

Rulemaking Comments

From: DeKock, Leola M - DHS [Leola.DeKock@dhs.wisconsin.gov]
Sent: Friday, November 07, 2008 4:47 PM
To: Rulemaking Comments
Cc: Schmidt, Paul S - DHS; Rogers, Cheryl K - DHS
Subject: RIN 3150-AI26 comments

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Wisconsin Agreement State Program Comments:

We have reviewed the Proposed Rule change to 10 CFR Part 35 affecting permanent implant brachytherapy.

There are some proposed changes that have the potential to negatively affect our licensees and the agreement state licensing and inspection processes.

30.40 Written Directives

30.40 (6) The proposed revision requires written directives to be prepared before administration (preimplantation), "(c)(1)" allows for a written revision to an existing written directive if it is dated and signed prior to the administration. Currently, a written directive is able to be modified after a procedure, to allow for changes in the dose.

The current practice allows for AU physicians to make modifications to written directives in response to the patient status. The treatment plans and written directives are often generated several days or weeks in advance of a permanent brachytherapy procedure. The brachytherapy sources are ordered from the manufacturer and received in advance. Inspectors have been informed by physicians that during the period between generation of the treatment plan and the actual implant procedure the area intended to be treated can change. One example of this is patients undergoing permanent brachytherapy for prostate carcinoma. Patients may have an ultrasound procedure several weeks in advance of the actual procedure. Medications prescribed and taken by the individual during the interval may reduce the size of the gland. The reduction in the size results in a reduction in the number of required seeds treatment and a change from the original written directive. The proposed change does not appear to continue to allow this practice.

35.3045 Report and notification of a medical event.

The proposed changes have added permanent implant brachytherapy to the reporting requirements. "(2)(iii)" indicates a brachytherapy source(s) implanted beyond 3 cm from the outside boundary of the treatment site, except for brachytherapy source(s) at other sites noted in the preimplantation written directive will be reportable as a medical event.

Compliance with this reporting requirement may be difficult for some licensees. The ability to identify an individual seed on a radiograph may be difficult for facilities in rural communities providing brachytherapy services. It may be more prudent to use a percentage of the total seeds implanted as the medical event criteria.

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