ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Lovelace Respiratory Research Institute

License No.: 30-29237-01

Docket No.:

Mail Control No.: 471444

Type of Action: Amend

Date of Requested Action: 07-20-07

Reviewer Assigned: Jackie Cook

ARM reviewer(s): Torres

Response	Deficiencies Noted During Acceptance Review
	[ ] Open ended possession limits. Limit possession. Submit inventory. [ ] Submit copies of most recent leak test results. [ ] Add - delete IC license condition. Add IC paragraph in cover letter. [ ] Split license from cover letter. Add SUNSI marking to license. [ ] Ask the licensee if they have any type-amount of EPAct Material.
N/A	**Submit appropriate radiation T&E documentation for Dr. McDonald.** current in on license

It appears Dr. McDonald does not meet T&E

Reviewer's Initials: JCC **Date:** 7/25/07

☐Yes ☐No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.

☐Yes ☐No Decommissioning notification should be completed within 30 days.

☐Yes ☐No Termination request < 90 days from date of expiration

☑Yes ☐No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)

☐Yes ☐No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** 7-20-07

SUNSI Screening according to RIS 2005-31

☐Yes ☑No **Non-Publicly Available, Sensitive** if <u>any</u> item below is checked

General guidance:

_____RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
_____Exact location of RAM (whether = or > than Category 3 or not)
_____Design of structure and/or equipment (site specific)
_____Information on nearby facilities
_____Detailed design drawings and/or performance information
_____Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

_____RAM quantities and inventory
_____Manufacturer's name and model number of sealed sources & devices
_____Site drawings with exact location of RAM, description of facility
_____RAM security program information (locks, alarms, etc.)
_____Emergency Plan specifics (routes to/from RAM, response to security events)
_____Vulnerability/security assessment/accident-safety analysis/risk assess
_____Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RTC **Date:** JUL 20 2007

Pre-Licensing Screening

Applicant Information: **Control No.** 471444

Name: Lovelace Respiratory Research Institute	Type of Request: Amend Program Code(s):
Location: NM	License No.: 30-29237-01 Docket No.:

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		Yes or No
A.	The request is from a new applicant.	No
B.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been **"highlighted"** by the reviewer	No

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])	Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226[2]	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

[1] The primary values are TBq. The curie (Ci) values are for informational purposes only.

[2] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. **NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).**	Yes , No, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule--multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

JUL 20 2007

License Reviewer and Date

Lovelace Respiratory Research Institute
2425 Ridgecrest Drive SE
Albuquerque NM 87108

Expedite.
RSO change effective
7/21/07.

facsimile transmittal

To:	Jacqueline D. Cook	Fax:	817-860-8263
From:	Scott A. Weiner	Date:	7/20/2007
Re:	License Amendment – RSO	Pages:	15
CC:			

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Dear Ms. Cook:

Stan Fitch has resigned from Lovelace Respiratory Research Institute and will no longer server as radiation safety officer (RSO). We have hired another Certified Health Physicist to take his place starting in mid-August. In the interim, we would like to amend our radioactive material license (#30-29237-01) to name one of our scientists, Dr. Jacob D. McDonald, as RSO. We will request to amend our license again when our new CHP begins work at LRRI.

Please contact me if you have any questions.

Thank you.

Sincerely,

Scott A. Weiner

Scott A. Weiner CIH MSPH
ES&H Manager
505-348-9672

Lovelace

July 20, 2007

Jacqueline Cook
DNMS/NMLB
U.S. NRC Region IV
Texas Health Resources Tower
611 Ryan Plaza
Arlington, TX 76011-4005

Dear Ms. Cook:

Lovelace Respiratory Research Institute has installed a new Radiation Safety Officer; therefore, LRRI is requesting amendment of radioactive material license number 30-29237-01. The following items require amending:

Condition 11.B. Replace the current text with: "The Radiation Safety Officer for this license is Jacob D. McDonald, PhD." 7/23/07 Noted that Mr. Weiner the Guest "I" Jake" are the same person.

Dr. McDonald is an employee for LRRI. Please find a copy of his curriculum vitae. Please contact me at (505) 348-9672 if you have any questions or comments.

Sincerely,

Scott A. Weiner

Scott A. Weiner CIH MSPH
ES&H Manager

CURRICULUM VITAE

Jacob D. McDonald, PhD

Lovelace Respiratory Research Institute
2425 Ridgecrest Dr. SE
Albuquerque, NM 87108
Fax: (505) 348-4980
jmcdonal@LRRI.org

EDUCATION

B.S. (Biology/Environmental Chemistry) 1996, University of La Verne
Ph.D. (Environmental Chemistry & Toxicology) 2000, University of Nevada

EMPLOYMENT

2/06 - Present — Scientist, Lovelace Respiratory Research Institute, Albuquerque, NM

2004 - Present — Program Manager, Inhalation Exposure and Analytical Chemistry Program, Lovelace Respiratory Research Institute, Albuquerque, NM
Dr. McDonald oversees development and validation of chemical methods and inhalation exposures that are applied to drug delivery, environmental science, chemical/biological defense, and basic biology (mechanism of disease).

2002 - Present — Director, Environmental Assessment and Exposures Core, New Mexico NIEHS Center, Albuquerque, NM
As Director of the NIEHS Environmental Assessment Facility Core, Dr. McDonald is involved in several multi-disciplinary studies to assess/link environmental exposures to health effects, including both population studies and laboratory based inhalation exposure studies. Studies range from indoor air assessments to analysis of biomarkers in environmental or occupationally exposed subjects.

2001 - 2004 — Supervisor, Analytical Chemistry, Lovelace Respiratory Research Institute, Albuquerque, NM
As Supervisor of the Analytical Chemistry Laboratory at LRRI, Dr. McDonald has been involved in the development and validation (often validated to Regulatory Standards) of analytical methods for the collection and analysis of chemical species in both environmental and biological matrices.

2001 - Present — Clinical Assistant Professor, College of Pharmacy, University of New Mexico, Albuquerque, NM
This position held concurrent to Lovelace positions. The adjunct appointment facilitates collaboration between the Lovelace and University campuses.

10/00 - 2/06 — Associate Scientist, Lovelace Respiratory Research Institute, Albuquerque, NM
Dr. McDonald conducts research that bridges his education and experience in analytical chemistry, aerosol science, and toxicology. He has experience in the aerosolization/vaporization of gases/ and particles for a wide range of applications. He has an interest in developing laboratory exposures that represent "real-world" conditions, and conducting characterizations of these

exposures that allow toxicity results to be placed in context of human exposures to either environmental pollutants or drug products. In his environmental research, Dr. McDonald's work spans from the study of complex mixtures, respiratory drug delivery, and metabolism in mammals. He conducts work evaluating and developing new techniques for associating chemical components to biological response, including the design of laboratory experiments and the evaluation of multivariate and other statistical approaches to elucidate the harmful component of inhaled mixtures. He also develops methods and approaches to analyzing and determining chemical components in air and biological matrices. His biological analyses include structural determinations of unknown metabolites by a wide range of spectroscopic and chromatographic techniques.

Dr. McDonald serves as Principal Investigator or Study Director on several studies, including studies that involve human or animal test subjects. Recent studies include investigations of inflammatory response to engine emissions, acute lethality of diisopropylethylmercaptan, inhalation and metabolite identification/quantification in humans and rodents exposed to butadiene, chemical disposition and enzyme toxicity in rodents after exposure to sodium tungstate, disposition and toxicity of C_{60} fullerene nanoparticles, and aerosol development/characterization of many pharmaceutical compounds.

2/00 - 9/00 Research Scientist, Lovelace Respiratory Research Institute, Albuquerque, NM
See description for Associate Scientist.

3/99 - 1/00 Environmental Chemist, Organic Analytical Lab, Desert Research Institute, Reno, NV
Responsible for trace level analysis (part per trillion) of volatile, semi-volatile, and particle bound organic compounds. Position required analytical separation skills for analysis of various media (air, soil, water, other) using microwave, soxhlet, and solid phase extraction techniques. Experience included work with GC/MS (IonTrap (EI,CI), Quadrupole (EI)), GC-FTIR, GC/FID/ECD, and HPLC (UV+Fluorescence) instrumentation. Data analysis involved work with multiple data acquisition (Chem Station, Chrom Perfect, Saturn, etc.) and data handling systems (Excel, Foxpro). Involved with field project organization, undertaking, and at times oversight. Project experience included source sampling of point and local emission sources, ambient monitoring, and personal exposure sampling. Examples of work include refinery stack emission sampling, high alpine (extreme conditions) sampling and meteorology work, tunnel sampling, and exposure assessment for miners working in underground gold mines.

9/96 - 2/99 Graduate Research Assistant, Organic Analytical Lab, Desert Research Institute Reno, NV
Developed comprehensive chemical profiles for wood combustion and meat cooking emissions. Aided in the construction of stationary wood combustion facility for conducting emissions testing. Conducted source tests using dilution sampling system and EPA method 5. Emission rates were developed for over 350 organic compounds and trace elements, including oxygenated species. Much of the work entailed structural identification of organic compounds using GC/FTIR/MS. These profiles were used as input files for the Northern Front Range Air Quality Study source apportionment models.

6/95 - 8/95 Analytical Instrument Technician, Chemistry Department, University of La Verne, La Verne, CA
Responsible for the repair and maintenance of gas and liquid chromatography equipment.

2/95 - 5/95 Laboratory Instructor, Developmental Biology, University of La Verne, La Verne, CA
Lead instructor and lab coordinator.

9/93 - 12/94 Laboratory Instructor, General Biology, University of La Verne, La Verne, CA
Lead instructor and lab coordinator.

CONTINUING EDUCATION

Epidemiology for Aerosol Scientists. 2002 American Association for Aerosol Research Annual Meeting, Charlotte, NC
Basic Neurobiology. 2004 Society of Toxicology Annual Meeting
Bioanalytical Methods Validation. NIAID Specialty Course, May 2004

AWARDS

Western Chapter of Air and Waste Management Scholarship, 1998
First place (Sciences Category): 1998 University of Nevada Graduate Student Association Paper Contest
Sierra Pacific Power Company Graduate Fellowship, 1998

PROFESSIONAL AFFILIATIONS

American Association for Aerosol Research
Society of Toxicology
American Chemical Society
Air and Waste Management Association

AREAS OF RESEARCH

Dr. McDonald's main research emphasis is the implementation of analytical chemistry and aerosol science to address questions of environmental relevance. In particular, Dr. McDonald has interests in composition:response relationships related to lung toxicity of complex mixtures. He has experience in the generation of gases/vapors/aerosols for detailed emission characterizations and controlled laboratory studies, primarily to assess the toxicology of materials. He has an interest in developing laboratory exposures that represent "real-world" conditions, and conducting characterizations of these exposures that allow toxicity results to be placed in context of human exposures to either environmental pollutants or drug products. He has been involved in the evaluation of techniques for associating chemical components to biological effects, including the design of laboratory experiments and the evaluation of multivariate and other statistical approaches to elucidate the harmful component of inhaled mixtures.

Dr. McDonald has interests in exposure assessment. As Director of the NIEHS Environmental Assessment Facility Core, he is involved in several multi-disciplinary studies to assess/link environmental exposures to health effects, including both population studies and laboratory based inhalation exposure studies. Involvement on these studies ranges from indoor air assessments to analysis of biomarkers in environmental or occupationally exposed subjects. As Program Manager of the Analytical Chemistry Laboratory at LRRI, Dr. McDonald has been

involved in the development and validation (often validated to Regulatory Standards) of analytical methods for the collection and analysis of chemical species in both environmental and biological matrices.

Dr. McDonald is actively involved in several studies assessing the absorption, disposition, metabolism, and excretion of environmental or pharmaceutical agents exposed by several routes of administration. These studies require measurement of active compounds with and without radiolabels, and also involve identification of unknown metabolites by mass spectrometry and other tools.

Dr. McDonald has served as Principal Investigator or Study Director on several studies, including studies that involve human or animal test subjects. Recent studies include investigations of inflammatory response to engine emissions, acute lethality of diisopropylethylmercaptan, inhalation and metabolite identification/quantification in humans and rodents exposed to butadiene, chemical disposition and enzyme toxicity in rodents after exposure to sodium tungstate, and aerosol characterization of several pharmaceutical compounds.

PUBLICATIONS

1. Fujita, E. M., J. McDonald, T. Hayes, B. Zielinska, J. Sagebiel, J. Chow and J. G. Watson: Northern Front Range Air Quality Study: Apportionment of Carbonaceous Aerosols. In *1998 National Air and Waste Management Meeting Conference Proceedings*, San Diego, CA, 1998.
2. McDonald, J., B. Zielinska, E. Fujita, J. Chow, J. Watson and J. Sagebiel: The Development of Chemical Emission Profiles for Residential Wood Combustion and Meat Cooking for Use in the Apportionment of Atmospheric Carbonaceous Aerosol. In *1998 PM-2.5: A Fine Particle Standard Conference Proceedings*, Long Beach, CA, 1998.
3. McDonald, J., B. Zielinska, E. Fujita, J. Chow, J. Watson, J. Sagebiel, L. Sheetz and S. Batie: Chemical Speciation of $PM_{2.5}$ Emissions from Residential Wood Combustion and Meat Cooking, Paper 98-RP92B.02. In *1998 National Air and Waste Management Meeting Conference Proceedings*, San Diego, CA, 1998.
4. Zielinska, B., E. Uberna, E. M. Fujita, J. McDonald and T. Hayes: Northern Front Range Air Quality Study: The Analysis of Ambient Fine Particulate Organic Matter. In *1998 National Air and Waste Management Meeting Conference Proceedings*, San Diego, CA, 1998.
5. McDonald, J. D., B. Zielinska, E. M. Fujita, J. C. Sagebiel, J. C. Chow and J. G. Watson: Fine Particle and Gaseous Emission Rates from Residential Wood Combustion. *Environ. Sci. Technol. 34(11):* 2080-2091, 2000.
6. McDonald, J. D., J. Costanzo, E. B. Barr, J. L. Mauderly, J. J. Schauer, B. Zielinska, J. C. Sagebiel, J. C. Chow, E. Grosjean and D. Grosjean: Characterization of Laboratory Exposure Atmospheres for Health Effects Studies. In *Proceedings of Air and Waste Management Annual Conference*, Paper No. 281 on CD-ROM for the National Air and Waste Management Meeting, June 2001.
7. Seagrave, JC., J. D. McDonald and J. L. Mauderly: Alveolar Type II Cells Cultured at an Air-Liquid Interface: Responses to Diesel Exhaust. In *Proceedings of the 2001 Diesel Engine Emissions Reduction Workshop*, Office of Transportation Technologies, U.S. Department of Energy, DOE/EE-DEER2001-CD.
8. Mauderly, J., JC. Seagrave, J. McDonald, A. Gigliotti, K. Nikula, S. Seilkop and M. Gurevich: Comparative Toxicity of Combined Particle and Semi-Volatile Organic Fractions of Gasoline and Diesel Emissions. In *Proceedings of the 2002 Diesel Engine Emissions Reduction Workshop*, Office of Transportation Technologies, U.S. Department of Energy, DOE/EE-DEER2002-CD.

9. McDonald, J. D., B. Zielinska, J. C. Sagebiel and M. R. McDaniel: Characterization of Fine Particle Material in Ambient Air and Personal Samples from an Underground Mine. *Aerosol Sci. Technol. 36(11):* 1033-1044, 2002.
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11. Tesfaigzi, Y., S. P. Singh, J. E. Foster, J. Kubatko, E. B. Barr, P. M. Fine, J. D. McDonald, F. F. Hahn and J. L. Mauderly: Health Effects of Subchronic Exposure to Low Levels of Wood Smoke in Rats. *Toxicol. Sci. 65:* 115-125, 2002.
12. Arrieta, D. E., C. C. Ontiveros, W.-W. Li, J. H. Garcia, M. S. Denison, J. D. McDonald, S. W. Burchiel and B. S. Washburn: Aryl Hydrocarbon Receptor-Mediated Activity of Particulate Organic Matter from the Paso del Norte Airshed Along the U.S.-Mexico Border. *Environ. Health Perspect. 111:* 1299-1305, 2003.
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14. Harrod, K. S., R. J. Jaramillo, C. L. Rosenberger, S. Z. Wang, J. A. Berger, J. D. McDonald and M. D. Reed: Increased Susceptibility to RSV Infection by Exposure to Inhaled Diesel Engine Emissions. *Am. J. Respir. Cell Mol. Biol. 28:* 451-463, 2003.
15. Knapp, K. T., S. B. Tejada, S. H. Cadle, D. R. Lawson, R. Snow, B. Zielinska, J. C. Sagebiel and J. McDonald: Central Carolina Vehicle Particulate Emissions Study. In *Society of Automotive Engineers International Conference Proceedings*, SAE Paper No. 2003-01-0299, 2003.
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17. McDonald, J. D., K. S. Harrod, M. D. Reed, JC. Seagrave and J. L. Mauderly: The Effect of Changes in Diesel Exhaust Composition and After-treatment Technology on Lung Inflammation and Resistance to Viral Infection. In *Proceedings of the 2003 Diesel Engine Emissions Reduction Workshop*, FreedomCar and Vehicle Technologies Program, U.S. Department of Energy, DOE/EE-DEER/2003-CD.
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19. McDonald, J. D., B. Zielinska, J. C. Sagebiel, M. R. McDaniel and P. Mousset-Jones: Source Apportionment of Fine Particulate Material in an Underground Mine. *J. Air Waste Manag. Assoc. 53:* 386-395, 2003.
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22. Burchiel, S. W., F. T. Lauer, J. D. McDonald and M. D. Reed: Immunotoxicity in AJ Mice Following Six Month Whole Body Inhalation Exposure to Diesel Engine Exhaust. *Toxicol. Appl. Pharmacol. 196(3):* 337-345, 2004.
23. March, T. H., P. Y. Cossey, D. C. Esparza, K. J. Dix, J. D. McDonald and L. E. Bowen: Inhalation Administration of All-*trans*-Retinoic Acid for Treatment of Elastase-Induced Pulmonary Emphysema in Fischer 344 Rats. *Exp. Lung Res. 30*: 383-404, 2004.

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33. Seagrave, JC. and J. D. McDonald: Respiratory Toxicity Testing: Alternatives to Inhalation Exposure. In *Proceedings of the International Inhalation Symposium, Effects of Air Contaminants on the Respiratory Tract – Interpretations from Molecules to Meta-analysis*, pp. 205-217, Hannover, Germany, 2004.
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35. Benson, J. M., F. F. Hahn, T. H. March, J. D. McDonald, A. P. Gomez, M. J. Sopori, A. J. Bourdelais, J. Naar, J. Zaias, G. D. Bossart, and D. G. Baden: Inhalation Toxicity of Brevetoxin 3 in Rats Exposed for Twenty-two Days. *Environ. Health Perspect. 113*: 626-631, 2005.
36. Benson, J. M., B. B. Stagner, G. K. Martin, M. Friedman, S. E. Durr, A. Gomez, J. McDonald, L. E. Fleming, L. C. Backer, D. G. Baden, A. Bourdelais, J. Naar and B. L. Lonsbury-Martin: Cochlear Function in Mice Following Inhalation of Brevetoxin-3. *J. Comp. Physiol. A Neuroethol. Sens. Neural Behav. Physiol. 191(7)*: 619-626, 2005.
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ABSTRACTS/PRESENTATIONS

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BETWEEN:

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and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20160831
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: LOVELACE RESPIRATORY RESEARCH INST
   Received Date: 20070720
   Docket No: 3037312
   Control No.: 471444
   License No.: 30-29237-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: _____
   Check No.: _____

3. COMMENTS

Signed Coleen Murnahan
Date 7-20-07

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 _____