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Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Comment on Draft NUREG-1556, Vol.9 Rev. 3

Dear Ms Bladey:

The following are my comments on the proposed Draft of NUREG – 1556, Volume 9, Revision3.

GENERAL COMMENT

The publication of this document is entirely premature without the "Final Rule" status of the revised 10 CFR 35. "Guidance" without a regulatory foundation would be meaningless. Additionally the inconsistencies with reality reveal just how out of touch the NRC is with medicine as practiced today.

SPECIFIC COMMENTS

- Dose Calibrator Appendix should be eliminated as written. Reference to the latest AAPM publication on this device must be included.
- Dose Calibrator Accuracy guidance is inconsistent with reality regarding individual sealed source activity being up to dosage "levels used". Meaning that some licensee's would be required to possess Cs-137 and Ba-133 sealed sources for accuracy testing equal to 200 mCi, which would equal dosage levels "used" for I-131 thyroid therapy. This guidance makes no sense.
- Dose Calibrator Linearity testing on an annual basis for non-Nuclear Pharmacy licensees is consistent with the proven operational stability of these devices and should be retained as guidance.
- Dose Calibrator Geometry testing should be eliminated as a requirement. Originally geometry testing was correctly required decades ago when the ionization chamber detectors were all small in size which makes the "sweet spot" for accurate measuring very small, possibly leading to inaccurate results with variations in source size and volume. This is no longer the case with the larger chamber dose calibrators in use today.
- Radiation Safety Officer notations are without merit. Guidance RSO verbiage notes that RSO's are usually employees of the licensee. An over whelming number of licensees have RSO's as physicians or physicists that are consultants to the licensee and not "employed". Additionally guidance notation is made that the RSO is "responsible" for licensed activities. Executive management is responsible, the RSO is charged with implementation of the Radiation Protection Program (RPP). These statements indicate how out of touch NRC is with the real world of medicine.

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- Package Receipt Documentation guidance notes the requirement of the "signature" of the individual receiving and monitoring the package. Nowhere in the NRC or DOT regulatory framework is a "signature" required. This guidance does not agree with your own regulations.
- Breastfeeding Guidance Tables have a gross omission of not recommending cessation of breast feeding for the administration of I-123 to the nursing mother. Given the production modes of I-123 it is well known that contamination with I-125 exists. The incurred radiation dose to the nursing infant from longer lived I-125 must be considered in the guidance to again reflect reality.
- Patient Release under 10 CFR 35.75 guidance if maintained in its' present form should be converted to a "Pass / Fail" criteria rather than a population dose that is calculated with unreal assumptions and outdated formulations. The available science behind radiation dosimetry for patient's, can make these "calculations" patient specific and therefore meaningful as an expected radiation dose to others. If this methodology is considered too complicated for most licensee's, maybe they should not perform these types of procedures.

The comments noted above are just highlights. This guidance document in its' revised form is just a bloated expansion of previous revisions that were equally out of touch with reality

Sincerely,

Thomas M. Kumpuris, M.S.

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