Essential Isotopes
1513 Research Park Dr
Columbia, MO 65211

Kevin Null
Nuclear Regulatory Commission
Region III Office
2443 Warrensville Rd, Suite 210
Lisle, IL 60532-4352

April 15, 2010

Kevin,

The enclosed documents are in response to the deficiencies and requests for clarification of Essential Isotopes application for NRC license control number 318475 and 318478. I hope that you find the responses satisfactory, if not please call me for further clarification

Sincerely,

Marc D. Weichelt RPh, BCNP
Essential Isotopes, LLC.
1513 Research Park Dr.
Columbia, MO 65211
573-882-0245

Essential Isotopes – Cyclotron Deficiencies Control # 318478

1. **Since you will be conducting licensed activities on the campus of the University of Missouri which involves utilizing University equipment and staff, please submit a letter signed by representatives of the University and Essential Isotopes (EI) which describes the relationship between both parties with regard to licensed operations conducted by Essential Isotopes. Please also delineate between the safety responsibilities of both parties with regard to activities that will be conducted under Essential Isotopes' license on the University campus.**

Response: See the attached letter.

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Columbia, MO 65211

Essential Isotopes, LLC Formation and Corporate Identity

Formation:

Essential Isotopes, LLC (EI) was formed in the State of Missouri in 2007. It is a partnership between Midamerica Cyclotron (MAC) and The Curators of the University of Missouri (MU). MAC is owned and operated by William McHugh and Scott Brower, who are both Nuclear Pharmacists and own Midamerica Isotopes in Ashland, MO. MU is represented by Ralph Butler who is the Director of the Missouri University Research Reactor (MURR).

Operating Agreement:

Mu provided the Facility, which amounted to 45% of the investment in EI and MAC provided the cyclotron and equipment which amounted to 55% of the investment in EI. EI has a Board of Directors to oversee the operation consisting of a representative of MU and the two owners of MAC. The Board meets regularly to review resource management and discuss items that pose significant risk or cost to the company. The structure of the Board is, President: Scott Brower, Treasurer: Ralph Butler, Secretary: Wm McHugh.

The Vice President and Director of Operations of EI is Marc Weichelt RpH, BCNP. As director he oversees the daily production of radioisotopes for human and research use. He also insures that the site is operated in manner that safe for employees of EI and MURR and maintains compliance with NRC regulations. The EI Radiation Safety Officer is Ron Dobey, a MURR employee, who has oversight of the EI Radiation Protection Program.

Essential Isotopes Signature: _____ Date: 4/8/10

MURR Representative: _____ Date: 4/6/10

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2. **With regard to the proposed Radiation Safety Officer, Ronald Dobey, describe the duties that he currently holds with the University and demonstrate how these duties will not impact his ability to perform the duties as RSO for EI's license. Describe the minimum amount of time that Mr. Dobey will dedicate to fulfilling the duties as RSO for EI.**

Response from applicant:

Mr. Dobey manages a staff of 4 Health Physics Technicians and 2 Health Physicists. This group monitors and provides support for activities at MURR. This support includes training for radiation workers, routine surveys and wipe tests, and support for projects and processes related to the production of radioactive isotopes. They also monitor personnel when performing new and dose intensive processes. The group also provides routine waste disposal services and effluent monitoring. Health Physics personnel are available on short notice in the event of an emergency.

As part of the contract between Research Reactor and Essential Isotopes both for physical space and services provided by the University, health physics coverage along with Mr. Dobey's expertise in radiological management was an agreed- to condition of the contract. As part of this agreement The Health Physics department provides all of the above mentioned services to Essential Isotopes. Mr. Dobey estimates he spends 10% of his time on issues related to Essential Isotopes.

The Director of Operations (Marc Weichelt) acts as Mr. Dobey's designee regarding pharmacy operations. Mr. Weichelt manages and monitors activities such as routine dose calibrator assays, daily production and shipment of radiopharmaceuticals and routine surveys and wipe tests of the production area. Mr. Weichelt also ensures that these activities are carried using the principles of ALARA.

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3. **Please note that the NRC cannot issue your new licenses until it has received and approved EI's financial assurance. We are currently reviewing EI's decommissioning funding plan (DFP) and Cost Estimate (CE); however, we are waiting for EI's submittal of its financial assurance instrument (FAI). Please advise us as to the status of your FAI.**

   Response from applicant:

   NRC has asked that the decommissioning funding plan be resubmitted pending comments from reviewer.

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4. **In your application you listed 4 Authorized Nuclear Pharmacists (ANP's) and 2 additional EI Staff members. Please identify which individuals you are requesting to be named as authorized users on the license. For each individual that you wish to be named on the license as an AU, please submit a description of their training and experience as requested in NUREG-1556, volume 21 pages 8-16 through 8-18. The resumes that you submitted in Item 7 of your application do not fully address the training and experience requirements of volume 21.**

Response from applicant:

In accordance with 10 CFR 35 and 10 CFR 32.72 the following individuals are authorized nuclear pharmacists working at Mid-America Isotopes, Inc. (MAI).

OK Scott C. Brower is a Board Certified Nuclear Pharmacist since 1989 and has worked at MAI as an authorized nuclear pharmacist and the Radiation Safety Officer since 1991.

OK William Brent McHugh has worked at MAI since 2000 as an authorized nuclear pharmacist.

OK Jon Woodward has worked at MAI since 2007 as an authorized nuclear pharmacist.

OK Marc D. Weichelt is a Board Certified Nuclear Pharmacist since 1992. His ANP status was added to the MAI Missouri license in 2007.

All of the above authorized nuclear pharmacists are listed in item11B on Materials License # 24-26241-01MD Amendment No. 10. A copy is attached.

Affidavits of training and experience are attached for Lawrence (Alex) Saale the cyclotron engineer and Joseph Gillispie the radiopharmaceutical production specialist (RPS).

The request is to add L. Saale as an authorized user as he will be performing routine maintenance on the cyclotron unsupervised. He will be handling activated materials from targets, valves and delivery lines.

J. Gillispie replaces J. Hoyt in the position of RPS. Mr. Gillispie will always work under the supervision of an ANP.

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5. **The training program describe in Item 8 of your application will need some clarification and revisions. For example, the program includes references to a Corporate RSO; Regional Health Physicists; Human Resources; Students/Temp workers; references to "PETNET SOP's, etc. Please describe the relationship of these references to EI. For example, your application did not identify a Corporate RSO. Reference is also made in Item 8 to an "Attachment 2" that contains training topics. However, the application that we received did not include Attachment 2. Please also explain the relevance of submitting the training booklet for the University Research Reactor. Although the University may require EI staff to be trained in accordance with this document due to the location of EI in the MURR facility, EI needs to develop a stand alone training program. Please clarify Item 8 and resubmit your Training Program in accordance with NUREG-1556, Volume 21, page 8-18.**

   Response from applicant: The corrected document with attachment-2 describing EI's Radiation Safety Training is attached. The MURR training booklet included with the Essential Isotopes application covers all the basic requirements for radiation workers as required in Part 19. Items covered include basic radiation protection, emergency response and security issues that are common to both Essential Isotopes and the research reactor facility. This booklet is used as an adjunct to a Power Point presentation that all new employees view when they gain access to both EI and MURR. The training booklet is also given to them to use as reference material. Essential Isotopes is in the process of developing a stand-alone Power Point based training system based on NUREG-1556, Appendix F. This presentation will cover the topics listed in Appendix F and be tailored to the specifics of Essential Isotopes. This Power Point presentation will be self directed for annual retraining and taught by the RSO or his designee upon the arrival of a new employee at EI. It will be revised at least annually to incorporate any changes in the Radiation Protection Program that may have occurred since the past training session.

STANDARD OPERATING PROCEDURE	
Radiation Protection Training	**RC-3**
Originator: Marc Weichelt	**Revision: A**
Management Approval: Radiation Safety Officer	
[redacted]	

I. PURPOSE

To provide the procedure for radiation protection training for employees, ancillary staff, and students/temporary workers

II. RESPONSIBLE

Radiation Safety Officer (RSO)
EI Management

III. SCHEDULE

Orientation: Prior to assuming duties involved with handling radioactive materials and/or cyclotron work.
Formal Training: Employees without prior experience in radiological activities prior to handling radioactive materials/cyclotrons
Re-training: Annually
Ancillary staff: Prior to performing duties in restricted area
Students/Temp workers: Prior to performing duties in restricted area

IV. EQUIPMENT AND MATERIALS

a. Applicable state or NRC regulations
b. Radioactive material license, cyclotron registration: applications, and relevant correspondence
c. RPP/Policies Manual
d. Radiation survey and measurement equipment
e. Laboratory safety equipment- as applicable
f. Manufacturing and testing equipment- as applicable

V. PROCEDURE

a. Orientation

i. The RSO or his designees must provide an orientation to the new employee before assuming duties involving handling of radioactive material (RAMs) and/or cyclotron work).
ii. Orientation must address the radiation protection considerations related to the new employee's work activities.

b. **Formal Training:**

i. The RSO or his designee must provide a formal training program to the new employees within 4 to 6 weeks of employment for individuals with prior radiological work experience or prior to allowing work with RAM/cyclotrons for individuals without any previous radiological work experience.
ii. Alll new employees shall be encouraged to "observe" the work activities in the pharmacy for a few days prior to attending the formal training program. No radiological work shall be performed by the new employee while observing the work activities.

c. **Re-training and Schedules:**

i. Re-training (refresher training) shall be provided for each staff member on an annual basis.
ii. Re-training shall be provided whenever there is a significant change in duties, regulations, terms of license, or Policies and Procedures.
iii. Re-training may be provided by RSO or designee.

d. **Training Scope- New Employees and Re-training:**

i. New Employees

1. Formal training shall be comprehensive with respect to the job responsibilities of the new employees;
2. Training shall include both the Radiation Protection (RP) and Transportation (DOT) programs;
3. RP training shall be based on the regulatory requirements, operational needs, and the individual's job responsibilities;
4. The RP training contents shall include information related to the radiological characteristics, dosimetry and ALARA requirements, instrumentation, safe use and storage of RAMs, incidents and emergency response, biological effects of radiation, applicable nuclear regulations, identification and reporting of radiological concerns, cyclotron related radiation protection, and applicable SOPs;
5. Training may be presented in a modular format; and
6. Training topics are provided in Attachment 2.

ii. Re-training (Refresher training)

1. Re-training shall be oriented towards review of essential RP and DOT requirements and practices;
2. Re-training shall also be provided whenever there is a significant change in duties, equipment or processes, regulations, the terms of the license, or policies and procedures;
3. Re-training shall be used to evaluate the effectiveness of the training programs, and to make appropriate modifications in controls/practices, as needed;
4. Re-training may be provided in multiple sessions.

e. Ancillary Staff Instructions

i. Ancillary staff is defined as housekeeping personnel and temporary maintenance workers who are not authorized to directly handle RAM/cyclotron work, but may require access to restricted areas.
ii. The RSO or his designee shall provide instructions to the ancillary staff prior to their access to the restricted area.

f. Students and Temporary Workers Training

i. The pharmacy interns and students (> 18 years of age) and temporary workers who may handle RAMs/cyclotrons shall be instructed in the radiation protection features applicable to their assignments- prior to assuming duties related to handling of RAM.
ii. The RSO or his designees shall provide training to the students/temp workers prior to their assuming duties with RAM/cyclotrons.

STANDARD OPERATING PROCEDURE	
Radiation Protection Training	**RC-3 Attachment 2**
Originator: Marc Weichelt	**Revision: A**
Management Approval: Radiation Safety Officer	
[redacted]	

New Employee: Formal Training

Employee Name (Print): _____

Employment Start Date: _____

Training Dates: _____

Required Training Topics	Trained (√)
1. Radiological Compliance Program	_____
2. RPP/Policies Manual	_____
3. RPP/SOPs Manual	_____
4. Radiation Protection Principles & Controls	_____
- Radiological Characteristics & Units	_____
- Exposure Controls	_____
- Contamination Controls	_____
5. Dosimetry Program	_____
6. ALARA Program	_____
7. Biological Effects of Radiation and Radiation Risks	_____
8. Radiological Instrumentation	_____
9. Radiological Emergencies & Incident Response	_____
10. Cyclotron Radiation Protection	_____
11. Nuclear Regulations & Licensing	_____
12. Radiation Protection: Practices & Precautions	_____

Employee's Signature_____ Date_____

Instructor's Signature_____ Date_____

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6. **Describe the use of alarming system that is employed in the cyclotron room that would be activated in the event of entry into the cyclotron room while the unit is in operation. Describe the interlock system and how with works.**

   Response from applicant:

   A description of the cyclotron vault alarm and interlock system is attached.

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Description of Cyclotron Vault Door and Interlock System

The door to the cyclotron vault has several systems in place to prevent entrance to the vault while the cyclotron is producing protons for target irradiation.

1. The vault door is only accessible from the cyclotron electronics room. The electronics room door is accessible by electronic proxy card. Only EI personnel have access to this door.

2. The vault door is magnetically locked. (figure 1) This lock can only be disengaged when the systems powering the cyclotron are turned off. There is an indicator light in the electronics room that indicates the cyclotron status. (figure 1) The light designations are as follows:

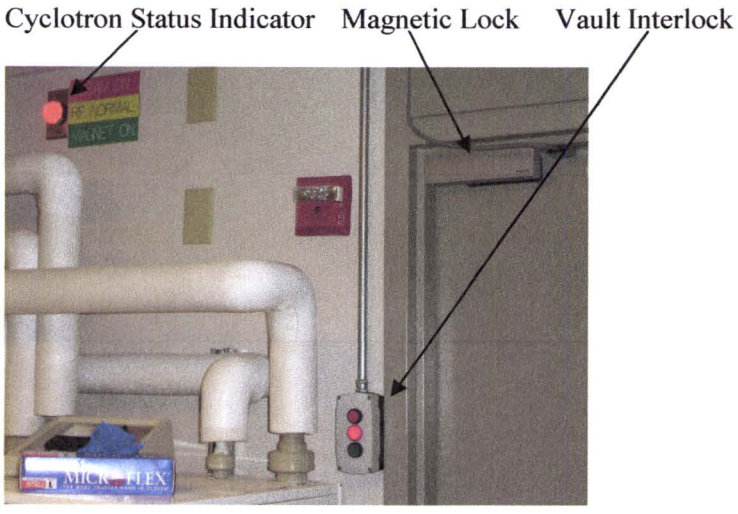
    a. No light – cyclotron power is off
    b. Green – systems are at standby
    c. Yellow – magnet and Rf systems are ready to produce beam
    d. Red – cyclotron is producing beam

3. The vault door is interlocked with the cyclotron power systems. If the interlock is not properly set the cyclotron will not power up. If the interlock is broken during irradiation power is immediately cut to all systems resulting in complete cyclotron shut-down.

4. There are two interlocks in the vault itself. These must be manually armed before leaving the vault before the final interlock can be engaged. The final interlock is outside the vault door (figure 1.) and must be engaged before the cyclotron can be powered up.

5. The Master Control System (MCS) monitors the vault door at all times. If the vault door is not secured an alarm will sound and a message will appear that identifies the interlock failure. There is no override from the MCS making it necessary for personnel to leave the production area to investigate and resolve the interlock failure.

6. Figure 1.



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7. **Describe the use of personnel dosimetry of staff that will be responsible for maintenance of the cyclotron and handling and removal of targets from the cyclotron. The use of alarming ratemeters with established set points should be considered for use, or provide justification why they are not used.**

   Response from applicant:

   Personnel involved with cyclotron maintenance will use an alarming rate meter system in addition to normal whole body and TLD extremity badges. This system uses a Siemens Electronic Pocket Dosimeter, Model Mk. 2. It is controlled via a Siemens DMS-2 data management system that allows users to pick pre-selected or special protocols from a selection menu. This system is set up such that the user can have an alarm go off if the worker exceeds either a set total dose limit or exceeds a specific dose rate.

11. **Describe your procedure for calibrating alarming ratemeters worn by staff who conduct maintenance on the cyclotron.**

    Response from applicant:

    The Siemens Electronic Personnel Dosimeters are calibrated on an annual basis by Siemens. They are sent to the manufacturer in staggered groups to ensure an ample supply remains available to MURR and EI staff.

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8. **Describe procedures that will be implemented to evaluate skin dose should an individual receive a skin dose due to exposure to any of the cyclotron products, e.g., F-18. Also, submit a bioassay program to evaluate staff for intake of cyclotron-produced material in the event of an airborne release in worker breathing zones.**

   Response from applicant:

   Essential Isotopes will utilize the VARSKIN code to assess skin contamination and any corresponding doses associated with such skin contamination. This program is used widely by the HP staff at the Research Reactor for the assessment of skin contamination and doses as the results of these contaminations. Mr. Dobey is quite conversant with its use at MURR, as are health physics staff members.

   A bioassay program is not required based on the expected potential internal doses for individuals employed at Essential Isotopes and a comparison of these expected doses to organ dose limits as explained in Part 20. Essential Isotopes produces F-18 in the form of water. After production in the cyclotron it is the F-18 is sent to the processing unit located inside a hot cell designed specifically to shield PET radioisotopes. Each hot cell is attached to the facility ventilation system. The production of F-18 as an aerosol is unlikely due to fact that it is produced in this form, i.e. water. In speaking with other health physicists who produce and use F-18 containing products and especially FDG, they know of no bioassay requirements or routine protocols for bioassay for the production and use of this isotope due to the extremely short half-life of the material. As an example of a routine dose to a *patient* injected with F-18 FDG, a typical patient dose is approximately 10 mCi. Using the value of 10 mCi and assuming that this is the amount ingested by a radiation worker, the dose to the lungs would be 0.64 Rem (ICRP 53, Volume 18, No. 1, 1987, page 76). Using the 10 CFR 20 weighting factor of 0.12 for the lungs, this would equate to a whole body exposure of 0.077 Rem or 77 mrem. (The lungs were chosen in this example as this organ has a published weighting factor according to ICRP.) Additionally, the dose to the bladder wall from a 10 mCi injection is 3.2 Rem. This is the highest exposed organ from an *injected* dose of F-18 FDG. This organ dose is less than 10% of the limit of 50 Rem for a dose to an organ, thus, monitoring would not be required if this person were a radiation worker. This example involved injected doses of F-18 FDG. It is hard to postulate an accident scenario that would exceed these amounts of inhalation or ingestion of F-18 or other isotopes.

As illustrated above, it is highly unlikely that an Essential Isotope employee could receive a dose in excess of 10% of the limits of 20.1201(a), especially considering the case above involves purposeful injection of the isotope into the individual; thus bioassay would not be required.
In the event Essential Isotopes would produce radioisotopes that require bioassays such as I-124, a suitable bioassay program will be developed and submitted along with the amendment for proposed use.

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9. **Describe how you will detect an accidental airborne release resulting from, for example, a defective valve in the transfer tubing between the cyclotron and hot and mini cells, or a release due to manual intervention in a normally automated synthesis procedure.**

   Response from applicant:

   Airborne releases can be detected in two ways within the production ventilation system. Small releases are normally indicated when the F-18 water is pushed between the cyclotron target area and the dose calibrator located in the FDG production area. It should be noted that during normal operations an airborne release would emanate from the target production area and any exposed surface area of the F-18 water or FDG compound in the processing equipment or dosing syringe. This would be occur due to any evaporative process that occurs with the material, thus it would be a small fraction of the initial activity.

   The first method of detection would be from the MediSmarts system. There is a detector in the stack that monitors emissions pre-filter. The level of emissions can be monitored from the computer display in the pharmacy. The real time data can be compared to historical data and used to determine if there has been an airborne release in the vault or production area.

   The second method used to detect airborne radioactive materials would be via the building stack monitoring system. This system has real time feedback to the facility Health Physics office which could alert an individual in the office of any unusual releases. It also has data logging capability so that a reconstruction could occur in order to quantify any releases should they occur. Any of these releases would be contained within the cyclotron or production area as they have airflow negative to the surrounding facility and would not enter the general laboratory space.

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10. **Submit calibration procedures for your Medi-Smart cyclotron room area monitor and effluent monitoring systems. Verify that the monitors will be calibrated on an annual basis, and after repair.**

    Response from applicant: Annual calibration of the MediSmarts system will be performed by Radiation Safety Controls Systems. In each instance calibrated detectors will be loaned to Essential Isotopes while the EI detectors are being calibrated. The procedure has been added to RC-13 Survey Meter calibration, which is attached.

STANDARD OPERATING PROCEDURE	
Survey Meter Calibration	**RC-13**
Originator: Marc Weichelt	**Revision: A**
Management Approval: Radiation Safety Officer	
[redacted]	

I. PURPOSE
   a. To establish a procedure to verify proper calibration of survey instruments

II. RESPONSIBLE
   a. Facility Radiation Safety Officer (RSO)

III. SCHEDULE
   a. Annually and after repair of the instrument

IV. PROCEDURE
   a. Instruments to be Calibrated
      i. Survey and count rate meters
      ii. Hand and foot monitors
      iii. Area monitors
   b. Instrument Calibration for survey meters and hand and foot monitors
      i. Instruments will be sent to the manufacturer (Ludlum) for calibration.
      ii. For instruments of the same type, do not send all instruments out for calibration at the same time.
   c. Instrument calibration of the MediSmarts area and stack monitors.
      i. Radiation Safety and Control systems will send calibrated loaner detectors.
      ii. The loaners will be installed and the EI detectors will be packed in the packaging provided and returned to RSCS.
      iii. Once the detectors are calibrated they will be reinstalled and the loaner detectors will be returned to RSCS.
   iv. The RSO must check the calibration record for the date of calibration, results, the name of the organization that provided the service, and accuracy of the record.
   v. When an instrument is returned from calibration perform a check with the dedicated check source. Information to be used for determining ranges are found in SOP RC-11.
   vi. Keep a file of the calibration records.

ACCEPTANCE CRITERIA

Instruments must be calibrated at intervals not to exceed one year and after repair.

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12. **Identify, by name, the cyclotron engineer(s) who will be responsible for target installation, target change-out, and performing maintenance on the cyclotron. Describe in detail the training and experience in performing these duties in accordance with NUREG-1556, Volume 21, pages 8-16 through 8-18.**

    Response from applicant.

    Alex Saale is the cyclotron engineer, an affidavit of experience and training is attached. In addition to the Navy and MURR training, Alex attended formal cyclotron service training in 2007 provided by General Electric. He has also had refresher training in 2008 provided by GE and EI and 2009 by David Smith of United Pharmacy Partners, Inc.

STANDARD OPERATING PROCEDURE	
Authorized User Training	**RC-10**
Originator: Marc Weichelt	**Revision: A**
Management Approval: Radiation Safety Officer [redacted]	

I. PURPOSE

To validate the training and experience for authorized users of RAM.

II. RESPONSIBLE

Radiation Safety Officer (RSO) or designee
Qualified staff

III. SCHEDULE

As Needed

IV. Procedure

Training Description:

Type	Where Trained	Duration of Training	Formal	On-the-Job
a) Principles and Practices of Radiation Protection	U.S. NAVY	AUG 1992 - AUG 1998	2 years	4 years
b) Radioactivity measurement, monitoring techniques, and instruments	U.S. NAVY	AUG 1992 - AUG 1998	2 years	4 years
c) Mathematics and calculations basic to the use and measurement of radioactivity	US NAVY	AUG 1992 - AUG 1998	2 years	4 years
d) Biological effects of radiation	US NAVY	AUG 1992 - AUG 1998	2 years	4 years

Experience:

Isotope of Use	*Maximum Amount (mCi)*	*Where Experience Gained*	*Duration*	*Type*
F-18	1 Ci	Essential Isotopes	August 2007 – PRESENT	On the job
Cu-64	500 mCi	Essential Isotopes ~~On the job training~~	May 2009 - present ~~1 year~~	On the job

Individual: _____ **Date:** 4/2/10

4. Statement of experience handling radioactive materials.

☑ I have a college degree or equivalent experience.

☑ I have completed a minimum of 40 hours of combined formal and on-the-job experience appropriate for handling radioactive materials in excess of exempt quantities

☑ I have a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material.

5. Signatures:

Individual: _____

Date: 4/2/10

RSO: Ron Dabey, CHP
(Print Name)

RSO Signature: _____

Date: 4/15/10

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