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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

TELEFAX TRANSMITTAL

DATE: 12/02/2009 NUMBER OF PAGES: 6
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SEND TO: Robert Bruce Loesch, QC Manager

LOCATION: APAC - Missouri, Inc.

FAX NUMBER: 573 - 449 - 5159 **VERIFY BY CALLING SENDER**

FROM: Jose Macatangay
(SENDER)

TELEPHONE NUMBER: 630 - 829 - 9892 FAX NUMBER: 630 - 515 - 1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE



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MESSAGE

NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone and return the original to the above address, by U.S. Mail. Thank you.

JOSE D. MACATANGAY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9892 FAX: (630) 515-1078

CONVERSATION RECORD

|TIME on |DATE

ACTUALLY FAXED? Yes.

12/02/2009

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Robert Bruce Loesch, QC Mgr.	APAC-Missouri, Inc	O: 573-449-0886 F: 573-449-5159

SUBJECT
License No.: Pending Control No.: 318549

SUMMARY

During our review of your application dated September 21, 2009, we find that we need additional information as follows:

Please note that certain sections of this NUREG have been modified since its last revision, as noted below:

1. For Item 5, we now require a **total possession limit** for each radionuclide requested, as well as **providing the "per source" activity** you need, which should match the Sealed Source and Device Registry (SSDR) certificate procured by the vendor. Please provide this information with the corresponding SSDR number. It is acceptable to request more sealed sources than you may actually need immediately, to allow for some growth, so long as the request is reasonable and realistic.
2. For Item 7, you will not be able to change and name your RSO internally; NRC must do that for you via the amendment process. Each proposed RSO must be qualified in accordance with the guidance in NUREG 1556, Vol 1, Rev. 1, Section 8.7, Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience. Please provide the training certificate of your proposed RSO and a written, signed and dated statement that stipulates your proposed RSO accepts the RSO position and understands the duties and responsibilities associated with the position. See enclosed Appendix I from NUREG 1556, Vol. 9, Rev. 2 for a sample document.

We will be unable to continue processing your request until we receive this information. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Record (PARS) component of NRC's document system (ADAMS) accessible from the NRC Website at <http://www.nrc.gov/reading-rem/adams.html>.

ACTION REQUIRED

Please submit a **signed written response** within 7-days or contact me to arrange an alternate response date. Be sure to reference control number 318549 to facilitate correct processing of your response.

If we do not receive a written response within 7-days, please note that we may void this request in order to enable you to prepare a quality application without time constraints. This would be done without prejudice to the resubmission of your request at a later date. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

Please note that a "Void" is an administrative procedure that puts your new license application "On Hold" (takes it out of our active casework database) until you reactivate it via submission of a written response.

Upon receipt of your response we will resume our review.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT (630) 829-9892.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Jose Macatangay		December 02, 2009

APPENDIX I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

APPENDIX I

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads