**Section 335.20 Definitions**

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using or storing radioactive material.

"Associate Radiation Safety Officer" means an individual who, for this Part only, meets the requirements in Sections 335.9010 and 335.9180 and is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on a specific medical use license issued by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State or on medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

"Authorized user" means a physician, dentist or podiatrist who meets the requirements in Subpart J or is identified as being authorized to use radioactive material on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Authorized medical physicist" means an individual who meets the requirements in Sections 335.9150(a) and 335.9180; or is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope medical use licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Case" means the performance of a clinical procedure on a patient.

"Classroom and laboratory training" means planned instruction outlined in a syllabus and offered by an individual or organization. It is comprised of lectures, demonstrations, hands-on laboratory exercises and tests.

"Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with Section 335.2120.

"Clinical procedure" means a method of using radioactive material for patient care in which the material or its radiation is administered to the patient. A specific clinical procedure specifies, either explicitly or in context, the indication for the procedure, the purpose (diagnosis or therapy), the radionuclide and its chemical and physical form, the dosage or dose and method of administration and patient follow-up. Diagnostic clinical procedures also include the method of collecting raw data, manipulating the data and interpreting the final results, which may be images, graphs or numbers.

"Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

"Gamma stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

"High dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Intravascular brachytherapy" means a type of brachytherapy in which the brachytherapy sources are placed into blood vessels at the point where the dose is prescribed for the treatment of in-stent restenosis.

"Low dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

"Management" means the chief executive officer or other individual having the authority to manage or administer the licensee's activities, or those individuals' delegates.

"Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medical event" means an event that meets the criteria in Section 335.1080.

"Medical institution" means an organization in which more than one medical discipline is practiced.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

"Mobile medical service" means the transportation of radioactive material to, and its medical use at, the client's address.

"Ophthalmic physicist" means an individual who meets the requirements in Sections 335.7100(b) and 335.9180; and is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; a permit issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State broad scope medical use licensee; or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

"Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"Physically present" means within audible range and in such proximity that immediate assistance can be given if required.

"Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

"Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

in a written directive; or

in accordance with the directions of the authorized user for procedures pursuant to Sections 335.3010 and 335.4010.

"Prescribed dose" means:

for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

for teletherapy, the total dose and dose per fraction as documented in the written directive;

for manual brachytherapy and intravascular brachytherapy, either the total dose or the total source strength and exposure time, as documented in the written directive; or

for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Pulsed dose rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose rate" range, and:

is approximately one-tenth of the activity of typical high dose rate remote afterloader sources; and

is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

"Radiation Safety Officer" means an individual who:

meets the requirements in Sections 335.9010 and 335.9180; or

is identified as a Radiation Safety Officer on:

a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; or

a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

"Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Type of use" means use of radioactive material under Section 335.2140, 335.3010, 335.4010, 335.5010, 335.6010, 335.7010 or 335.8010.

"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Visiting authorized user" means a temporary (i.e., less than 60 days each year) authorized user who is not identified on the license of the licensee being visited and who has been approved by the Radiation Safety Committee in accordance with Section 335.1060(b).

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Section 335.1110.

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