State of Alabama

# DEPARTMENT OF PUBLIC HEALTH

State Office Building
Montgomery, Alabama 36130

IRA L. MYERS, M.D.
STATE HEALTH OFFICER

July 7, 1983

- Log
- Bolling
- Response to ALA NMSS
- Due 7/29

Mr. Donald A. Nussbaumer
Assistant Director for State
Agreements Program
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Nussbaumer:

The purpose of this letter is to report the discovery of a generic problem with AECL Theratron 80 Teletherapy Device and to recommend that NRC amend its Sealed Source Catalog (entry NR 16901544) and order AECL to take corrective action.

During a recent source change (6927 Ci) of the Theratron 80 at Mobile Infirmary, Alabama License No. 375, a head leakage survey indicated a hot spot in excess of 100 mR/hr at position number 4 (attached diagram) when measured with typical, small cross section GM survey meter as used by our inspectors as well as AECL service representatives. At the same position, a Victoreen Panoramic, Model 470, Portable Ion Chamber indicated a dose rate in excess of 16 mR/hr. Since these measurements made by our inspector and the licensee indicated head leakage rates in excess of the 10 mR/hr regulatory limit (NRC Standard Condition No. 70), the new source was removed and AECL was requested to correct the situation. AECL maintained that the dose rate at the hot spot would not exceed 10 mR/hr when averaged over a 100 square centimeter area as provided for in NCRP Report No. 33. AECL also stated that this was a generic problem with all Theratron 80 devices and that, for this reason, AECL measures head leakage with a detector having a cross sectional area of 100 square centimeters. Accordingly, the information submitted to the NRC for certification did not indicate the existence of these hot spots.



AECL subsequently reinstalled the new source and measured a head leakage dose rate of 9.3 mR/hr at position 4 with their 100 square centimeter detector and the licensee measured 16 mR/hr. After an improved and larger end cap was installed on the source to provide additional shielding to the bore, the head leakage measurements at position 4 were 4.7 mR/hr and 6 mR/hr respectively. Accordingly, the new source was deemed in compliance with our regulations and the license condition.

From the above information, the following conclusions are obvious:

(a) A hot spot in excess of 10 mR/hr exists at position 4. Averaging of the dose rate over a 100 square centimeter area about this hot spot as provided for in NCRP Report No. 33 is necessary to comply with the 10 mR/hr maximum.

(b) With a source of the maximum activity (9000 Ci) allowed by the NRC certificate, the 10 mR/hr limit is exceeded even with averaging over 100 square centimeters.

(c) The sealed source catalog entry does not reflect the existence of the hot spot. Use of a 100 square centimeter detector is not authorized for head leakage surveys by NCRP Report No. 33 but only for resolving "small areas of reduced protection". The AECL data submitted to NRC were determined with a 100 square centimeter detector.

(d) The dose rate at position 4 can be substantially reduced by installation of the new end cap.

Accordingly, it is recommended that NRC take the following actions:

(1) Amend the sealed source catalog to reflect the true head leakage dose rates and limit the strength of the source to 7000 curies when the existing end cap is used.

(2) Order AECL to install the new end cap on all existing units containing more than 7000 curies.

(3) Consider ordering AECL to install the new end cap in all Theratron 80 units as a matter of compliance with the ALARA principle.

Sincerely,

Aubrey V. Godwin, Director
Bureau of Radiological Health
Environmental Health Administration

AVG:ARP:psc

Attachment

TELETHERAPY HEAD SURVEY
(Source in "OFF" position.
Measurements taken [redacted] from source)

| Position No. | | Radiation Level (mR/hr) |
|---|---|---|
| View A | 1 | |
| | 2 | |
| | 3 | |
| | 4 | |
| View B | 5 | |
| | 6 | |
| | 7 | |
| | 8 | |
| View C | 9 | |
| | 10 | |
| View D | 11 | |
| | 12 | |
| | 13 | |
| | 14 | |

Average value _____

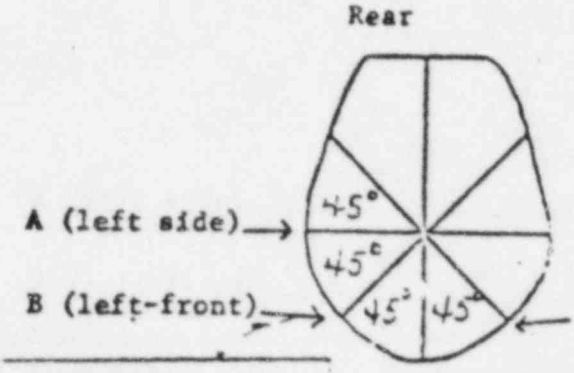
Maximum value _____

Instrument used _____

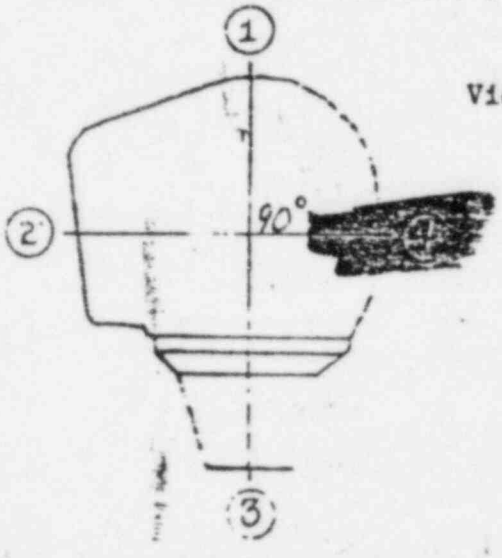
Curies & Date _____

Manufacturer's name & model # teletherapy unit _____

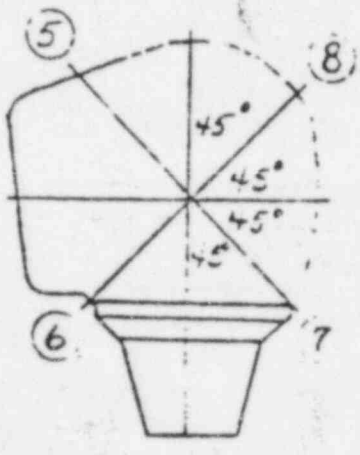
Top View - Showing orientation of Views A through D



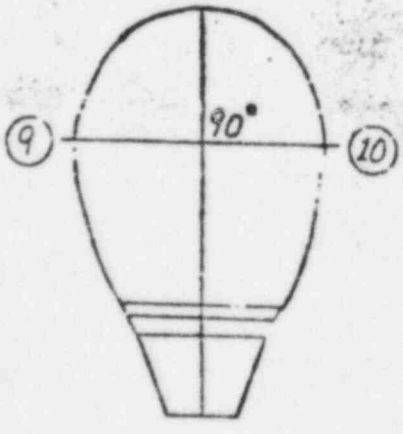

View A - Vertical from left side



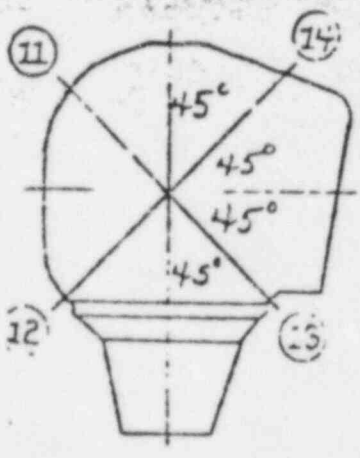

View B - Vertical from left-front




View C - Vertical from front




View D- Vertical from right-front



SSINS No.: 6830
Accession No:
8006190078
IN 80-33



UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

September 15, 1980

IE Information Notice No. 80-33: DETERMINATION OF TELETHERAPY TIMER ACCURACY

Description of Circumstances:

New requirements for full calibration and spot-check measurements of teletherapy units in §§35.21 - 35.25 of 10 CFR Part 35 became effective on July 9, 1979. One of the determinations required is "timer accuracy" [§§35.21(b)(4) and 35.22(b)(1)]. Recent inspections conducted by the U.S. Nuclear Regulatory Commission (NRC) have determined that many licensees and consultant physicists have misunderstood this requirement. The purpose of this information notice is to clarify the meaning of "determination of timer accuracy (i.e., timer error)" as used in these regulations.

There is a finite error in source output measurements due to the time required for the source shutter mechanism to travel from the full "off" to full "on" condition and return. This error may be positive or negative, depending on when the timer movement starts with respect to source travel. It is the determination of this "timer error" that is required in the regulations as part of full calibrations and monthly spot-check measurements. The timer error, once determined, may be corrected by adding its value (positive or negative) to the treatment time or exposure time during calibrations and spot-check measurements. Omission of this correction may introduce substantial error into short irradiations. Further, a significant change in timer error from month to month may indicate a timer malfunction or source movement mechanism failure or both.

The timer error and acceptable methods for its determination are described in detail in §4.14 of ANSI Standard N449.1-1978*. Comparison of the console timer with a stopwatch is not an acceptable substitute for this determination.

ACTION TO BE TAKEN BY LICENSEES:

Full calibration and spot check measurements performed on your teletherapy unit should include the determination of timer error as described above.

This information notice should be brought to the immediate attention of the qualified expert (10 CFR Part 35.24) performing these calibrations and measurements.

No response to this information notice is required. If you need additional information regarding this matter, contact the Fuel Facility and Material Safety Branch of the appropriate NRC Regional Office.

* Copies of ANSI Standard N449.1-1978 may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

File notes:

5-01-84 Call to Jack Krohmer (313) 494-4742 from Norman McElroy

1. Is it ok to continue treating patients if the teletherapy television breaks? All have backup, but leave decision to the doctor.
2. Where should collimators in a teletherapy head be during head leakage survey? With them open, typically 20x20, but I've seen only one case where there was a difference.
3. Do you use a large area ionization chamber for measurements? 100cm$^2$ is about the area of some meter detectors, for example the cutie pie. You must use an ionization chamber because of the energy dependence of GM meters. See NCRP 57 (para. 3.2.4.1).

5-04-84 Note to Norman McElroy from John Klucsik, ELD

I've run out of time [resigning shortly]. Dorian [ELD] will take over. He very well may suggest decoupling the licensing from the operating rule and expanding the licensing section to a subpart which really describes what we want to see from the licensee--probably incorporating much from reg guide. I can't say I disagree w/ that approach but it has been more than I've been willing to push for at this time. Tom [Dorian] believes there may be a legal problem w/ not telling the applicant more than we do in regs. but that is an indictment of virtually all NRC regs. as well.

I'll call you once I get settled Thanks for your cooperation John

6-13-84 Call to Dorian from Norman McElroy

I talked with Dorian ELD re new Part 35 section on licensing.

D: not a whole new subpart, jsut a list of the steps involved in getting a license. Should be in reg, but can go in preamble or reg guide. nlm: I'll write up a para for preamble. If you want to press the issue we'll handle it during comment period. I have to turn in a schedule. D: should be longer than a para, but ok. nlm 6-13-84

Telephone call Harriet Karagiannis IE from Norman McElroy 9-18-84

11.5 SY = 24684 hr/FY Inspection time (does not include travel, but some include travel time in this). 800 med insp./FY (40%) 2000 total insp. 30 inspectors 32% of time to be spent out of office (travel. prep, @ site) yields

7680 hr field time for all inspections, about 3200 hr field time for medical, about 640 hr (20%) reviewing paper

See forms 766 for details (filled out by inspector, has time, code, enf. action, etc.; but computer staff is backlogged, therefore unavailable)

nlm 8 22 85

March 10, 1983

Debbie, Bill:

re dose calibrator, ANSI N42.13-1978 ". . .Calibration and usage of dose calibrator. . ." is the latest edition available as of today (I called their sales department).

re Vacca item 4

1. S 4.3 says "Suitable standard sources . . .shall be used for routine calibration. . ."; it makes no mention of the suitable activity of those sources.

2. S 4.5.1 suggests use of 100 to 200 uCi 137Cs and 1 to 5 mCi 57Co for "regular testing" (read "daily check"). The S would require a check on each work shift.

3. S 4.6.1 says, for a source hotter than 100 uCi, the instrument should be accurate within 10%. "Accuracy of measurements. . .below 100 uCi may not fall within the ±10% limits and should be determined for each instrument. . ." This S recognizes that the instrument may not perform well below 100 uCi. The S does not require the use of a 100 uCi source for the accuracy test. [redacted] If the instrument is accurate below 100 uCi and is linear over the range of use (most do and are, at least every one I have seen), there is no measurement problem.

4. S 6.2 recognizes that non-linearity problems may be encountered above 100 uCi. A discussion of non-linearity below 100 uCi is conspicuous in its absence.

5. I think the coupling of the linearity test in S 35.50 with the accuracy test therein is sufficient to show accurate measurements.

6. I think the commenter has misinterpretted the standard.

nlm

nlm

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| OFFICE ▶ | | | | | | | |
| SURNAME ▶ | | | | | | | |
| DATE ▶ | | | | | | | |

NRC FORM 318 (10-80) NRCM 0240

OFFICIAL RECORD COPY

AA73-1
PDR
B.6

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

July 13, 1982

NOTE TO: Deborah Bozik, HEBR
Norman L. McElroy, OPBR

FROM: John F. Klucsik, OGC JFK

SUBJECT: NEED FOR EXEMPTION FROM § 20.105 IN PROPOSED § 35.75

You have asked whether the proposed Part 35 requires an exemption from and a conforming change to § 20.105. Other portions of Part 20 make an exemption and conforming amendment unnecessary.

The proposed § 35.75 would require that medical licensees not authorize the release of radioactive patients until the exposure rate from the patient is less than 5 milliroentgens per hour at a distance of one meter. Section 20.105 provides that no licensee shall use or transfer byproduct material (except in accordance with specific license conditions) if the use or transfer results in a radiation level of 2 millirem per hour in an unrestricted area.

The administration of byproduct material to a patient is a use or transfer of byproduct material. The administration of byproduct material to a patient may result in radiation levels greater than 2 millirem per hour in unrestricted areas if:

1) the source is of high enough activity; and

2) the licensee cannot guarantee the patient's confinement

Under these conditions, administration of byproduct material to a patient would be prohibited by § 20.105 unless another regulation exempts such administration from the operation of § 20.105. Section 20.107 does this. It provides that nothing in Part 20 shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical treatment.

Since § 20.107 removes administration of byproduct material to patients from the scope of § 20.105 (at least as regards administration to patients who subsequently leave

confinement against medical advice), no exemption from § 20.105 is needed in the proposed revision of Part 35. Neither is any conforming amendment needed.

If possible, you should conform the units of radiation dose used in the proposed § 35.75 (milliroentgens) with those used in § 20.105 (millirems). You may wish to explain in the preamble the choice of 5 milliroentgens in § 35.75 in contrast with the 2 millirem standard of § 20.105.

AA73-1
PDR
B.7

By telephone
November 1982

# RESULTS OF IN-VIVO GENERAL LICENSE SURVEY

| | | |
|---|---|---|
| Doing in-vivo studies under NRC 482 | 5 | (8.6%) |
| No longer using tracers | 13 | (22.4%) |
| Using under other NRC license | 18 | (31%) |
| Could not locate or contact | 13 | (22.4%) |
| No longer at hospital | 4 | (6.8%) |
| Retired/deceased/out of business | 4 | (6.8%) |
| Other | 2 | (3.4%) |
| TOTAL | 58 | |

Manufacturers:

| | |
|---|---|
| Abbott | 3 |
| Mallinckrodt | 4 |
| Squibb | 2 |
| Amersham | 1 |
| Nuclear Pharmacies (manufacturers of kits not known) | 3 |

Each tenth registrant was telephoned.