Patient Release Criteria Conditions Superceding the Current Requirements of He-P 4035.25, NHRCR (effective, 2003)

[00]. Notwithstanding the requirements of He-P 4035.25, NHRCR, the licensee is authorized to release patients in accordance with procedures and criteria submitted in letter[s] dated ******* **, ****, and License Conditions Nos. [01 – 04], below. Conditions [01 – 04] shall prevail over the statements contained in the referenced documents unless such statements are more restrictive than these conditions.

[01]. A. The licensee may authorize the release of any individual who has been administered [radioactive drugs or implants containing radioactive material] if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (mrem).

B. For patients administered radioactive material for which a written directive is required, the licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

C. Release of the patient must be approved by an individual listed as an authorized user in Condition [user condition], and who is approved for the type of radioactive material use for which the patient being released has received.

D. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with Condition [02].

E. The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Condition [02].

F. Notwithstanding Part A of Condition [01], the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

G. The licensee shall immediately notify the Agency in accordance with Condition [03], if a patient departs prior to an authorized release.

H. The licensee shall notify the Agency in accordance with Condition [04]:

(1) When they are aware that a patient containing radioactive material and who has been released in accordance with Condition [01] dies; and

(2) If it is possible that any individual could receive exposures in excess of 500 mrem as a result of the deceased's body.

[02]. A. The licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for three years after the date of release.

B. The licensee shall retain a record for three years after the date of release that the instructions required by Part B of Condition [01] were provided to a breast-feeding woman.

[03]. A. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under Part A of Condition [01].

B. The licensee shall submit a written report to the Agency within thirty (30) days after discovery of the unauthorized departure. The written report must include:

(1) The licensee's name;

(2) The date and time of the unauthorized departure;

(3) The projected date and time when release would have occurred;

(4) The address of the patient's or human research subject's home or anticipated destination following departure;

(5) The radionuclide, chemical and physical form and calculated activity at time of release;

(6) The apparent reason(s) for the departure prior to authorized release; and

(7) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

[04]. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of limits specified in He-P 4020.13, NHRCR, as a result of the deceased's body.