



**MIDWEST RESEARCH INSTITUTE**

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February 4, 2009

Materials Licensing Section  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Subject: LICENSE AMENDMENT APPLICATION**  
**License No: 24-02564-02**

Midwest Research Institute (MRI) requests an amendment to the U.S. Nuclear Regulatory Commission (NRC) Radioactive Materials License, as detailed below. The item numbers below correspond to those on the NRC Form 313, Application for Material License. Only those items that are pertinent to this amendment are listed.

**Item 1.** This application is for amendment of license no. 24-02564-02.

**Item 2.** The name and mailing address of the applicant are as follows:

Midwest Research Institute  
425 Volker Boulevard  
Kansas City, MO 64110-2299

**Item 3.** Same address as above.

**Item 4.** The person to be contacted about this application is Mr. James M. McHugh, Radiation Safety Officer, phone (816) 360-5338; fax (816) 360-2466; e-mail [jmchugh@mrresearch.org](mailto:jmchugh@mrresearch.org).

**Item 7. Authorized Users**

MRI requests the **addition** of the following person as an authorized person for the radioactive materials listed:

Name	Radioactive Material
Bruce N. Dief, Ph.D.	Carbon-14 and Hydrogen-3

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## **Bruce N. Diel, Ph.D.**

Manager, Pharmaceutical Sciences Section  
Midwest Research Institute

**Education:** B.S., Chemistry, San Diego State University, San Diego, California 1976;  
Ph.D., Inorganic Chemistry, University of Colorado – Boulder, Boulder, Colorado, 1980.

**Training:** Dr. Diel received his initial training in the handling of radioisotopes, primarily providing radioanalytical chemistry support to the Department of Energy, during previous employment (1993-1995) with Rust Federal Services (a Waste Management, Inc. company) at the Clemson Technical Center in Clemson, SC. This work involved environmental sample analysis and waste treatment technology development/demonstration directed towards remediation of DOE sites. This work focused on low-level radioactive waste containing a variety of fission products/radionuclides.

At MRI, Dr. Diel attended four training sessions on radiation safety since 2002, the last one occurred on February 21, 2008. The radiation safety training includes the following topics:

- Principals of radiation safety
- Routes of exposure (internal vs. external)
- Biological effects of radiation
- ALARA concept
- Method to minimize exposure (time, distance, and shielding)
- Functions, responsibilities, and authority of the RSO
- Material control and accountability, including transfer and disposal
- Personal dosimetry
- Radiation safety program audits
- Record keeping
- Contamination surveys
- Required postings and labeling of containers
- Handling and reporting of incidents or events
- Licensing and inspection by the NRC
- Applicable NRC regulations and license conditions
- Each individual's obligation to report unsafe conditions to the RSO
- Appropriate response to spills, emergencies, or other unsafe conditions
- Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
- Elements of the contamination survey, dosimetry, and bioassay programs
- Radioactive waste disposal
- Radiation detection equipment

- Procedures for receiving packages containing radioactive materials
- Procedures for opening and examining packages
- Safe handling of research animals use in radiolabeled studies
- Use and testing of sealed sources

**Experience:** At MRI, Dr. Diel led the design/renovation of the current Radiosynthesis & Radioanalytical Laboratories, oversaw the development of all current operating procedures for radiosynthesis operations, including the evaluation, selection and implementation of the computerized Radioactive Materials Inventory System used for tracking all radioactive materials received, products shipped and waste disposal. As manager of the Pharmaceutical Sciences Section, Dr. Diel hired all personnel within the Radiosynthesis Group, has participated in all radiation safety training, and serves on MRI's Radiation Safety Committee. Dr. Diel provides technical oversight for all radiosynthesis and radioanalytical operations within the Pharmaceutical Sciences Section, and has collaborated in or directed the synthesis of all radiolabeled compounds produced within the Section over the last five years.

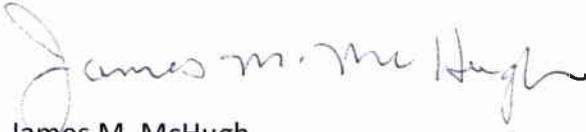
In support of metabolism studies of biologically active compounds and drug development projects, as well as other commercial custom synthesis projects for both government and industrial clients, Dr. Diel has synthesized under the direction of an authorized user and/or supervised the synthesis of numerous radioactive ( $^3\text{H}$ ,  $^{14}\text{C}$ ) small molecule building blocks and executed or managed synthesis projects incorporating those building blocks in the multi-step synthesis of many complex organic molecules, typically of pharmacological interest. For example, Dr. Diel has collaborated in the synthesis of a variety of  $^{14}\text{C}$ -labeled steroids including [4- $^{14}\text{C}$ ]fluasterone, [4- $^{14}\text{C}$ ]testosterone, [4- $^{14}\text{C}$ ]estrone, [4- $^{14}\text{C}$ ]estradiol, [4- $^{14}\text{C}$ ]ethynyl estradiol, [4- $^{14}\text{C}$ ]cortisone, as well as a number of proprietary steroid-based drugs. Most of these syntheses begin with the most basic building block,  $\text{Ba}^{14}\text{CO}_3$ , and build the complex final product via multi-step synthetic sequences.

Dr. Diel is also responsible for the design and execution of complex multi-step synthesis, characterization, and purification projects involving [ $^3\text{H}$ ]-labeled organic compounds, all thus far involving proprietary products for pharmaceutical clients. These syntheses routinely involve exchange reactions with  $>10$  Ci of [ $^3\text{H}$ ]-labeled water (THO), catalytic tritium exchange ( $\text{T}_2$ ) using the IN/US TriSorber Tritiation manifold, or any of a variety of tritide reducing agents ( $\text{NaBT}_4$ ,  $\text{LiAlT}_4$ , etc.) for the tritium incorporation reactions.

All of the synthetic work described requires routine use of radio-TLC, preparative-TLC, radio-HPLC (IN/US  $\beta$ -RAM radiodetectors) and flash column (normal or reverse phase) chromatography, scintillation counting, as well as IR, UV, and NMR as basic tools to detect, purify and characterize the target compounds.

If you have any questions or require additional information, please contact me at the number(s) listed in Item 4. Thank you in advance for your prompt action on our behalf.

**MIDWEST RESEARCH INSTITUTE**

A handwritten signature in cursive script that reads "James M. McHugh". The signature is written in dark ink and is positioned above the printed name.

James M. McHugh  
Radiation Safety Officer



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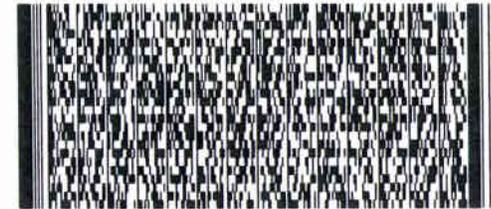
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