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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Gentlemen:

We have just recently become aware of Regulatory Guide 10.8, A Guide for the Preparation of Applications for Medical Programs, and more particularly Appendix D, Section 2, Methods for Calibration of Dosecalibrators.

First is is inconceivable that such a procedure could be written without input or consultation from the major (or all) manufacturers of dosecalibrators. As a major manufacturer of dosecalibrators for over 10 years, we have a wealth of knowledge which would have proven invaluable in writing these procedures. The method as recommended in the publication dated January 1979 indicates a basic lack of knowledge of dosecalibrator characteristics, plus offers some techniques which are scientifically incorrect and will add significantly to the cost of a nuclear medicine departments operation without proper justification.

Our comments and recommendations regarding the proposed method follows:

A. 1. Instrument linearity (at installation and annually thereafter)
Comment: Loss of linearity after a unit has been demonstrated to be linear is extremely rare. Linearity is a function of three parts of the dosecalibrator, the ionization chamber, the amplifier(s), and the range selection. Linearity of the ionization chamber cannot change with time, state of the art in amplifier technology is such that they do not change with time. Range selectors do occasionally drift.

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2. Geometrical variation (manufacturer)
Comment: Geometry corrections are purely a function of the physical characteristics of the ionization chamber. All dose-calibrators with the same ionization chamber have identical geometrical variations (or lack of geometrical variation). Radx, and I'm sure the other dosecalibrator manufacturers would be happy to submit to the NRC the particular geometry characteristics of their chambers thus negating the cost of user performance of this task.

3. Instrument accuracy (at installation and quarterly thereafter)
Comment: Drift of chamber output or individual isotope correction is much more common and likely than changes of linearity with time (see 1 above). In fact, it is our opinion that the accuracy analysis is practical on a daily basis by adding to your procedures C1 and C2, the paragraph of Section G.

B. O.K.

C. 1. Measure and record the activity of several radionuclides of varying energies which are traceable to the NBS such as Cs 137, Co 57, Ba 133. (Rest of the paragraph is O.K.)

2. O.K.
Comments: The addition of two more known standards to the daily check procedure turns the daily check procedure to a Daily Test for Instrument Accuracy and adds less than two minutes to the daily check procedure. Step 2 of Section G could be added.

D. O.K.

E. Test of Instrument Linearity
The method given is scientifically incorrect. The assignment of the 30 hour reading as the starting point implies that the 30 hour reading is accurate ± 0%, whereas in fact it could be ± 5% and still be valid. Proper scientific technique requires that the "best fit straight line" on semi log graph paper be drawn through all the points applying equal weight to each point, and then determining the variation of each point from this best fit straight line.

We recently had an instrument returned because it did not pass your linearity test. It passed our linearity test and a review of the data by your procedure clearly indicates that the problem arose from applying validity to the 30 hour reading which was neither warranted nor deserved. This cost the user over $400.00.

E. 3. Your correction factors are off by approximately 1% for the 0, 6, and 48 hour samples. Since the discrepancy allowed is only 5%, this represents 20% of the error which is far too great.

E. 4. Should be plotted on semi-log not log-log graph paper.

F. Test for Geometrical Variation - See comments in Section A.2. above. Additional comments: The use of Co 57 for this procedure would be very expensive because Co 57 is expensive.

F. 7. Significant differences have also been noted between the glass vials used by various manufacturers (see attached graph). The user should obtain such correction information from the dose-calibrator manufacturer.

G. Test for Instrument Accuracy - See comments in A.3.

H. Test for Instrument Constancy - This is redundant and is covered in its entirety in your Sections C1 and C2 or our recommendation found in A.3.

H. 4. Since Co 57 has a relatively long half-life and Cs 137 a very long half-life (by nuclear medicine standards), it is not practical to plot these daily readings on semi-log graph paper. A log with periodic check points (weekly for Co 37 and semi annually for Cs 137) is much more reasonable.

GENERAL COMMENTS - There are a number of items throughout this procedure which do not take into account peculiarities of various dosecalibrators, for example few or none have been designed to, or can actually read background. Such items will only tend to confuse the user.

RECOMMENDATION - It is our recommendation that each dosecalibrator manufacturer include in their Operator's Manual a calibration procedure

for that particular model, which considers linearity, accuracy, consistency, and geometry and that these procedures be submitted to you prior to publication for approval.

If this is not within your authority and/or jurisdiction, then it could be done on a voluntary basis with users of dosecalibrators that do not have approved procedures submitting their own procedure inline with your guide. If this were unacceptable, then it could be done in conjunction with the Medical Devices Act under the FDA.

Since there are only four dosecalibrator manufacturers in the U.S. and such a procedure should be a part of their manual, we do not see this as burdensome to either the manufacturers or the NRC.

Sincerely,

Gerald M. Timpe

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