

THE CLEVELAND CLINIC FOUNDATION

9500 Euclid Avenue Cleveland, Ohio 44106 U.S.A.

John L. Horton, Jr., Ph.D.
Radiation Therapy
216/444-5583 216/444-5571

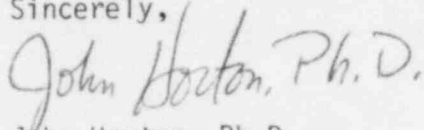
August 12, 1982

C. E. Norelius, Director
Division of Engineering and Technical Programs
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Mr. Norelius:

Enclosed you will find response to your letter of July 21, 1982.

Sincerely,



John Horton, Ph.D.
Certified Therapeutic Radiological Physicist,
Chief Physicist

JH:mrj
Enc.

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In January, 1982, the Keithley 616 electrometer which had been calibrated by the Victoreen Regional Calibration Laboratory in March, 1980 experienced an intermittent failure in the electronics which made the electrometer unreliable. When this occurred the Victoreen Regional Calibration Laboratory was contacted to request an emergency calibration of a Keithley 602 electrometer and Data Precision Digital Multimeter. We were told at this time Victoreen had discontinued their Regional Calibration Laboratory in late 1981. We then contacted M.D. Anderson Hospital Regional Calibration Laboratory and they agreed to calibrate the Keithley 602 electrometer and Data Precision Multimeter on February 9, 1982. However, the annual calibration on the Cobalt teletherapy unit had to be performed in January, 1982 according to 10CFR35.2(a,3) as the previous calibration had been performed in January, 1981.

During the January, 1981 annual Cobalt calibration the Keithley 602 electrometer and Data Precision Multimeter were calibrated in house and the calibration factor was determined to be 1.010. At the time of the January, 1981 calibration the agreement between the measured output and the stated output was 0.16%. During the following 11 monthly spot checks agreement between the measured output and the stated output averaged 0.6%. Additionally the Radiological Physics Center visited the Cleveland Clinic in April, 1981. During this visit the Radiological Physics Center performed measurements which may be considered to be an annual calibration using instruments calibrated by the M.D. Anderson Regional Calibration Laboratory. The results of these measurements indicated the agreement between the Radiological Physics Center and the Cleveland Clinic measurement of dose was within 1% for a 6 cm x 6 cm field size and was within 0.3% for all other field sizes measured.

Since the Keithley 616 electrometer was broken and could not be repaired before time for the annual calibration it was decided to use the Keithley 602 electrometer and Data Precision Multimeter for the annual calibration and then have this system calibrated as quickly as possible (10 days). This system had been calibrated in-house and its calibration factor was determined to be 1.010. Further, since the agreement between stated output and measured output over the previous 11 spot checks averaged 0.6% and the calibration performed by the Radiological Physics Center agreed with Cleveland Clinic measurements to within 1% for one field size and 0.3% for all other field sizes it was felt that the stated dose was known with a high degree of accuracy.

On February 9, 1982, the M.D. Anderson Regional Calibration Laboratory determined the calibration factor on the Keithley 602 electrometer and Data Precision multimeter to be 1.006. This agreed to the in-house calibration to within 0.4%. Using the calibration factor of 1.006 yielded agreement between the measured output and the stated output to within 0.8%. The spot checks

performed using the Keithley 602 electrometer and Data Precision Multimeter between February, 1982 and July, 1982 have agreed with the stated value to within 0.7%. It was suggested by the Nuclear Regulatory Commission that when the Keithley 616 broke and we found it impossible to have it repaired and re-calibrated before the deadline for an annual calibration that we should have contacted them for an extension of time to perform the annual calibration. This suggestion is appreciated and will be followed in the future should similar circumstances arise. However, such a helpful suggestion is not proffered in 10CFR35 and it did not occur to us. We do not see how delaying the calibration with the Nuclear Regulatory Commission's approval would have yielded greater accuracy of dose delivery. Based on the data presented, it is our judgement that at no time was patient safety compromised. We feel that we are in compliance with all applicable federal regulations now. We further feel that we have always been in compliance. The only possible time we may not have been in compliance was between January 30, 1982 and February 9, 1982. If in fact we were not in compliance during this period it was only in the strictest technical manner possible. However, considering that the Radiological Physics Center performed a full calibration in April, 1982 and was in agreement with the stated dose, it may be argued that we were in compliance during the period January 30, 1982 and February 9, 1982.

To summarize our answers to your questions:

- 1) Corrective action taken and results achieved - Electrometer calibrated on February 9, 1982, agreement within 0.4%.
- 2) Corrective action to be taken to avoid further noncompliance - We do not believe we are in non-compliance, however, if such an incident occurs in the future the Nuclear Regulatory Commission will be contacted and an extension of time in which to do the calibration requested.
- 3) The date when full compliance will be achieved - We believe we are in full compliance and always have been in full compliance considering the Radiological Physics Center calibrations.

Sincerely,

John Horton, Ph.D.

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