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Miller/McElroy

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Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety
United States Nuclear Regulatory
Commission
Washington, D.C. 20555

RE: Revision of Part 35
and Regulatory Guide 10.8

Dear Mr. Cunningham,

The revision of PART 35 and REGULATORY GUIDE 10.8 has been most thorough in accomplishing its purpose of consolidation and simplified presentation.

I trust my suggestion will be helpful and that my comment and enclosure will be of interest.

Sincerely,

V.P. Collins, M.D.

encl: (2)

VPC/ag

Revision of 10 CFR Part 35 and Regulatory Guide 10.8

Review and Comment

35.30 ALARA Program

There is repeated reference to the ALARA program, but I find no mention of Maximum Permissable Dose.

ALARA is a euphonic admonition to be careful, but the M.P.D. is an objective standard by which to measure exposure and affirm that radiation safety is being maintained within acceptable limits. If the current M.P.D. of 5 rem/year is not acceptable, then some lower level should be set.

One could no more oppose ALARA then to deny the virtue of Motherhood or Sunday school but "reasonable" is a quality that exists in the mind of the "reasonable man" who is called to court whenever a decision must be made on the basis of conflicting testimony in our adversary system of law. He is an outstanding example of a decision making device known as a "fiction of law". (See definition in Black's Law Dictionary attached.)

ALARA is the delight of plaintiff's attorneys and the bane of defense attorneys. This accounts at least in part, for the final decision in the Silkwood case, where 'reasonable men' on a jury, and 5 out of 9 'reasonable men' on the U.S. Supreme Court, felt that $10 million worth of damage had been done, even though no radiation injury was shown and the body burden of plutonium was found to be 8.8 nanocuries, far below tha permissable level of 40 nanocuries

A copy of the recent Supreme Court decision on the Silkwood case is attached with an index of pertinent passages. A policy statement should be provided to clarify whether and when ALARA may override M.P.D. in distinguishing between care and negligence.

To paraphrase George Orwell, 'all men are reasonable, but some are more reasonable than others' (or vice versa).

35.415 (p 51) Safety Precautions

Isolation in a private room is necessary for brachytherapy patients. Isolation would be discontinued with a removal of a temporary implant, as with Iridium 192, and according to Sec. 35.75, a patient with 30 mCi or less of Gold 198 could be discharged.

However, some patients with a permanent implant of Gold 198 may require continuing hospitalization after the radioactivity falls below 30 mCi, or 6 mR/hr. at a meter.

It may be advisable to continue isolation under these circumstances rather than permitting the room to be shared by another patient. The ALARA principle would seem to require this as well as recognition of the apprehension of the patient, visitors and nursing staff for any level of radioactivity.

Some policy statement should be provided for two reasons.

1. If continued isolation is indicated, this would constitute a "medical necessity", the basis for continued coverage of a private room by the patient's insurance.

2. If continued isolation is not to be the policy for residual body burden below 30 mCi or 6 mR/hr at a meter, and another patient is admitted to the same room, a question of radiation safety arises. Is the hospital protected by observation of the stated levels or will radiation safety be judged on the basis of ALARA? A pregnant visitor to the room might express anxiety by instituting suit.

Sec. 35.75 (p 75) Release of patients containing radiopharmaceuticals or permanent implants.

A release limit of either 30 mCi body burden or 6 mR/hr. at one meter is approved.

It should be recognnized that quite different problems exist for Iodine 131 administered orally, and a permanent implant with Gold 198 or Iodine 125, for brachytherapy. Contamination of other members of a household with excreted Iodine 131 has been reported in HEALTH PHYSICS about 2 years ago (reference not immediately available). Written instruction for appropriate precautions at home might be required, as written instructions are required for management of patients in hospital.

35.930 Training for Therapeutic Use of Radiopharmaceuticals

This indicates as authorized user, only a physician certified in nuclear medicine by the American Board of Nuclear Medicine.

It should also include a physician certified in therapeutic radiology by the American Board of Radiology.

Under requirements for supervised clinical experience, it states training must include:

(ii) Use of soluble phosphorous-32 for the treatment of polycythemia vera, leukemia or bone metastases, 3 cases.

(iii) Use of colloidal phosphorous-32 for intracavitary treatment of malignent effusions in 3 individuals.

(v) Use of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

These uses (ii, iii, v.) were common 10 to 20 years ago. At present there is very little use of these agents, even in teaching institutions.It might be difficult or impossible for a trainee to find the opportunity to comply with these now largely discontinued uses of radiopharmaceuticals.

A license to use should be available if requested, but experience with these little used agents should not be a requirement for a general authorization for use of radiopharmaceuticals.

V.P. Collins, M.D.
May 1, 1984