

### Brian T. Eller, MD, FACC. Board Certified Nuclear Cardiology

February 14, 2012

UNITED STATES NUCLEAR REGULATORY COMMISSION

Region III, Materials Licensing Section

2443 Warrenville Road, Suite 210

Lisle, IL 60532-4352

Re: Amendment to License No. 21-32375-01, My Heart Partners, P.C.

#### PLEASE EXPEDITE

- 1. Remove Timothy S. Knapp, CNMT as Radiation Safety Officer. He is no longer at our facility.
- 2. Add Dawn Edwards, M.S. as Radiation Safety Officer. She is currently listed as Radiation Safety Officer on NRC license number 21-32068-01.

Ms. Edwards will spend a minimum of one day each quarter at our facility. Management will have direct oversight of the day-to-day operations and some daily safety duties will be delegated to the Nuclear Medicine Technologist. Ms. Edwards will perform a radiation safety review, quarterly testing and inventories during her visits.

Her response time in the event of an emergency is approximately 75 minutes.

Thank you for your cooperation in this matter. If you have any questions, please contact me at 269-428-4620 (<u>beller@myheartparetners.com</u>) or Dawn Edwards at 734-662-3197 (<u>dedwards@mpcphysics.com</u>).

Sincerely,

Brian T. Eller, M.D., Owner

My Heart Partners, P.C.

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## RSO / EXECUTIVE MANAGEMENT LETTER OF UNDERSTANDING

February 14, 2012

Dawn Edwards, MS
Radiation Safety Officer
Medical Physics Consultants, Inc.
214 E. Huron Street

Re: Radiation Safety Officer / Executive Management

Letter of Understanding

Dear Ms. Edwards:

Ann Arbor, MI 48104

You have been appointed the Nuclear Medicine Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35. This section of the regulations requires that you agree in writing to the following:

Assume responsibility for implementing the Radiation Protection Program

- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.
- Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:
- > Specific written notation of your authority, duties and responsibilities, see attached.
- > Sufficient authority, organizational freedom, time, resources and management prerogative to:
  - 1. Identify radiation safety problems;
  - 2. Initiate, recommend, or provide corrective actions;
  - 3. Stop unsafe operations; and,
  - 4. Verify implementation of corrective actions.

Our signatures noted below will attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

Brian T. Eller, M.D., Owner

My Heart Partners, P.C

Dawn M. Edwards, MS

Radiation Safety Officer

# RADIATION SAFETY OFFICER AUTHORITY, DUTIES AND RESPONSIBILITIES

The Radiation Safety Officer (RSO) shall:

- 1. Have the authority to implement the Radiation Protection Program as referenced in 10 CFR 20.1101.
- 2. Have the authority, organizational freedom, time, resources, and management prerogative to:
  - a. Identify radiation safety problems;
  - b. Initiate, recommend or provide corrective actions,
  - c. Stop unsafe operations; and,
  - d. Verify implementation of corrective actions.
- 3. Investigate deviations from the radiation safety practices approved by facility management and/or the Radiation Safety Committee, if applicable.
- 4. Collect in a centralized location, executive management approved procedures that can include policy and technical issues which, would make the Radiation Protection Program as follows:
  - a. Authorization for the purchase of radioactive material.
  - b. Receipt and opening of packages containing radioactive material.
  - c. Storage of radioactive material.
  - d. Inventory control of radioactive material.
  - e. Safe use of radioactive material.
  - f. Emergency procedures in the event of loss, theft, etc.
  - g. Periodic radiation surveys and wipe tests
  - h. Checks of radiation survey and other radiation safety instruments.
  - i. Disposal of radioactive material.
  - j. Personnel training of those who work in or frequent areas of radioactive material use or storage.
- 5. Oversee a record system of the Radiation Protection Program per 10 CFR 20.2102 to include at least the following:

The provisions of the Radiation Protection Program until the license is terminated by the NRC such as:

- a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.
- b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

Audits and other reviews of the Radiation Protection Program content and implementation for a period of three (3) years after the record is made.

## RADIATION SAFETY OFFICER



RSO Authority, Duties & Responsibilities

page 2

- 6. Periodically evaluate "action levels" for continued appropriateness to ensure compliance with 10 CFR 20.1501 and 1502 for the following:
  - a. Personnel exposure investigation levels
  - b. Area surveys dose rate and contamination levels
  - c. Bioassays, if necessary
  - d. Radioactive effluent concentrations, if necessary
- 7. Review the following Radiation Protection Program records, if applicable:
  - a. Sealed source inventories
  - b. Sealed source leak tests
  - c. Dose calibrator linearity tests
  - d. Dose calibrator accuracy tests
  - e. Dose calibrator geometrical variation tests
  - f. Occupational radiation exposure reports
  - g. Medical event documentation
  - h. Spill / incident reports for cause and corrective action
  - i. Dose rate and contamination survey results
  - j. Changes in the radiation safety program
- 8. Ensure the use of reasonable practices and controls to strive to maintain doses to workers and to the public are ALARA, in compliance with 10 CFR 20.1101(b).
- 9. Review with facility management at least annually of the content of the Radiation Protection Program and determine if the written program is being implemented in compliance with 10 CFR 20.1101(c).
- 10. Ensure as a part of the ALARA effort that individual members of the public shall not receive a Total Effective Dose Equivalent (TEDE) of more than 10 mrem (0.1 mSv) per year from airborne radioactive material releases as per 10 CFR 20.1101(d) as necessary.

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