

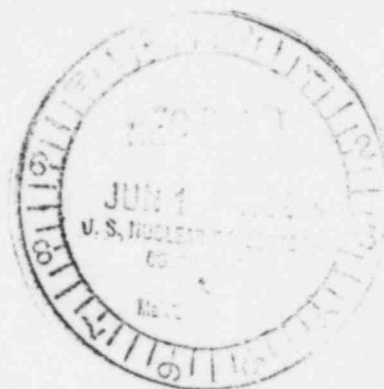
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June 9, 1982



William J. Walker, Jr., Ph.D.  
Material Licensing Branch  
Division of Fuel Cycle and Material Safety

Re: Draft of Proposed Review  
of 10 CFR Part 35  
on Human Uses of Byproduct  
Material.

Dear Dr. Walker:

From the years of experience in functioning under current rules, the evident deficiencies and the options for revisions have been carefully analyzed in the Value/Impact Statement. Recognizing the intensive study and preparation that produced the proposed revision, no major addition can be offered but several suggestions are appended that may merit consideration.

VPC:jl

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ADDENDUM:

pages 47, 48, 49

Subpart C -- General Technical Requirements

The term "dose" is used both for the amount of radionuclide administered to a patient in millicuries, and in calibration and exposure records in units of Roentgens, rads or rems. The expression of "dose" as a single number is at best an incomplete description of exposure or absorption, and valid only if there is a clear understanding as to all variables implied and inferred.

For the same numerical "dose", the effect will vary with the time factor. The same biologic effect may be obtained with different numerical factors again depending upon time of exposure or administration.

It would be well to provide a definition of "dose" appropriate to purpose of the regulation.

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"Sealed source" should be defined.

page 71

35.641 (a) (1)

The "average radiation levels at one meter" should be clarified. This could mean several measurements taken at any one point at one meter at different times, or multiple measurements taken at one time in different positions about the teletherapy source.

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Subpart J -- Training and Experience Requirements

When these requirements are stated in round numbers of hours this simplifies the writing of regulations and allows discretion in individual programs but one must expect a wide variation in content unless the end point is qualification by examination.

An expected variation in course content is implied in the varying numbers of hours but there is no indication as to what this might be.

For example one wonders what the additional hours for radiation protection, mathematics and radiobiology should be devoted to in qualification for the use of sealed sources as opposed to teletherapy. Granted the potential exposure of personnel is greater in the use of sealed sources but I do not understand why one requires 5 hours less instruction in mathematics and radiobiology.

page 79

35.930 (b) (2)

There are few if any centers using soluble phosphorus-32, colloidal phosphorus-32 or colloidal gold-198.

A requirement to have had supervised clinical experience in the use of these agents might be difficult or impossible to obtain. Personally I consider the risk involved in use of these to be greater than the benefit, particularly with the availability of satisfactory chemotherapy regimes.

(Incidentally the use referred to would be intracavitary rather than intercavitary.)