**Section 335.5010 Use of Unsealed Radioactive Material for Which a Written Directive is Required**

a) A licensee may use any unsealed radioactive material identified in subsection 335.9050(b)(2)(F) prepared for medical use and for which a written directive is required that is:

1) Obtained from a person specified in Section 335.30 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements;

2) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 335.9040, 335.9050, or an individual under the supervision of either as specified in Section 335.1050; or

3) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a protocol accepted by FDA; or

4) Prepared by the licensee for use in research in accordance with an application or a protocol accepted by FDA.

b) Prior to any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131 to a patient capable of childbirth, the licensee shall conduct a pregnancy test and obtain those results to determine pregnancy. If the delay caused by conducting a pregnancy test would jeopardize the patient's health, the test may be forgone provided that action is noted by the authorized user on the written directive required by Section 335.1110. The written directive must also indicate the patient was informed of the decision to forego the pregnancy test or the reason for omission of the patient notification. Nothing in this Section relieves the licensee from meeting the requirements of Section 335.1100 regarding reporting of exposures to a fetus/embryo.

c) Records of the pregnancy test in subsection (b) shall contain the patient's name, identification number if one has been assigned, the type of test performed, results of the test, the date of the test, date the results became available if different from the test date, and identity of the licensee's staff interpreting the test or, as applicable, the determination by a physician that pregnancy test was not required.

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