4731.4409 PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVE.

A. For any administration requiring a written directive, a licensee must develop, implement, and maintain written procedures to provide high confidence that:

(1) the patient's or human research subject's identity is verified before each administration; and

(2) each administration is in accordance with the written directive.

B. At a minimum, the procedures required by item A must address the following that are applicable to the licensee's use of radioactive material:

(1) verifying the identity of the patient or human research subject;

(2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) checking both manual and computer-generated dose calculations;

(4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized under part 4731.4404 or 4731.4463;

(5) determining if a medical event, as defined in part 4731.4525, has occurred; and

(6) determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

C. A licensee must retain a copy of the procedures required under item A according to part 4731.4501, subpart 2.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440; 46 SR 791*

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