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

Commercial Products
Produits Commerciaux

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TERA

File: Q2.9.3.
QA79-11-334
1979 November 14

79-169-000

Mr. Ernst Volgenau, Director,
Office of Inspection and Enforcement,
US Nuclear Regulatory Commission,
Washington, D.C.,
USA 20555

Dear Mr. Volgenau:

Re: -10 CFR21 Notification-
^{60}Co Beam Teletherapy Equipment

In accordance with 10 CFR21.21, we have to advise you of an incident which is reported to have occurred on November 6, 1979 during clinical use of an AECL-CP beam teletherapy unit located in the USA.

The details of this incident, as we understand them, are as follows:

(1) Informant

Mr. Bruce Curran
Tufts University School of Medicine,
New England Medical Centre Hospital (NEMCH),
Department of Therapeutic Radiology,
171 Harrison Avenue,
Boston, Mass. 02111

(2) Identity of Facility

Model Theratron 80, ESE-Type 2, Teletherapy Unit,
Serial No. 232A.

(3) Facility Location

Same as Item (1)

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168 121

7912180 075

(4) Radioactive Material Type and Content

Type C-146, Serial No. 52406, sealed source. Activity in the form of cobalt metal pellets. Source contains 5600 Ci ^{60}Co (92.4 Rmm ICRU) as measured in our laboratories on August 5, 1975.

(5) Facility Use

Treatment of cancer in humans.

(6) Irradiation Equipment and Source Manufacturer

Atomic Energy of Canada Limited,
Commercial Products, (AECL-CP),
P.O. Box 6300, Station J,
Ottawa, Ontario K2A 3W3

(7) Nature of Reported Incident

Source exposure mechanism malfunction.
A copy of the Licensee's incident report, dated November 6, 1979, is attached for your examination.

(8) AECL-CP Investigation and Findings

The incident was reported to AECL-CP on November 8, 1979 (P.M.).

The report was promptly investigated by our Product Hazards Committee and its findings were as follows:

(a) The report cited an intermittent failure of an electrical relay (designated K-BON) as being the cause of the initial malfunction of the source exposure mechanism.

(b) Continued use of the equipment led to a "frozen" condition and permanent failure of the relay.

(c) The exposure mechanism "failed safe" during the initial observations of the malfunction, i.e., the source was automatically returned to the safe storage position after each intermittent failure or it was prevented from moving into the exposure position when exposure was initiated by the operator.

(d) The installed emergency stop system and power cut-off systems functioned properly at all times.

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(e) The Licensee has diagnosed a cause for failure of the system and has implemented corrective action. This action consisted of replacing the defective relay (K-BON) with an "extra heavy duty relay and several other small components".

(f) AECL-CP acknowledges that relay K-BON, and other relays, can fail. It has not been established whether the mode of relay failure as reported, refers to welded contacts or mechanical failure of relay components.

(g) AECL-CP service records indicate that the relay under consideration has likely been in service since the equipment was commissioned in early 1970. If this is the case, then this relay is estimated to have performed in excess of 8×10^4 cycles during its useful lifetime; this estimate is based on typical usage of 2000 hours/8000 treatments per clinical year.

(h) A re-examination of the design specifications confirms that the relay meets the required performance criterion. However, in view of the reported incident, AECL-CP is redesignating relay K-BON as a critical component. The recommended replacement interval is to be specified as two years (typical usage 4000 hours/16,000 treatments) with replacement service to be performed by the user (in accord with instructions provided by AECL-CP).

(i) The total population of Theratron 80, ESE-Type 2, units currently in clinical use world wide is six (6). Of these, three (3) are located in the USA;

- Serial 172A
  Southeast Missouri Hospital
  Cape Girardeau, Missouri 63701

- Serial 211A
  Magee Women's Hospital
  Pittsburgh, Pennsylvania 15213

- Serial 232A
  New England Medical Centre
  Boston, Massachusetts 02111

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(9) AECL-CP Follow-up Action

(a) A request has been forwarded to NEMCH for complete details of their corrective actions. These will be evaluated by AECL-CP on receipt .

(b) A "User Bulletin" is being prepared to advise all users of the affected equipments that relay K-BON has been designated as a critical component with a recommended replacement interval of two (2) years. Notification to users is expected to be complete by November 21, 1979.

We trust this Notification and the actions undertaken by AECL-CP meet with your approval. If we can be of further assistance to you in this regard, please contact the writer at your convenience.

Yours truly,

E.F. Rideout,
Product Licensing Officer,
Quality Assurance Division.

/cpg
Encl.

TUFTS UNIVERSITY SCHOOL OF MEDICINE · NEW ENGLAND MEDICAL CENTER HOSPITAL

DEPARTMENT OF THERAPEUTIC RADIOLOGY
MEDICAL PHYSICS DIVISION

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AREA CODE 617 956 6171

MEMORANDUM

TO: E.S. Sternick

FROM: Bruce Curran

DATE: November 6, 1979

Rec'd P.M. T80-232A
8 NOVEMBER, 1979
BBC

SUBJECT: Source Mechanism Failure 6 Nov. 79

At 8:30 A.M. intermittent failures were observed in the source mechanism for Cobalt-1 (S.N. 232). These failures included occasional source retractions, and failures of the source to leave its safe position. At this time, the unit was checked by myself and the shut-down relay replaced. The operation of the unit was checked, found to be normal, and re-instated to service. At approximately 9:30, a similar source failure occured. At this time, pressure sensing elements were tested and adjusted to manufacturer's specifications. The operation of the unit was again tested, found satisfactory, and returned to patient service.

At 11:00 A.M. a third failure occurred. At this time, the unit was permanently removed from service and extensive diagnostic testing was done to locate the problem. Approximately one hour later, during a test of the shutdown/safety system, the source extended immediately upon turning the unit on, rather than after a treatment initiate signal. This type of failure continued until air pressure in the system became so low that pressure over rides prevented the source from leaving its safety position. (NOTE: At all times, both emergency and power cut-offs did cause the source to retract, however door and timer interlocks had no effect).

The incident was finally traced to a defective relay K-BON, which is controlled by the time/interlock logic to initiate and halt treatment periods. This relay had been "frozen" in the "ON" state, causing the source mechanism to permanently initiate the source extension cycle. An extra heavy duty replacement relay was obtained from a local electronics distributor and several small components were also replaced to prevent any further failures to the system. The unit was again tested, and seems this time to be operating correctly.

In review of the operation of the system, there is no method whereby the system verifies the logic's definition of the operating state vs. the actual operating state. The operator can verify the state by observing

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either the BEAM ON/OFF indicators or the radiation monitors, but no feedback system is used for the system to shut itself off in case of failures such as occurred today. These points will be discussed with AECL service personnel to determine possible changes in system design to prevent any future recurrences.

DHC:lfm

cc: F. Thomas
F.X. Masse
L.F. Downes (A.E.C.L. Service Manager)

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