NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 10/16/2014

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Ross Larson, Radiation Safety Officer (RSO) / Nicole Engler	10/16/2014	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS: r.larson@mo-ana-labs.com / nicole@mo-ana-labs.com	TELEPHONE NUMBER: (314) 241-8772	

ORGANIZATION	DOCKET NUMBER(S)
Missouri Analytical Laboratories, Inc.	030-05138
LICENSE NUMBER(S): 24-12366-01	CONTROL NUMBER(S): 584168

SUBJECT

Additional information needed to complete the review of your renewal application, dated June 26, 2014
Please submit requested information within 30 days of the date of the date of our phone conversation listed on this request.

SUMMARY AND ACTIONS REQUIRED:

We have reviewed your license renewal application and find that we are unable to continue this action until we have received additional information outlined on page 2 of this conversation record.

Direct any questions you have to me at (630) 829-9892 or sara.forster@nrc.gov.

When submitting additional information, please reference Control No. 584168, 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 15, 2014.

As outlined on Page 2, we have requested that the licensee provide additional information:

- Submit management-signed and dated cover letter or NRC Form 313; and RSO MOU/DOA
- Confirm that no field studies will be conducted under this license
- Provide additional training program details including topics, methods, frequency, and assessment, as applicable
- Expand facilities description including support for the conclusion that airborne materials are not subject to airborne transmission
- Confirm that safe use & emergency procedures have been developed

Continue on Page 2

NAME OF PERSON DOCUMENTING CONVERSATION

Sara A. Forster, M.S., Materials Licensing Branch, Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532

SIGNATURE: Sara A. Forster 10/16/2014

CONVERSATION RECORD (continued)

SUMMARY and ACTIONS REQUIRED (Continued from page 1) C/N 584168

R. Larson /N. Engler

PROGRAM MANAGEMENT:

1. Please submit dated cover letter, signed by a designated management official, incorporating your application. Refer to NUREG 1556,Vol. 7, "Program-Specific Guidance about Academic, Research and Development, and other Licenses of Limited Scope," found at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/ when providing additional requested information, as noted below. Note that the June 26, 2014, application, need only be referenced in the text of your response letter. It is not necessary to resubmit the information contained in that request.

2. If not already addressed in your application, include a description of the RSO's responsibilities with your response. The RSO responsibilities should be submitted via a Memorandum of Understanding/Delegation of Authority (MOU/DOA) document, signed and dated by a member of senior management and the designated Radiation Safety Officer (RSO). Note that sample RSO duties and Responsibilities that may be included in such an MOU/DOA document may be found on pp. I-1 to I-2 of NUREG 1556, Vol. 7. (Copy enclosed for your reference.)

AUTHORIZED RADIOACTIVE MATERIALS USE:

3. Please confirm that no field studies will be conducted under this license, unless specifically requested and authorized.

TRAINING REQUIREMENTS

4. Your application described your radiation safety training program and included some concepts students may be expected to learn, but did not include other groups of workers, training frequencies, or assessment methods. Please resubmit a description of the radiation safety training program, as requested in NUREG 1556, Vol. 7, pp. 8-18 to 8-19. Please refer to NUREG 1556, Vol. 7, Appendix J, pp. J-1 to J-5 (copy attached for your reference), which includes recommended training frequency, and topics that should be included in the training program, when preparing your response.

FACILITIES & EQUIPMENT

5. The application indicated that the radioactive materials used by the licensee are not subject to airborne transmission. Please explain details supporting this statement. (e.g., bound state of the P-32 and/or facilities and equipment used to control any volatile materials, including airflow rates, pressures, filtration equipment, and monitoring equipment). Please refer to NUREG 1556, Vol. 7, p. C-4 and Appendix K which facility considerations that should be included in the description, where applicable, when preparing your response. (Copy enclosed for your reference.)

6. Three facility diagrams were enclosed with the application. Please explain the relationship between the diagrams, and discuss how material is transported from and to shipping and receiving, between laboratories, and to any waste storage areas.

RADIATION SAFETY PROGRAM

7. The referenced application included a copy of the licensee's SOP 69, "Radiation Protection Program" but was unclear as to whether this or any other procedure has been developed, maintained, and implemented for safe use of radionuclides and emergencies. Please confirm that safe use of radionuclides and emergency procedures have been developed, as noted in NUREG 1556, Vol. 7, p. C-6.

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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.

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Radiation Safety Training Topics

This Appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Frequency of Training

A. Before assuming duties with, or in the vicinity of, radioactive materials

B. Whenever there is a significant change in duties, regulations, or the terms of the license

C. Annually (refresher training).

General Information

A. Radiation safety

1. radiation vs. contamination
2. internal vs. external exposure
3. biological effects of radiation
4. ALARA concept
5. use of time, distance, and shielding to minimize exposure.

B. Regulatory requirements

1. RSO
2. material control and accountability
3. personnel dosimetry
4. radiation safety program audits
5. transfer and disposal
6. record keeping
7. surveys
8. postings

9. labeling of containers
10. handling and reporting of incidents or events
11. licensing and inspection by NRC
12. need for complete and accurate information
13. employee protection
14. deliberate misconduct.

Licensee-Specific Program Elements

A. Authorized users and supervised users.

B. Ordering and receiving radioisotopes.

C. Applicable regulations and license conditions.

D. Areas where radioactive material is used or stored.

E. Potential hazards associated with radioactive material in each area where the individuals will work.

F. Appropriate radiation safety procedures.

G. Licensee`s in-house work rules. (For instructions on laboratory safety and uses of radioisotopes, see Section IV.)

H. Each individual's obligation to report unsafe conditions to the RSO.

I. Appropriate response to spills, emergencies or other unsafe conditions.

J. Worker`s right to be informed of occupational radiation exposure and bioassay results, if applicable.

K. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

L. Emergency procedures:

1. RSO name and telephone number
2. immediate steps to prevent or control spread of contamination
3. clean-up instructions, decontamination.

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M. Survey program:

1. survey instrument accessibility
2. who is responsible
3. types, contamination and area
4. frequency
5. levels of contamination
6. personnel, hands, shoes
7. records.

N. Waste

1. liquid
2. solids
3. sanitary sewer
4. burial (transfer to low level waste repository)
5. storage
6. decay-in-storage
7. waste storage surveys
8. incineration
9. records.

O. Dosimetry

1. whole body
2. extremities
3. lost or replacement badges and dose assessment
4. bioassay procedures
5. records.

P. Instrumentation

1. survey meters-use, calibration frequency, use of check sources
2. analytical instruments-gas chromatographs, liquid scintillation counters.

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Q. Procedures for receiving packages containing radioactive materials.

1. normal
2. off-duty
3. notification of user and RSO
4. security
5. exposure levels
6. possession limit
7. receipt of damaged packages.

R. Procedures for opening and examining packages

1. leakage and contamination
2. monitoring packages
3. monitoring packing materials
4. gloves
5. transferring material to users.

S. Animal experiments

1. description of facilities
2. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
3. security.

T. Sealed sources

1. leak test requirements
2. inventory requirements
3. exempt quantities
4. records.

U. Other topics, as applicable

V. Question and answer period.

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For Laboratory Safety and Use of Radioisotopes

A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.

B. Protective clothing and what laboratory apparel to wear and what equipment to use.

C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma emitting licensed materials are handled.

D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.

E. Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.

F. Decontamination procedures to use and whom to contact in case of an emergency.

G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.

H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.

I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.

K. Records to be maintained on use and disposal of licensed materials.

L. Prohibition of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are used.

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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.

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- 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: Thursday, October 16, 2014 3:07 PM
To: 'r.larson@mo-ana-labs.com'; 'nicole@mo-ana-labs.com'
Subject: Additional Information Request for Missouri Analytical Laboratories, Inc., NRC Lic. 24-12366-01
Attachments: 03620.584168.24-12366-01 NRC 699 signed.pdf

Dear Mr. Larson and Ms. Engler,

See the attached file for additional information needed to complete the review of the renewal application for NRC Lic. No. 24-12366-01. Note that the attached conversation record requests additional information by November 15, 2014, as discussed during our phone conversation. 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 Including Gas Chromatographs and X-Ray Fluorescence Analyzers," 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
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Protecting People and the Environment