SARA A.B. FORSTER
MATERIALS LICENSING BRANCH

TELECON & FAX TRANSMITTAL

TO: Jackie, Nuclear Medicine

COMPANY: Cardiovascular Associates of Southern Indiana, PSC

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
(630) 829-9892 FAX: (630) 515-1259

PAGES: 13 TEL.: (812) 948-2232

FAX : (812) 945-0869

CONVERSATION RECORD		TIME	DATE
		8:30 am	February 13, 2012
NAME OF PERSON(S) CONTACTED	TELEPHONE NO.	ORGANIZATION	
Jackie, Nuclear Medicine	(812) 948-2232	Cardiovascular Associates of Southern Indiana, PSC	
REPRESENTED PERSON or PERSONS		ORGANIZATION	
Srinvasaro Manchikala, M.D., RSO		Cardiovascular Associates of Southern Indiana, PSC	
SUBJECT			
License No.: 13-32350-01		Control No.: 576071	

SUMMARY

We have reviewed your requesting license renewal application and find that we are unable to continue this action until we have received information regarding the following:

(1) The renewal application responds to Items 9, 10, and 11, as listed on NRC Form 313, with multiple references to NRC Regulatory Guide 10.8, Revision 2. However, RG 10.8 is now in its third revision. Revision 3 refers to procedures found in NUREG 1556, Volume 9, Revision 2, which includes Table C.3, a checklist for information required to respond to Items 9, 10, and 11, as listed on the NRC Form 313. A copy of the referenced Appendix C checklist is attached to this correspondence.
Please resubmit responses to Items 9, 10, and 11, according to the guidance in NUREG 1556, Volume 9, Revision 2. If the referenced checklists are used, relevant items should be indicated with a checkmark, as indicated on the attached documents.

(2) Under 10 CFR 35.24, a proposed licensee's management shall appoint a Radiation Safety Officer in writing.
Per our discussion, please provide a current, signed RSO Memorandum of Understanding/Delegation of Authority, which conforms to the requirements as specified in 10 CFR 35.24(b) and 10 CFR 35.24(e). A sample is attached to this record.

(3) Under 10 CFR 35.12(b)(1), a license renewal application must include a facility diagram. The diagram should follow the guidelines found in NUREG 1556, Vol. 9, Rev. 2.
Please resubmit your facility diagram. The facility diagram should be drawn to scale, indicate what that scale is, show use areas and any room numbers, and describe what is adjacent to the radioactive materials use areas.

(4) From the application, it is unclear whether PET will be used under this license. If PET is being used, additional shielding calculations would be required to demonstrate that shielding is adequate. Based on our conversation, PET isotopes are not being used at your facility.
No additional information regarding the use of PET isotopes is required.

We have requested that you submit the referenced items–

(1) Responses to Form 313 Items 9, 10 & 11, according to NUREG 1556 Vol. 9, Rev. 2;
(2) RSO/management Memorandum of Understanding & Delegation of Authority;
(3) Facility diagram and personnel qualifications;

– via facsimile, to (630) 515-1078. Please reference the Control No. 576071, as listed at the top of this memo.

For future reference, please always include the name, phone number and fax number of at least one person whom we may contact for additional information when reviewing your licensing correspondence and requests.

Please submit the requested information within **10** days of our phone conversation. **Include reference control number 576071, with your response. Please FAX your response to my attention at (630) 515-1078.** You may also scan your response and send to me via email, as a pdf file. The additional information should be submitted within, or as an attachment to, a letter signed by management.

Please direct any questions you have to me at **(630) 829-9892** or **sara.forster@nrc.gov.**

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Sara A.B. Forster	Sara A.B. Forster	02/13/2012

U.S. NUCLEAR REGULATORY COMMISSION

September 2008
Revision 3

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.8

(Draft was issued as DG-0018, dated April 2008)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL USE PROGRAMS

A. INTRODUCTION

This regulatory guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for preparing and reviewing an application for a medical use license. Title 10, Part 35, "Medical Use of Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 35) (Ref. 1) regulates the medical use of byproduct material. In addition to the requirements of 10 CFR Part 35, medical use licensees may be subject to those portions of 10 CFR Part 20, "Standards for Protection Against Radiation" (Ref. 2), that relate to radiation safety and the sections of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material" (Ref. 3), that relate to licensing and the noncommercial transfer of specific radioactive drugs to medical use licensees within a consortium.

This regulatory guide endorses the methods and procedures for medical licensing applications contained in the current revision of NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses" (Ref. 4), as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

* See attached checklist for required information, under NUREG 1556, Vol. 9, Rev. 2

Volume 9 of NUREG-1556 addresses the issues that an applicant must respond to when preparing a license application on NRC Form 313, "Application for Materials License," and the NRC Form 313A series of forms. The NUREG also includes (for clarification purposes) descriptions of certain key elements of a medical use program that do not require a response on NRC Form 313.

This regulatory guide contains information collection requirements covered by 10 CFR Parts 20, 30, and 35 and NRC Form 313 that the Office of Management and Budget (OMB) approved under OMB

The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions—1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies of this guide and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML081960579.

control numbers 3150-0014, 3150-0017, 3150-0010, and 3150-0120, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

As part of its redesign of the materials licensing program, the NRC consolidated and updated numerous guidance documents for materials licenses into the multivolume NUREG-1556. Various volumes in the NUREG-1556 series provide current, program-specific guidance on testing, licensing, decommissioning, and terminating materials licenses.

Volume 9 of NUREG-1556 provides program-specific guidance about medical use licenses. It identifies the information needed to complete NRC Form 313 and the NRC Form 313A series of forms. NUREG-1556 provides an overview of the types of licenses issued by the NRC, the commitments and responsibilities that a licensee must undertake, applicable regulations, the process for filing a license application, and the contents of applications for different medical uses of byproduct material. In particular, Volume 9 of NUREG-1556 gives an item-by-item description of the information the applicant should provide. Because of the wide variety in the types of medical use programs, NUREG-1556 contains indicators to alert applicants for particular types of medical use licenses to information that pertains to those types of uses. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. The agency intends for this approach to be less prescriptive and to allow licensees the flexibility to implement the agency's regulations in a manner that is more specific to their needs yet still meets the regulatory requirements. By supplying examples, the NRC seeks to provide information to meet the needs of applicants for licensure without being prescriptive. Guidance in NUREG-1556 represents one means of complying with NRC regulations. It is not the only means of satisfying the regulatory requirements.

C. REGULATORY POSITION

This regulatory guide endorses the method(s) of preparing a medical use program license application or revision request described in the current revision of NUREG-1556, Volume 9, as a process that the NRC has found to be acceptable for meeting the regulatory requirements.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

In some cases, applicants or licensees may propose or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REFERENCES

1. 10 CFR Part 35, "Medical Use of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[1]

2. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.

3. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.

4. NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," U.S. Nuclear Regulatory Commission, Washington, DC, most current date and revision.[2] (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)

---

[1] All NRC regulations listed herein are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and email PDR@nrc.gov.

[2] All NUREG-series reports listed herein are published by the U.S. Nuclear Regulatory Commission. These volumes are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/nuregs/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and email PDR@nrc.gov. In addition, copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328, telephone (202) 512-1800; or from the National Technical Information Service (NTIS), at 5285 Port Royal Road, Springfield, VA 22161, online at http://www.ntis.gov, by telephone at (800) 553-NTIS (6847) or (703) 605-6000, or by fax to (703) 605-6900.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	☐
	AND	
	Written attestation, signed by a preceptor AMP, that the required training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized User for nonmedical uses	*Note:* For purposes of this section of the table, the term "authorized user" is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.	
	For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:	
Name(s): Requested types, quantities, and nonmedical uses for each individual	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.	☐
	For individuals qualifying under 10 CFR 30.33(a)(3):	
	Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	☐
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	☐
	• Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
	• Drawings should be to scale, indicating the scale used.	☐

See pg. 8-38, NUREG 1556, Vol. 9, Rev. 2, for sample diagram.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	☐
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☐
	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). (IF PET isotopes are used)	☐
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."	☐
	AND/OR	
	A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."	☐
	AND	
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.	☐
	AND	
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☐
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☐

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j), • A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." **OR**	☐
	• We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.	☐
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	☐
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	☐
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	☐
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room; • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and • Emergency response equipment.	☐ ☐ ☐ ☐ ☐ ☐

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	☐
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " **OR**	☐
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	☐
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	☐
Item 10: Spill/Contamination Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	☐
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: **AND**	☐
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	☐
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	☐
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."	☐
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	☐
	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	☐

Sample delegation of authority document & info.

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;

- 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,

_____ _____

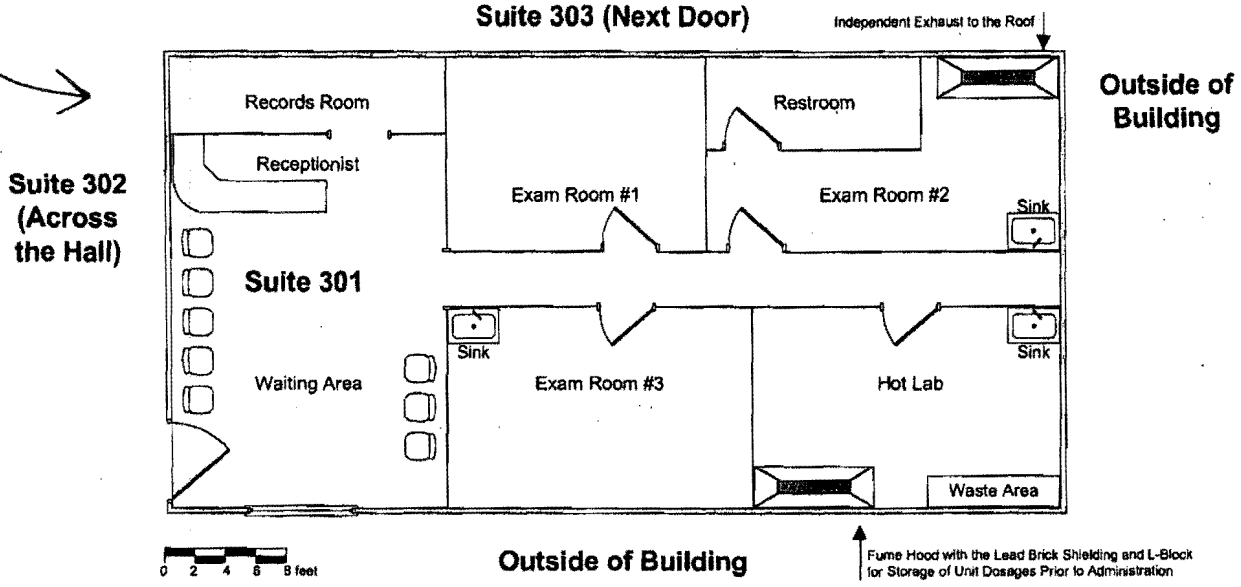
Signature of Radiation Safety Officer Date

cc: Affected department heads

Sample Facility Diagram

Attachment 9.1

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



- Suite 301 is on the top floor.
- Suite 301 is located at a corner of the building.
- Suite 302 is occupied by an accounting firm.
- Suite 303 is occupied by a law firm.
- Directly below Suite 301 is an insurance company.

1556-095.ppt
10142002

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, the facility diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8.1 Facility Diagram for Nuclear Medicine Suite

Most applicants requesting the use of PET radioactive drugs will designate an area or room as a "quiet room" where patients wait after the PET radioactive drug is administered. This room should be included in the facility diagram. The location and design of the "quiet room" should be considered when implementing the ALARA requirements in 10 CFR 20.1101. The applicable public dose limits are discussed in Section 8.33 of this document.

When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. For types of use permitted by 10 CFR 35.300 and 35.400, applicants should provide the above information and, in addition, they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75. The discussion should include a description of shielding, if applicable. For types of use permitted by 10 CFR 35.500, the applicant should provide the room numbers of use.

For types of use permitted by 10 CFR 35.600, and production of PET radioactive drugs, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. Applicants should also describe the equipment used in the PET radioactive drug production area (e.g., hot cells, remote manipulation devices in the hot

TRANSMISSION VERIFICATION REPORT

TIME : 02/13/2012 10:28
NAME : USNRC RIII
FAX : 6308299782
TEL :
SER.# : 000A7J925774

DATE,TIME	02/13 10:25
FAX NO./NAME	88129450869
DURATION	00:03:05
PAGE(S)	13
RESULT	OK
MODE	STANDARD ECM

SARA A.B. FORSTER
MATERIALS LICENSING BRANCH

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
(630) 829-9892 FAX: (630) 515-1259

TELECON & FAX TRANSMITTAL

TO: Jackie, Nuclear Medicine

COMPANY: Cardiovascular Associates of Southern Indiana, PSC

PAGES: 13 TEL.: (812) 948-2232

FAX : (812) 945-0869

CONVERSATION RECORD		TIME 8:30 am	DATE February 13, 2012
NAME OF PERSON(S) CONTACTED Jackie, Nuclear Medicine	TELEPHONE NO. (812) 948-2232	ORGANIZATION Cardiovascular Associates of Southern Indiana, PSC	
REPRESENTED PERSON or PERSONS Srinvasaro Manchikala, M.D., RSO		ORGANIZATION Cardiovascular Associates of Southern Indiana, PSC	
SUBJECT License No.: 13-32350-01		Control No.: 576071	

SUMMARY

We have reviewed your requesting license renewal application and find that we are unable to continue this action until we have received information regarding the following:

(1) The renewal application responds to Items 9, 10, and 11, as listed on NRC Form 313, with multiple references to NRC Regulatory Guide 10.8, Revision 2. However, RG 10.8 is now in its third revision. Revision 3 refers to procedures found in NUREG 1556, Volume 9, Revision 2, which includes Table C.3, a checklist for information required to respond to Items 9, 10, and 11, as listed on the NRC Form 313. A copy of the referenced Appendix C checklist is attached to this correspondence.

Please resubmit responses to Items 9, 10, and 11, according to the guidance in NUREG 1556, Volume 9, Revision 2. If the referenced checklists are used, relevant items should be indicated with a checkmark, as indicated on the attached documents.

(2) Under 10 CFR 35.24, a proposed licensee's management shall appoint a Radiation Safety