**Section 335.2140 Other Medical Uses of Radioactive Material or Radiation from Radioactive Material (Emerging Technologies)**

A licensee may use radioactive material or a radiation source that is not specifically addressed in Subparts D through I, or if the use is inconsistent with those Subparts, if:

a) The licensee has submitted the information required by 32 Ill. Adm. Code 330.250 and any other necessary information consistent with 32 Ill. Adm. Code 330;

b) The application contains at least the following:

1) A request signed by management that is consistent with the requirements of 32 Ill. Adm. Code 340.310(b);

2) A description of:

A) The facilities, with a diagram;

B) The necessary equipment and its calibration or maintenance; and

C) Training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officers, authorized users, authorized medical physicists, and ophthalmic physicists, if not already previously submitted;

3) Procedures, as applicable, that describe:

A) The radionuclide, form and activity;

B) The expected levels of contamination and the procedures to control them;

C) The general safety precautions;

D) The safety instructions to be provided to staff that are specific to the proposed use; and

E) The methodology for measurement of dosages or doses to be administered to patients or human research subjects;

4) If applicable, a description of the sealed source and/or device as per 32 Ill. Adm. Code 330.280(i) and (k), as applicable, or, alternately, identification of the product in the Sealed Source and Device Registry.

c) In addition to the requirements in subsection (b)(2), an application for a license or amendment for medical use of radioactive material as described in this Section shall also include information regarding any aspects of the medical use of radioactive material that are applicable to radiation safety that is not addressed in Subparts A through C.

d) The applicant or licensee has provided any other information requested by the Agency in its review of the application.

e) The licensee has received written approval from the Agency in the form of alicense amendment and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the safe use of the material.

AGENCY NOTE: The FDA accepted protocols may be submitted as partial application towards the information requested in this Section.

(Source: Amended at 46 Ill. Reg. 966, effective December 21, 2021)