

641—42.13(136C) Written directives. Each registrant shall meet all of the following.

42.13(1) *Written directive.* A written directive must be dated and signed by an authorized user prior to the administration of radiation.

a. If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose or the next fractional dose.

d. The registrant shall retain a copy of the written directive for three years.

42.13(2) *Procedures for administration.* The registrant shall have written procedures that provide all of the following information:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by completing all of the following:

(1) Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive;

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

d. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken;

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

[ARC 0182D, IAB 4/1/26, effective 7/1/26]