October 24, 2011

Dear Dr. Fritsch:

Please find attached the **Authorized User Responsibilities** form required by ***St.Vincent Hospital*** as a physician authorized user licensed at this facility.

All possession and use of radioactive material within ***St.Vincent Hospital*** must be by or under the supervision of an Authorized User approved by the NRC. Authorized Users approved by the USNRC are named on our license along with the types of radioactive material and uses authorized. Before submission to the NRC, a prospective Authorized User must be approved by the Radiation Safety Committee. Training and experience requirements for human use are found in Subpart J of 10CFR35. Each Authorized User accepts responsibility for maintaining compliance with all hospital, State, and federal regulations for the safe use of radioactive material by supervised individuals as further described in the Authorized User Responsibilities form attached.

Please **read, sign and return** this form to me by **November 7, 2011**. I will maintain this form in our file should a USNRC materials inspector request a review of this documentation. If you have any questions, please do not hesitate to contact me at the telephone number noted below.

Sincerely,

Edward E. Wroblewski, MA, DABSNM

Edward E. Wroblewski, M.A.
Diplomate, ABSNM
Radiation Safety Officer
Diagnostic Physics Services
317/338-2381

AUTHORIZED USER RESPONSIBILITIES

All possession and use of radioactive material within *St. Vincent Hospital* must be by or under the supervision of an Authorized User approved by the Nuclear Regulatory Commission (NRC). Authorized Users approved by the NRC are named on the hospital's NRC byproduct materials license along with the types of radioactive material and uses authorized. Prior to submission to the NRC, a prospective Authorized User must be approved by the Radiation Safety Committee. Training and experience requirements for human use are found in Subpart J of 10CFR35. Human use of non-byproduct (naturally-occurring and accelerator-produced) radioactive materials within *St. Vincent Hospital* must be by or under the supervision of an Authorized User approved by the NRC for comparable byproduct radioactive material and uses. **Each Authorized User accepts responsibility for maintaining compliance with all hospital, State, and federal regulations for the safe use of radioactive material by supervised individuals**. Accordingly,

Authorized Users shall be responsible for:

1. Possession and use of only those radioactive materials and uses for which the Authorized User has been approved by the NRC and/or the Radiation Safety Committee.

   Steven A. Fritsch, M.D. is approved for:

35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55931 Oct. 1, 2007]

35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in § 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this

section or the physician who is an authorized user in paragraph (b)(2) of this section;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55932 Oct. 1, 2007]

2. Limitation of use of radioactive material under their supervision to only those individuals over whom they have direct supervisory responsibility.

3. Examination of patients and medical records to determine if a radiation procedure is appropriate.

4. Prescription of the radiation dosage or dose and how it is to be administered, documented as:

   a) part of a protocol in a Procedure Manual, or

   b) a written directive as required by the Quality Management Program.

5. Direction of technologists or other paramedical personnel in the use of radioactive material.

6. Interpretation of results of diagnostic procedures and evaluation of results of therapeutic procedures.

7. Instruction of supervised personnel in the principles of radiation safety appropriate to each individual's use of radioactive material.

8. Ensuring that supervised personnel are familiar with and practice those aspects of the radiation safety program appropriate to each individual's use of radioactive material, including but not limited to:

   a) rules, regulations and requirements of the NRC as contained in 10CFR19, 10CFR20, 10CFR35, the hospital NRC license, license conditions and associated documentation/correspondence,

   b) the ALARA concept and the need to maintain exposures ALARA,

c) personnel monitoring requirements,

d) maintenance of required records of receipt, use, storage, and disposal of radioactive material, instrument calibration, area surveys, and sealed source inventories and leak tests,

e) obligation to report unsafe conditions, spills or accidents involving radioactive material immediately to the Radiation Safety Officer.

9. Review of each planned new use of radioactive material to insure that adequate safety precautions are taken and that doses will be kept ALARA.

10. Consultation with the Radiation Safety Officer and the Radiation Safety Committee during the planning stage before a new use of radioactive material.

11. Periodic review of the supervised individual's use of radioactive material and the records kept to reflect this use.

By signing below, I am acknowledging that I have read and understand the uses of byproduct material for which I am licensed. Additionally, I also acknowledge my responsibilities as an authorized user at *St. Vincent Hospital.*

Physician Signature: _____ Date: 10/27/11