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July 10, 1985

John E. Glenn, Ph.D.
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Locket No. 30-09466
License No. 29-15615-01
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Dear Dr. Glenn,

Thank you for extending the reply date to July 22, 1985. Following our conversation, Mr. John Miller and I discussed his inspection report and the previous correspondence. The following reflects our conversation, plus my post-conversation analysis.

1) The October 4, 1983 Linearity Tests: As we discussed, I perform unannounced audits of the program at Garden State. These audits occur in the evening, on weekends, as well as during working hours. This allows me to see how the program and personnel are actually functioning. The disadvantage with this practice is that I may not see every report each month. But the Nuclear Medicine supervisor informs me about test results and other developments in the department at least monthly or more frequently. In October, 1983, the Nuclear Medicine supervisor informed me that the linearity tests were performed, and the test results were within the required limits. During the November audit, I reviewed the written test results and saw that the 48 hour test result did not comply with the +5% requirement. A written note flagging these results was attached to the report form. After reviewing these test results with the supervisor, she repeated the test within a few days. The results of the repeat test indicated that the linearity response of the dose calibrator was within +/-5%.

During this October and November period, the daily dose calibrator readings for the Cobalt-57 reference standard were within +/-5% of its calculated activity (i.e. 1.39mCi to 1.26mCi). This reinforced the supervisor's evaluation that the dose calibrator was operating properly. Since the Cobalt-57's activity corresponded to the low activities administered to patients during this time period, no patient's safety was jeopardized.

Very simply summarized, the report was misread. This mistake was detected, documented and corrected. If I understand your position, the violation is that we were too slow in accomplishing the correction. The major points are how did the mistake occur, and how can the response time be improved. Following Mr. Miller's inspection, the Nuclear Medicine

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supervisor and I reviewed the linearity testing procedures conducted at Garden State Hospital. As a result of this review, I came to the conclusion that the format of the linearity report form was the reason the results were misread, not the lack of competency of the technician performing the tests. She has repeatedly demonstrated her competency in this area. We are currently reviewing new formats for the linearity report forms. We have also changed our filing system for the linearity test results which has increased our control in this area.

If the linearity test results are not within the allowed limits, the technicians know to repeat the tests and to keep me informed. However, if a mistake occurs and is not detected by the technician, then our back up safety check is the monthly audit I perform.

2) May 7, 1984 Linearity Test: As you know, I requested a copy of Mr. Miller's calculations, since there still seemed to be a discrepancy between his calculations and mine. Mr. Miller called and we reviewed them over the phone. The disputed test result is the 30 hour measured activity compared to the 30 hour calculated decayed activity. The critical point is the value of the decay factor used in calculating the decayed activity. Mr. Miller's point is that since three significant figures are used initially (i.e. 62.5 mCi), then three significant figures should be used for the decay factor. The mathematics are as follows:

Original Activity x Decay Factor = Calculated Decayed Activity.

The decay factor for Technetium-99m for 30 hours equals 0.03125. I used 0.03. The following calculations show the significance of the number of decimal places used:

Orig. Act.	Decay Fact.	Calculated Act.	+5%	-5%
62.5 mCi	0.03	1.88 mCi	1.97mCi	1.79mCi
[Rounded Values I Reported = 1.9			2.0	1.8]
62.5	0.031	1.94	2.04	1.84
62.5	0.0312	1.95	2.05	1.85
62.5	0.03125	1.95	2.05	1.86

Using a decay factor of 0.03, the measured activity of 1.8 mCi is within +/-5% of the calculated activity. However, if 0.031 is used, then the measured activity of 1.8 mCi is 7.2% too low. Mr. Miller is correct: There is a significant difference if the third decimal integer is used.

In the future, we will use at least the same number of integers in the decay factor as there are in the original activity when evaluating the linearity test results.

I do feel compelled to comment that this reported violation focuses on the mathematical fine points involved, and not on a situation affecting the health and safety of patients or personnel.

Please contact me directly, if any additional information is required.

Sincerely,

Mary E. Moore

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Radiation Safety Officer
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