STATE OF NEW YORK
DEPARTMENT OF HEALTH
Flanigan Square 547 River Street Troy, New York 12180-2216

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissione

January 8, 2010

Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Reis:

Enclosed please find copies of the sections in the current 10 NYCRR 16 which specify the criteria for the release of patients who contain radioactive material administered for a medical procedure.

RATS ID	Title
1997-3	Criteria for the Release of Individual Administered Radioactive Material

We believe that the requirements in 10 NYCRR 16.123 satisfy the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 518-402-7550 or Robert Dansereau at 518-402-7550 or red07@health.state.ny.us.

Sincerely,

Stephen M. Gavitt, CHP, Director
Bureau of Environmental Radiation Protection
New York State Department of Health

Enclosures: As stated

16.2 (78) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

16.2 (89) "Public dose" means the dose received by a member of the public from exposure to sources of radiation. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

16.123(b) Medical uses of radioactive material. A licensee may use radioactive materials described in the following, only if such use is authorized by the license:

(1) Use of radiopharmaceuticals for uptake, dilution and excretion studies:

(i) A licensee may use any radioactive material only if authorized by a license for such use, in any radiopharmaceutical for diagnostic uses involving measurements of uptake, dilution or excretion. The licensee shall use such radiopharmaceuticals in accordance with the manufacturer's instructions for radiation safety.

(ii) The licensee shall confine patients undergoing procedures authorized by subparagraph (i) of this paragraph until the total effective dose equivalent for the individual (other than the patient) likely to receive the greatest dose is 5 mSv (500 mrem) or less.

(iii) When the total effective dose equivalent to any individual that could result from the release of a patient is likely to exceed 1 mSv (100 mrem), the licensee shall provide the patient, or his/her competent representative, written information on risks of radiation and methods for reducing the exposure of individuals, and shall keep records of such patient release for a period of five years.

(2) Use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies.

(i) A licensee may use any radioactive material only if authorized by a license for such use, in any diagnostic radiopharmaceutical or reagent kit, except for aerosol and gaseous forms, for preparation and diagnostic use of a radiopharmaceutical for studies involving imaging and localization. The licensee shall prepare and use such radiopharmaceuticals in accordance with the manufacturer's instructions for radiation safety.

(ii) The licensee shall confine patients undergoing procedures authorized by subparagraph (i) of this paragraph until the total effective dose equivalent for the individuals (other than the patient) likely to receive the greatest dose is 5 mSv (500 mrem) or less.

(iii) When the total effective dose equivalent to any individual that could result from the release of a patient is likely to exceed 1 mSv (100 mrem), the licensee shall provide the patient, or his/her competent representative, written information on risks of radiation and methods for reducing the exposure of individuals, and shall keep records of such patients release for a period of five years.

(3) Use of radiopharmaceuticals for therapy.

(i) A licensee may use any radioactive material only if authorized by a license for such use, in any radiopharmaceutical for a therapeutic use. The licensee shall prepare and use such radiopharmaceuticals in accordance with the manufacturer's instructions for radiation safety.

(ii) A licensee shall confine a patient for medical care after the administration of a radiopharmaceutical for therapeutic purposes until the total effective dose equivalent for the individual (other than the patient) likely to receive the greatest dose is 5 mSv (500 mrem) or less.

(iii) When the total effective dose equivalent to any individual that could result from the release of a patient is likely to exceed 1 mSv (100 mrem), the licensee shall provide the patient, or his/her competent representative, written information on risks of radiation and methods for reducing the exposure of individuals, and shall keep records of such patient release for a period of five years.

(4) Use of sources for radiation therapy by surface, intracavitary or interstitial application (brachytherapy).

(i) A licensee shall use the following sources in accordance with the manufacturer's radiation safety, handling and maintenance instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

(e) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(f) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

(ii) A licensee shall confine a patient for medical care after the administration of a permanent implant of a radioactive source or sources until the activity in the patient is such that the total effective dose equivalent for the individual (other than the patient) likely to receive the greatest dose is 5 mSv (500 mrem) or less.

(iii) When the total effective dose equivalent to any individual that could result from the release of a patient is likely to exceed 1 mSv (100 mrem), the licensee shall provide the patient, or his/her competent representative, written information on risks of radiation and methods for reducing the exposure of individuals, and shall keep records of such patient release for a period of five years.