



Dr. Lizette Roldán-Otero
Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region IV
1600 East Lamar Blvd
Arlington, Texas, 76011

09May2013

RECEIVED

MAY 10 2013

DNMS

Dear Dr. Roldán-Otero,

SUBJECT: License 030-29237-01 Amendment Request / Change in RSO

The intent of this request of license amendment is to submit Dr. Janet Benson as Lovelace Respiratory Research Institute's (LRRI) Radiation Safety Officer (RSO) effective upon approval by NRC licensing personnel. She will be replacing the current RSO, Scott Weiner. Dr. Benson is being proposed as the RSO, with qualifications pursuant to NUREG-1556, volumes 11, 7, and 17. As requested, the name of the proposed RSO, her associated training and experience that demonstrate that she is qualified to perform the duties required under the license, and the statement delineating RSO's duties and responsibilities and Radiation Safety Officer Delegation of Authority, signed by LRRI executive management, follow.

Name of proposed RSO:

Janet M. Benson, PhD, DABT

Training and Experience for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license:

Dr. Benson is qualified by training and experience in radiation protection which is relative to the licensed material requested in the application, pursuant to the requirements in NUREG1556, volume 11. Specifically, Dr. Benson has held scientific positions at LRRI since 1977, making her particularly familiar with the type of research conducted under this license. Dr. Benson's direct research experience with radioactive materials (RAM) includes designing, executing, and managing studies with RAM. Experimentation involving RAM, animals, and aerosolization of materials poses a unique environment at LRRI; one with which Dr. Benson has a significant amount of direct experience. Dr. Benson has been responsible for protocol development, assisted with the design of aerosol generation systems, and has synthesized and characterized radiolabeled nickel compounds for multiple aerosol deposition and clearance studies. Due to her

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PUBLIC

☐ Immediate Release
☒ Normal Release

NON-PUBLIC

☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Lovelace Respiratory Research Institute
2425 Ridgcrest Dr. SE, Albuquerque, NM 87108

Reviewer: LRO Date: 5-10-13

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vast experience in leading these types of studies, Dr. Benson is also a LRRI-certified qualified trainer for other Study Directors interested in conducting radiation studies.

Some examples of direct research experience with radioactive materials include, but are not limited to the following studies/ publications. The experiment title (including test system and method delivery), date, material type and activity, as well as Dr. Benson's specific role on the studies are listed below:

NICKEL COMPOUNDS

Benson, J. M., E. B. Barr, W. E. Bechtold, Y. S. Cheng, J. K. Dunnick, W. C. Eastin, C. H. Hobbs, C. H. Kennedy and K. R. Maples: Fate of Inhaled Nickel Oxide and Nickel Subsulfide in F344/N Rats. *Inhal. Toxicol.* 6(2): 167-183, 1994.

Benson, J. M., I. Y. Chang, Y. S. Cheng, F. F. Hahn, C. H. Kennedy, E. B. Barr, K. R. Maples and M. B. Snipes: Particle Clearance and Histopathology in Lungs of F344/N Rats and B6C3F₁ Mice Inhaling Nickel Oxide or Nickel Sulfate. *Fundam. Appl. Toxicol.* 28: 232-244, 1995.

- Principal Investigator with overall responsibility for the synthesis, chemical and radiochemical characterization of the ⁶³Ni-labeled compounds, inhalation study design, implementation and reporting.
- Participated in design of the aerosol generation system, actively participated in animal exposures, animal euthanasia and tissue harvest, and characterization of the exposure atmosphere.

The starting material for all syntheses was ⁶³NiCl₂ (10.6 – 11.0 mCi/mmmole).

⁶³NiSO₄ was prepared by recrystallizing 70 g of NiSO₄·6H₂O from 100 mL deionized water containing 800 mCi of ⁶³NiCl₂. The specific activity of the product was 2.7 mCi/mmmole Ni.

⁶³NiO was synthesized by reacting ⁶³NiCl₂ with ammonium bicarbonate to yield nickel carbonate that was then calcined at 1000°C to form ⁶³NiO. The specific activity was 1.6 mCi/mmmole Ni. Fourteen grams of product were obtained

⁶³Ni₃S₂ was synthesized by H₂ reduction of ⁶³NiSO₄·6H₂O. The specific activity of the product was 2.96 mCi/mmmole Ni. Seventeen grams of product were obtained.

For the study examining the fate of inhaled ⁶³NiO and ⁶³Ni₃S₂, aerosol concentrations were 15 and 6 mg/m³, respectively. Animal were exposed by nose-only inhalation. For the ⁶³NiO study, animals were euthanized from 1 hour



to 180 days post exposure. For the $^{63}\text{Ni}_3\text{S}_2$ study, animals were euthanized from 4 hour to 64 days post exposure.

For the study examining the effect of repeated nickel compound inhalation on subsequent clearance of ^{63}Ni labeled compound, aerosol concentrations for the ^{63}NiO and $^{63}\text{NiSO}_4 \cdot 6\text{H}_2\text{O}$ were $\sim 10 \text{ mg/m}^3$.

- Clearance of inhaled ^{85}Sr -polystyrene latex particles also assessed in the 1995 study. The specific activity was 21.5 mCi/g. Clearance was followed over a 100 day period.

Benson, J. M.: Final Report to the Nickel Producers Environmental Research Association, Inc., 1995.

- This report was a summary of in vitro and in vivo studies on the fate of ^{63}Ni labeled nickel oxide, nickel sulfate and nickel subsulfide. Compounds synthesized above were used.
- Aerosol deposition, tissue distribution and clearance in non human primates were reported.
- Dr. Benson participated in exposure system development, inhalation exposures and sample collections.
- The studies took place over approximately two years.

VOLATILE COMPOUNDS

Benson, J. M., B. M. Tibbetts, K. D. Thrall and D. L. Springer: Uptake, Tissue Distribution, and Fate of Inhaled Carbon Tetrachloride: Comparison of Rat, Mouse, and Hamster. *Inhal. Toxicol.* 13(3): 207-217, 2001.

- Responsible for protocol design, study implementation and reporting.
- Oversight of nose only inhalation exposures and sampling collections of animals in metabolism cages (exhaled air and excreta).
- ^{14}C labeled CCl_4 obtained from a commercial vendor, had a specific activity of 9 mCi/mmol. Vapor concentration was 20ppm $^{14}\text{CCl}_4$. Animals were euthanized from immediately after exposure to 48 hours post exposure.

Benson, J. M., B. M. Tibbetts and E. B. Barr: The Uptake, Distribution, Metabolism, and Excretion of Methyl Tertiary-Butyl Ether Inhaled Alone and in Combination with Gasoline Vapor. *J. Toxicol. Environ. Health A* 66: 1029-1052, 2003.

- Responsible for protocol design, study implementation and reporting.



- Assist with nose only inhalation exposures, tissue, sample collections (exhaled air and excreta) and oversight of sample processing.
- The methyl tertiary butyl ether (MTBE) used for this study obtained from a commercial vendor. It was uniformly labeled with ^{14}C . The specific activity was 2 mCi/mmol. The vapor exposure concentrations were 4, 40, and 400 ppm ^{14}C -MTBE. Animals were euthanized immediately after exposure up to 72 hours post exposure. The study was conducted over a period of two years because there were multiple animal studies involving inhalation of ^{14}C -MTBE alone and then in combination with gasoline vapor.

NATURAL PRODUCT

Benson, J. M., D. L. Tischler and D. G. Baden: Uptake, Tissue Distribution, and Excretion of Brevetoxin 3 Administered to Rats by Intratracheal Instillation. *J. Toxicol. Environ. Health* 57: 345-355, 1999.

- Responsible for protocol design, study implementation and reporting.
- ^3H -brevetoxin was labeled at the C-42 position. It was synthesized at the Center for Marine Sciences, University of North Carolina, Wilmington. The compound specific activity was 15.5 Ci/mmol. Rats were dosed by intratracheal instillation of a solution containing 10 $\mu\text{Ci/mL}$ compound. Animals were euthanized up to 48 hours post dosing.

CHEMICAL WARFARE AGENT

Benson, J. M., B. M. Tibbetts, W. M. Weber and G. R. Grotendorst: Uptake, Tissue Distribution, and Excretion of ^{14}C -Sulfur Mustard Vapor Following Inhalation in F344 Rats and Cutaneous Exposure in Hairless Guinea Pigs. *J. Toxicol. Environ. Health* 74: 875-885, 2011.

- Protocol design, study implementation, tissue harvest and data reporting.
- The ^{14}C labeled sulfur mustard was synthesized at Lovelace. The specific activity was 0.19 mCi/mmol. Vapor concentration for the inhalation exposures in rats was 256 mg/m^3 . Vapor concentration for the cutaneous exposures in guinea pigs was 52 mg/m^3 . Animals were euthanized over a period of 168 hours.



CARBON TETRACHLORIDE IN COMBINATON WITH PLUTONIUM-239 NITRATE OR ⁸⁵Sr-LABELED FUSED ALUMINOSILICATE PARTICLES

- Protocol design, study implementation, tissue harvest and data reporting.
- Rats and Syrian golden hamsters were exposed whole body to 5, 20 or 100 ppm CCL₄ 6 hours/day, 5 days per week for four weeks. Subgroups were exposed by nose only inhalation to ²³⁸Pu(NO₃)₄ or ⁸⁴Sr-fused aluminosilicate particles. Carbon tetrachloride exposures continued for an addition 12 weeks during which animals were euthanized at selected time intervals, and tissues harvested for quantitation of ²³⁸Pu or ⁸⁵Sr, and evaluation of histopathological changes.

RADIATION SAFETY PROGRAM INVOLVEMENT

Dr. Benson has additional experience with LRRI's radiation safety program as an Authorized User as well as a member of LRRI's Radiation Safety Committee (RSC) under LRRI's broad scope license. In her role as an RSC member, Dr. Benson has contributed consistently and extensively to the review and re-write of Standard Operating Procedures (SOP) associated with the license as well as with Radiation Work Permit (RWP) development and implementation since January 2013. As such, not only is Dr. Benson very aware of LRRI's current SOPs, she is also aware of proposed refinements to the procedures and associated license.

Dr. Benson has received course training on LRRI's Broad Scope License (29-31Jan2013), attended training sessions on LRRI RSC expectations (13Dec2012), and has received radiation worker training at LRRI (27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012).

ADDITIONAL FORMAL & HANDS-ON TRAINING

The training and experience listed above serves as further qualification of Dr. Benson as an RSO in compliance with NUREG 1556, volumes 7 and 17. Dr. Benson also received formal training in obtaining her PhD., including one course on the principles of radiation. Other specific training requirements in these volumes are met as follows:

- Radiation Protection Principles
 - Attended formal course training on this topic 27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012 . Documented read and understood training on related LRRI procedures 27Feb2004, 22Dec2006, 18Jul2008, 31Dec2012, 01Jan2013, and 07Apr2013.



- Characteristics of Ionizing Radiation
 - Attended formal course training on this topic 27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012
- Units of Radiation Dose and Quantities
 - Attended formal course training on this topic 27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012
- Radiation Detection Instrumentation
 - Attended formal course training specific to surveys on 18Jul2012. This topic was also covered in courses attended 27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012. Documented read and understood training on related LRRI procedures 27Dec2012, 29Dec2012, 31Dec2012, 27Jan2013, and 07Apr2013.
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of byproduct material to be used)
 - Attended formal course training on this topic 27May1999, 02Feb2001, 02Nov2004, 23Jan2008, 05Jan2009, 16Mar2010, 30Mar2011, and 18Jul2012
- NRC Regulatory Requirements and Standards
 - Attended courses 10Jul2012 and 13Dec2012.
- Hands-on use of radioactive materials.
 - Dr. Benson has been involved directly in handling radioactive materials including synthesis, in vivo inhalation exposure operations, packaging waste, sample collection, etc. This did include handling of transuranics (Plutonium) and mixed waste (Nickel and organic solvents in scintillation cocktail). Dr. Benson has 20 years of on the job experience in working with RAM.

RADIATION DOSE MONITORING

Dr. Benson has significant experience with both internal and external occupational dose monitoring. She and her team have been required to participate in bioassays (urine collections) while working on the RAM inhalation studies at LRRI in the past. Dosimeters are to be worn when working with gamma emitting compounds or instruments (ie. the gammacell irradiator at north), x-rays producing instruments (ie. the LINAC, and the x ray machines or fluoroscope in our clinic) or for research purposes (ie. Phillips RT 250 X-ray Therapy Unit). In addition, dosimeters are also issued to and worn by those working with low or high energy beta emitters.



QUALIFICATIONS SUMMATION

Dr. Benson meets the educational requirements listed in NUREG 1556, volume 7, which states the RSO should have as a minimum, a college degree at the bachelor level, or equivalent training and experience in physical, chemical, biological sciences, or engineering. NUREG 1556, volume 17 also requires sufficient knowledge of physical, chemical, biological sciences, or engineering. Dr. Benson exceeds educational requirements in both volumes with a B.S. in Chemistry earned at the University of California-Berkeley (1972) and Ph.D. in Comparative Pharmacology and Toxicology at the University of California-Davis (1978).

Consideration of the ability for the RSO candidate to run a program was also given, and Dr. Benson has proven capable of successfully running large programs and contracts at LRRI over the past 30 years. This also included management of personnel (group supervisor as well as direct supervision of laboratory personnel and program staff) and resources as well as working closely with executive management at LRRI.

Dr. Benson is also familiar in working with external and internal auditors, including regulatory agencies. She has herself conducted facility inspections at LRRI as a member of various committees in order to assure regulatory compliance. In addition to being a member of the RSC, she is currently a member of the LRRI Select Agent, Biological Toxins Security Committee, and IACUC committees, so is aware of a wide variety of LRRI safety and security programs and initiatives.

Upon approval of this amendment, Dr. Benson's role will immediately shift to focus on RSO duties, making her available for advice and assistance on radiological safety matters.

In summary, LRRI feels that Dr. Benson's high level of education, experience in working with as well as managing programs involving a wide variety of RAM, training on and development of LRRI-specific SOPs related to the radiation safety program, and familiarity with unique aspects of LRRI's aerosolization techniques qualifies her as an RSO pursuant to the applicable regulations, cited above.

PUBLIC

- ☐ Immediate Release
- ☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
- ☐ A.7 Sensitive Internal
- ☐ Other: _____

Reviewer: JWE Date: 05/10/13

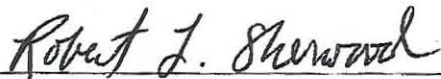


Statement delineating RSO's duties and responsibilities:

The RSO's responsibilities will remain consistent with the previously approved duties assigned of:

1. Assuring that licensed material possessed by the licensee conforms to the material authorized by the license.
2. Assuring that only individuals authorized by the license use the licensed material.
3. Instructing personnel in proper radiation protection practices.
4. Conduct or have conducted radiation surveys where indicated and keep records of such surveys, including summaries of corrective measures recommended and/or instituted.
5. Assuring that individual monitoring devices are used where indicated and exchanged at required intervals, and that records are kept of the results of such monitoring.
6. Assuring that postings are properly located.
7. Investigating each known or suspected case of excessive or abnormal exposure to determine the cause and take steps to prevent recurrence. Unusual events will be reviewed as they are reported to the RSO and, as action is taken, until resolved.
8. Being immediately available to serve as a point of contact with the Commission and give assistance in case of emergency (e.g. damage, fire, theft, etc).
9. Assuring that the proper authorities (i.e. the NRC, local police, U.S. Department of Transportation, etc.) are notified promptly in case of accident, damage, theft, or loss of licensed material.
10. Assuring that the terms and conditions of the license are met and that the required records (including personnel exposure, leak test, accountability, and survey results) are maintained and reviewed for compliance with Department regulations and license conditions.
11. Ensuring that procedural changes will not result in a reduction in safety.

Kind Regards,



Dr. Robert Sherwood

Sr. Director Applied Life Sciences/Sr. Scientist

& Radiation Safety Committee Chairman

Radiation Safety Officer Delegation of Authority, signed by LRRI executive management:

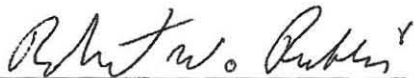
DELEGATION OF AUTHORITY

RADIATION SAFETY OFFICER

Memorandum To: All Employees
From: Dr. Robert W. Rubin, President and Chief Executive Officer
Subject: Delegation of Authority for Radiation Safety Officer

Janet M. Benson, Ph.D., has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of byproduct material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of byproduct material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.



Robert W. Rubin, President/CEO

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03610
Status Code: Pending Amendment
Fee Category: 1D 3L
Exp. Date: 08/30/2016
Fee Comments:
Decom Fin Assur Req: Y

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: LOVELACE RESPIRATORY RESEARCH INST
Received Date: 05/10/2013
Docket Number: 3037312
Mail Control Number: 580716
License Number: 30-29237-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____



DATE

05/16/2013

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Lovelace Respiratory Research Institute
ATTN: Scott Weiner, RSO
2425 Ridgecrest Drive, S.E.
Albuquerque, NM 87108

LICENSE NUMBER

30-29237-01

MAIL CONTROL NUMBER

580716

LICENSING AND/OR TECHNICAL REVIEWER

cmurnahan

cm

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION

DATED: 05/09/2013

The initial processing, which included an administrative review, has been performed.

☒ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

- ☒ There were no administrative omissions identified during our initial review.
- ☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.
- ☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Blvd.
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(817) 200-1103 or (817) 200-1140

*ah ltr sent via
e-mail to licensee.
5-16-13*