer is also a requested AU for all materials to be authorized under the license. Information provided in response to the request to add Mr. Schaffer as RSO is also sufficient to add him as an AU. If he is the sole AU to be listed on the license, no additional AU training and experience information is needed. However, for additional AUs, please provide additional training and experience details for each AU to be added to the license.

The amount of training and experience needed will depend upon the type, form, quantity and proposed use of the licensed material requested, but it should cover the subjects stated.

An AU is considered to be supervising the use of radioactive materials when he/she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

Response from Applicant: Provide the following:

- Name of each proposed AU with the types and quantities of licensed material to be used
- Information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that an ARDL licensee will use or otherwise have available. Not every ARDL applicant will need to address each topic in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

APPENDIX K

- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.

Forster, Sara

From: Forster, Sara
Sent: Friday, April 10, 2015 8:26 AM
To: 'alan.schaffer@health.mo.gov'
Subject: Additional Information Request for Missouri Public Health Laboratory, C/N 585831
Attachments: 03124.585831.New License telecon signed.pdf

Dear Mr. Schaffer:

See the attached file for additional information needed to complete the review of the new license application for the above referenced entity. **Note that additional information is requested on or before April 20, 2015. If you are unable to respond by that date, please contact us as soon as possible.** 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 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
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892

