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

PART 21 IDENTIFICATION NO. 80-264-000 COMPANY NAME Atomic Energy of Canada Ltd.

DATE OF LETTER 7/28/80 DOCKET NO.

DATE DISTRIBUTED 7/31/80 ORIGINAL REPORT [X] SUPPLEMENTARY [ ]

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ACTION:

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

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

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8008070008

REV: 7/9/80

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80-264-000

FILE: Q2.9.3
QA80-7-426

REGISTERED MAIL

1980 July 28

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

Dear Sir:

- 10 CFR 21 NOTIFICATION -
DISCOVERY OF POTENTIAL HAZARD
ON AECL-CP TELETHERAPY UNITS

In accordance with the requirements of 10 CFR 21.21, we have to notify you of additional failure modes which have been discovered during design testing of the radiation field defining light systems currently used on Theratron 60, Theratron 80, Eldorado 6 and Eldorado 8 teletherapy units manufactured by Atomic Energy of Canada Limited, Commercial Products (AECL-CP). Certain failure modes and potential consequences associated with these components were previously reported to the USFDA and USNRC via our 10 CFR 21 Notification to USNRC dated 3 July, 1980.

As you are aware, AECL-CP is currently planning a "firm initiated medical device recall action" to resolve the original problems indicated in the earlier Notification. Corrective action for the additional problems has still to be determined.

Details of this 10 CFR 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

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(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 a source drawer light housing, electrical cord guide roller, keeper screw, cord reel and front drawer stop bar.

Laboratory tests (in process on 26 July, 1980) of the current design in use on the aforementioned units indicated that if a cord reel were to fail, the source may be prevented from reaching the fully on position by up to 3 cm. This condition may not readily be detectable by the operator.

(iv)(b) SAFETY HAZARD

The quality, quantity, and direction of the useful beam would be deteriorated if this malfunction should occur. In this event the beam delivery system may become non-compliant and this could lead to inadvertant mis-administration of the prescribed treatment.

(v) DETAILS OF REPORTS OF ALLEGED UNPLANNED EXPOSURE

The reported malfunctions occurred during laboratory testing by AECL-CP of the system design at its Ottawa facilities on 26 July, 1980.

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(vi) NUMBER AND LOCATION OF AFFECTED UNITS

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

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

(a) No remedial action for this latest malfunction has been determined to date. These matters are to be discussed at a planned meeting of AECL-CP personnel with representatives of USFDA and USNRC in Rockville, Maryland on 30 July, 1980.

Remedial actions and schedules, designed to deal with malfunctions described in the 3 July, 1980, Notification, are now subject to review and adjustment since this latest discovery is intimately related. Accordingly, planned field trials and corrective actions on a production basis have been abandoned until further notice.

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

We trust this Notification meets the intent of the Regulations under 10 CFR 21. Since certain important facets of a new 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

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

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