1. ATTACHED IS A PART 21 REPORT FROM IE MAIL UNIT - ROOM 359 E/W

PART 21 IDENTIFICATION NO. 80-247-000 COMPANY NAME Atomic Energy of Canada Limited

DATE OF LETTER 7/3/80 DOCKET NO.

DATE DISTRIBUTED 7/15/80 ORIGINAL REPORT [X] SUPPLEMENTARY [ ]

DISTRIBUTION:

REACTOR (R) [X]

IE FILES
AD/ROI (2)
AD/RCI (2)
REGIONS I,II,III,IV,V
VENDOR BR. R-IV
LOEB / MPA MNB 5715
AEOD MNB 7602
NRR/DOE
NRR/DSI
NRR/DST
NRR/DOL
CENTRAL FILES 016
CENTRAL FILES (CHRON)
PDR
LPDR
TERA

FUEL CYCLE & MATERIALS (MD [ ]

IE FILES
AD/FFMSI
REGIONS I,II,III,IV,V
VENDOR BR. R-IV
NMSS / FCMS SS-396
LOEB / MPA MNB 5715
AEOD MNB 7602
CENTRAL FILES 016
CENTRAL FILES (CHRON)
PDR
LPDR
TERA

SAFEGUARDS (S) [ ]

IE FILES
AD/SG
AD/ROI
REGIONS I,II,III,IV,V
VENDOR BR. R-IV
NRR/DOL
NMSS / SG SS-881
LOEB / MPA MNB 5715
AEOD MNB 7602
CENTRAL FILES 016
CENTRAL FILES (CHRON)
CENTRAL FILES SS-396
PDR
LPDR
TERA

ACTION:

PRELIMINARY EVALUATION OF THE ATTACHED REPORT INDICATES LEAD RESPONSIBILITY FOR FOLLOWUP AS SHOWN BELOW:

IE [X] NRR [ ] NMSS [ ] OTHER [ ]

RCI
ROI
SG
FFMSI

8007240391

REV: 7/9/80

Atomic Energy of Canada Limited
L'Énergie Atomique du Canada, Limitée

Commercial Products
Produits Commerciaux

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FILE: Q2.9.3
QA80-7-129

REGISTERED MAIL

1980 July 3

80-247-000

Director,
Office of Inspection & Enforcement
U. S. Nuclear Regulatory Commission
Washington, D. C., 20555
U.S.A.

Dear Sir:

- 10 CFR 21 NOTIFICATION -
REPORTED INCIDENTS
ON AECL-CP TELETHERAPY UNITS

In accordance with the requirements of 10 CFR 21.21, we have to notify you that there have been reports of unplanned exposures occurring in the U.S.A. involving the radiation field defining light system on Theratron 60, Theratron 80, Eldorado 6 and Eldorado 8 teletherapy units manufactured by Atomic Energy of Canada Limited (AECL-CP). These incidents have been previously reported to both the USFDA and USNRC.

AECL-CP is currently beginning a "firm initiated medical device recall action" which will resolve this problem.

Details of this 10 CFR 21.21 notification are as follows:

(i) INFORMANT

Eric F. Ridout, Manager
Regulatory Affairs Branch,
Quality Assurance Division,
Atomic Energy of Canada Limited,
Commercial Products, (AECL-CP),
P. O. Box 6300
Ottawa, Ontario, Canada

Telephone: (613) 592-2790
Telex: 053-4162

(ii) IDENTITY OF EQUIPMENTS INVOLVED

Affected equipment models are:

Theratron '60', Theratron '80',
Eldorado '6', Eldorado '8'.

(iii) MANUFACTURER

Atomic Energy of Canada Limited,
Commercial Products

Address as in Item (i)

(iv)(a) NATURE OF DEFECT

Affected sub-system is the radiation field light system assembly consisting of source drawer light housing, electrical cord guide roller, keeper screw and cord reel.

Reports of malfunctions essentially describe interference with free source drawer movement into a shielded position at termination of the prescribed radiation exposure period on timer.

(iv)(b) SAFETY HAZARD

Alleged unplanned radiation exposure of technologists and patients under treatment, at termination of prescribed treatment cycle and during performance of subsequent emergency procedures.

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(v) DETAILS OF REPORTS OF ALLEGED UNPLANNED EXPOSURE

(1) Reported by BRH, FDA via USP Problem Report 35622 - - Eldorado 8, Serial #75, located at Baptist Memorial Hospital, Memphis, Tennessee. Reported to have occurred on or around 10 January, 1980, Originally reported to Informant on 3 March, 1980.

(2) Reported by BRH, FDA via USP Problem Report 36033 - - Theratron 80, Serial #152, located at Wausau Hospital Center, Wausau, Wisconsin. Reported to have occurred on or around 17 March, 1980. Originally reported to Informant on 25 April, 1980.

(3) Reported by BRH, FDA via USP Problem Report 36031 - - Theratron 80, Serial #222, located at Georgetown University Hospital, Washington, D. C. Reported to have occurred on or around 27 March, 1980. Originally reported to Informant on 25 April, 1980.

(4) Reported by BRH, FDA via USP Problem Report 1-80-56- - Theratron 80, Serial #124, located at Medical Center of Princeton, Princeton, New Jersey. Reported to have occurred on or around 9 April, 1980. Originally reported to Informant on 25 April, 1980.

(5) Reported by USNRC via telephone - - Theratron 80, Serial #118, located at Bridgeport Hospital, Bridgeport, Connecticut. Reported to have occurred on or around 18 June, 1980. Reported to Informant on 19 June, 1980.

(6) Reported by USNRC via telephone - - Theratron 80, Serial #385, Located at Charlotte Hungerford Hospital, Torrington, Connecticut. Reported to have occurred on or around 18 June, 1980. Reported to Informant on 19 June, 1980.

(iv) NUMBER AND LOCATION OF AFFECTED UNITS

Our current records indicate the following populations of affected units in the U.S.A.:

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Theratron '60'	- -	26 units
Theratron '80'	- -	239 units
Eldorado '6'	- -	46 units
Eldorado '8'	- -	54 units
Total Population	=	365 units

A detailed list of affected units, by model and location, was lodged with BRH, FDA on 26 June, 1980.

(vii) REMEDIAL ACTION - CURRENT AND PROPOSED

(1) All users of record of the affected units were advised (by registered mail) via Medical Device Warning Notice WN-80-1 (dated 20 June, 1980), of the status of the recall i.e. details of units possibly affected, the nature of the problem, the potential consequences, recommended immediate inspections to be undertaken by the user, a request for unit information from the user to assist AECL-CP in establishing all failure modes which may be evident, and inclusion of a modified Critical Components replacement schedule for certain light system components.

(2) AECL-CP is currently conducting a full engineering investigation into these problems. Both BRH, FDA and USNRC are being kept informed of actions and further developments.

Field modifications proposed by AECL-CP with a staggered schedule for completion in two stages are currently under examination by the authorities.

(3) Our engineering assessment should be completed by 25 July, 1980, or thereabouts. At that time the recall plan should be complete and submitted to the authorities for approval during the latter part of July, 1980.

As soon thereafter as is possible, supplementary Recall Notices will be issued to all users of record to advise them of the results of the investigation, more details of the approved remedial action and an overall completion schedule for implementation in two stages.

(4) AECL-CP is responsible for the recall action.

(5) For discussion of schedule see preceding item (2).

(viii) ADDITIONAL ADVICE TO USERS

No further advice to users is anticipated until completion of the engineering assessment of the overall problem. In the meantime users have been advised (WN-80-1) to contact our local Service Centre for emergent service if required.

We trust this Notification meets the intent of the Regulations under 10 CFR 21. Since certain important facets of the recall plan are still to be established, (e.g. final design and procedures) we shall keep you informed of developments in this regard.

If we can be of further assistance to you in these matters please contact this office at your convenience.

Yours sincerely,

E. F. Ridout, Manager
Regulatory Affairs Branch,
Quality Assurance Division

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