CARDIOVASCULAR CONSULTANTS

Gary A. Frick, D.O., M.S., F.A.C.C., F.A.C.O.I.

Board Certified in Cardiovascular Disease & Internal Medicine • Fellow of the American College of Cardiology Fellow American College of Osteopathic Internists • Diplomate National Board of Examiners for Osteopathic Physicians & Surgeons

May 10, 2011

Ms. Sarah Foster
U.S. Nuclear Regulatory Commission, Region I
2443 Warrenville Rd., Suite 210
Lisle, IL 60532-4352

Ph: 630.829.9892

Re: Control No. 574308

Dear Ms. Foster:

Attached please find the information needed to complete the request for renewal of License No. 13-32301-01 for the Cardiovascular Consultants of Marion, P.C.

Feel free to call me at 303.541.0044 if you have any questions or need additional information.

Sincerely,

Gary A. Frick, D.O., M.S., F.A.C.C., F.A.C.O.I.
Cardiovascular Consultants

Cc: file

Encs.

1123 North Western Avenue • Marion, Indiana 46952 • Ph: 765 651-9347 • Fax: 765 651-9346

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).	☐
	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.	☐

Response Attachment

Item 9. (p. C-18, NUREG-1556, Vol. 9, Rev 2) Radiation Monitoring Instruments

We state that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

and

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.

and --see attachment – Description of Instrumentation.

Item 9. Dose Calibrator and Other Dosage Measuring Equipment

We state that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

And

Dosages will be determined by relying on the provider's dose label for the measurement of radioactivity and a combination of volumetric measurement and mathematical calculations.

Gary A. Frick DO, FACC

Dr. Gary Frick, DO, FACC
Cardiovascular Consultants of
Marion, P.C.

5-10-11
Date

Radiation Detection Instrumentation

Instrument	Supplier/Model	Use
Gamma Camera System	SPECT System furnished by: **NC Systems, Inc.** **5660 Airport Blvd., Suite 101** **Boulder, Colorado 80301** or equivalent	Nuclear medical imaging.
Nuclear Medical Computer	Supplied by **NC Systems, Inc, or equivalent** listed above	Nuclear medical data presentation and analysis.
Dose Calibrator	or supplied by: **NC Systems, Inc.** **5660 Airport Blvd., Suite 101** **Boulder, Colorado 80301**	Assay of radiopharmaceutical doses.
Survey Meter Survey Meter	Ludlum Model 14c Portable supplied by **NC Systems, Inc.** **5660 Airport Blvd., Suite 101** **Boulder, Colorado 80301** External PGM(pancake) furnished by **NC Systems,** listed above	Daily ambient exposure surveys, package surveys, spill and contamination surveys
Sample Analysis	Cardio-Wipe II System, **NC Systems, Inc.**, listed above	Counting of wipes for surveys, spills, and other analysis. System capable of detecting <2000 dpm.
Personnel Dosimeters * TLD, FILM or OSL	Furnished by: **NC Systems, Inc.** Radiation Detection Company 8095 Camino Arroyo Gilroy, CA 95020	Whole body personnel monitoring of all individuals who frequent areas where radioactive materials are received, used, manipulated or stored.
Personnel Dosimeters * Extremity TLD	Furnished by: **NC Systems, Inc.** Radiation Detection Company 8095 Camino Arroyo Gilroy, CA 95020	Monitoring the extremities of all personnel who handle radioactive materials.

Calibration of the Survey Instrument

The applicant will not calibrate their survey instruments, but will have a contractor perform the calibration on an annual (NOT TO EXCEED12 months) basis, or after any repair other than the replacement of batteries. The applicant's procedure for obtaining meter calibration is outlined below:

1. The selected contractor will have an NRC or Agreement State License to perform calibrations and their license will be documented by the applicant prior to contracting this service. It is anticipated that the calibration will be performed either by the manufacturer of the instrument, or by NC Systems, Inc. 5660 Airport Blvd. Suite 101, Boulder CO 80301

2. If a contractor is remote from the location of the facility is used, either a replacement survey meter will be obtained during the calibration, or the facility will not operate during the time the system is not present. The replacement meter will match the performance of the original meter.

3. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined.

4. The report of survey meter calibration, obtained from a contractor after calibration, will include, but not be limited to, the following information:

    a. The owner of the instrument;
    b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;
    c. A description of the calibration source, including exposure rate at a specific distance on a specified date, and the calibration procedure;
    d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
    e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);
    f. The angle between the radiation flux field and the detector;
    g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
    h. The apparent exposure rate from the check source; and
    i. The name of the person who performed the calibration and the date on which the calibration was performed.

5. The following information will be attached to the instrument as a calibration sticker or tag:

    a. The source that was used to calibrate the instrument;
    b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
    c. For each scale or decade, one of the following as appropriate;
        (1) The average correction factor,
        (2) A graph or graphs from which the correct factor for each scale or decade may be deduced, or
        (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
    d. The angle between the radiation flux and the detector during the calibration; and
    e. The apparent exposure rate from the check source.

    Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

Radiation Safety Equipment

Table Top Barrier Shield

The shield most suited to your work load. Provides exceptional protection to the clinician when setting up technetium generators, filling syringes, etc.

1/2" thick wall protects the torso while the base provides ample working surface and balance against tipping. Face shielding is optically clear 1/4" thick lead glass, cantilevered for unimpaired viewing of work area. The lead equivalent of the glass is 2.00mm.

Pro-Tec® Syringe Shield

Pro-Tec Syringe Shields are the first functional, safe, unobtrusive, easy to use, unbreakable, and lightweight syringe shields available. The slimline design is comfortable for both patient and clinician. The patented spring loaded twist lock of the stainless steel and brass screw lock keep disposable syringes snug inside the shield. Pro-Tec Syringe Shields are half the weight of other syringe shields, yet the Pro-Tec will normally reduce exposure from ^{99m}Tc by a factor of 20. The Pro-Tec Vu-Thru has a viewing port, so that drawing and injecting can be accomplished with the syringe in the shield. A special optical glass window with a density of 2.3 gm/cc covers the port.

Lead Lined Storage Container

For Contaminated Syringes

- Safely holds used hot syringes
- Rapid, safe disposal

Specifications:

Lead Shielding:	1/8" Lead Shielding
Measures:	6 3/4" high, 5" diameter
Weight:	7 lbs.

Vial Shields - Optional*

This lead shield, available in either 0.5" or 0.25" thickness, was designed to permit safe, convenient handling of vials containing liquid radionuclides. It is particularly important when milking "cows." The vial provided with the generator may be placed in the shield, and the generator eluted in accordance with the manufacturer's instructions.

The shield has a high density lead-glass panel, with shielding thickness equivalent to that of the lead wall, so that the entire process may be viewed. The shield has a screw-type cover with an opening through which a syringe needle may be inserted for withdrawal of the radionuclide from the vial.

*Vial shields will not routinely be maintained unless the license or amendments allow the preparation of radiopharmaceutical kits and/or possession and use of ^{99}Mo/^{99m}Tc Generators.

Equipment Quality Control Phantoms

Emission Phantom

Extra Large Flood Phantom Source

- 15" diameter pool completely includes a patient's lungs, allowing accurate patient position when using a diverging collimator
- 16.5" x 16.5" x 1" thick, with 15" diameter x 0.5" cavity for suitable radionuclide.
- Easy to fill—drain ports provided.

Transmission Phantom

Standard High Resolution Bar Phantom

- Bar Widths: 1/4", 3/16", 5/32", 1/8" (6.4 mm, 4.8 mm, 4.0 mm, 3.2 mm)
- 15" field across bar configuration (38 cm)

CARDIOVASCULAR CONSULTANTS, P.C.
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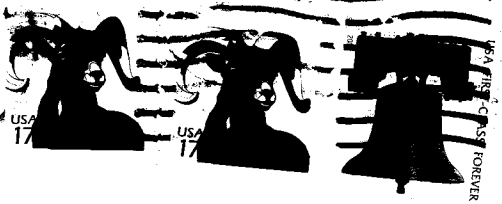
1123 NORTH WESTERN AVENUE
MARION, INDIANA 46952

KOKOMO, IN
PM
11 MAY
2011



USA FIRST-CLASS FOREVER

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