

AUG 15 1977

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Neutron Products, Inc.  
ATTN: Mr. Marvin Turkanis  
Vice President  
22301 Mt. Ephraim Road, Box 68  
Dickerson, Maryland 20753

Gentlemen:

Subject: Inspection 77-01

This refers to the inspection conducted by Mr. B. O'Neill of this office on August 5, 1977, at the Chester County Hospital, West Chester, Pennsylvania, of activities authorized by NRC General License, and to the discussions of our findings held by Mr. O'Neill with Mr. J. Fogle of your staff at the conclusion of the inspection.

The inspection was an examination of activities conducted under your NRC General License as they relate to compliance with the NRC's Regulation 10 CFR 150 "Exemptions and Continued Regulatory Authority in Agreement States under Section 274." The inspection consisted of selective examinations of procedures, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Within the scope of this inspection, no items of noncompliance were observed.

In accordance with Section 2.790 of the NRC's "Rules of Practice", Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room.

No reply to this letter is required; however, should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Robert O. McClintock, Chief  
Materials Radiological Protection  
Section

9212100154 920504  
PDR FOIA  
MOUTVIC92-93 PDR

OFFICE	MRPS-PPMS	MRPS-PPMS				
SURNAME	O'Neill:kk	McClintock				
DATE	8/12/77	8/12/77				

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Neutron Products, Inc.

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AUG 15 1977

bcc:

IE Mail & Files (For Appropriate Distribution)

Central Files

Public Document Room (PDR)

Local Public Document Room (LPDR)

Nuclear Safety Information Center (NSIC)

REG:I Reading Room

State of Maryland

Commonwealth of Pennsylvania

Office of State Programs (OSP)

OFFICE▶						
SURNAME▶						
DATE▶						

# DATA SHEET

10 CFR PART 21 REPORT IDENTIFICATION AND  
RECORDING OF IE ACTIONS

PART 21 IDENTIFICATION NO. 77-020-000		DATE	
NAME(S) OF LICENSEE(S), VENDOR(S) PERSON(S) OR OTHER ORGANIZATION(S) Atomic Energy of Canada Limited REPORTING			
GENERAL SUBJECT OF REPORT Improperly marked source and source drawer			
DATE OF INITIAL NOTIFICATION (48 HOUR REPORT)		DATE(S) OF PART 21 REPORT(S), (5 DAY & SUPPLEMENT) 12/5/77	
FACILITY(IES) INVOLVED: Hoffman and Birmingham and Associates 40 Clay Street Tiffin, Ohio 44883			
RESPONSIBLE IE ORGANIZATION(S)		FF&MSI 1 SI RCI ROI	
LEAD = 1 SUPPORTIVE = 2			
IE ACTIONS -- CHECK OR PROVIDE DATA AS APPROPRIATE			
LIST OTHER NRC OFFICES INFORMED			
DISCUSSED WITH INITIATOR? DATE:	YES	NO	REPORT IS REQUIRED UNDER PART 21?
		X	
REQUEST MADE FOR ADDITIONAL INFO? DATE RECEIVED:		X	INQUIRY?
PRESS RELEASE(S)		X	INSPECTION?
REFERRED FOR POTENTIAL A/O (MC 1110) DATE:	X		INVESTIGATION?
TRANSFERRED TO OTHER NRC OFFICE?	X		ENFORCEMENT?
BULLETIN ISSUED? NO.		X	CORRECTIVE ACTION TAKEN?
DATE OF CLOSEOUT:			CIRCULAR ISSUED? NO.
CLOSEOUT M AOD: Transferred to Office of State Programs. +			
IE REPORT NUMBERS: Letter from H. J. Moe to W. L. Fisher dated January 25, 1978			
DATE OF FINAL REVIEW & DISTRIBUTION: (XOOS)			
ADDITIONAL COMMENTS: * Transferred to Office of State Programs for action. See enclosed memo from from L. J. Cunningham to G. Wayne Kerr dated Feb. 3, 1978. ** IE recommended the State of Maryland investigate the operations of Neutron			

(Use other side of form if additional space is required)

Products, Inc. since several potential items of noncompliance were identified during IE's Part 21 review. See page 3 of the enclos Jan. 25, 1978 memo to W. L. Fisher from H. J. Moe regarding potential items of noncompliance.

December 5, 1977

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

11. 12-12-77

77-512-500 (16)

December 5, 1977

Mr. Ernst Volgenau, Director,  
Office of Inspection & Enforcement,  
U.S. Nuclear Regulatory Commission,  
WASHINGTON, D.C.  
U.S.A. 20555

Dear Mr. Volgenau:

- 10 CFR 21 NOTIFICATION -  
TELETHERAPY UNIT SOURCE AND SOURCE DRAWER  
NON-COMPLIANT COMPONENTS

In accordance with the requirements of 10 CFR 21.21, we have to advise you of an incident which has occurred in the State of Ohio. The incident, as reported, involved the use of non-compliant components during source replenishment operations which were conducted on a Theratron C-II teletherapy unit.

The identity of the equipment, and evidence of non-compliance are as follows:

1. Informant

Eric F. Ridout,  
Product Licensing Officer,  
Atomic Energy of Canada Limited,  
Commercial Products,  
P.O. Box 6300,  
Postal Station "J",  
OTTAWA, Ontario, CANADA  
K2A 3W3

2. Identity of Equipment and Licensee of Record

AECL-CP Model Theratron C-II, Serial No. 4.  
Licensee of Record is Hoffman and Birmingham  
and Associates.

Facility Location

Hoffman and Pincus, Inc.  
40 Clay Street,  
Tiffin, Ohio, U.S.A. 44883.

Radioactivity Content of Facility

Currently unknown. It is believed that this equipment has now been relocated in Buenos Aires, Argentina.

5. Facility Use

T-

Teletherapy treatment of humans.

6. Teletherapy Equipment Manufacturer

Atomic Energy of Canada Limited,  
Commercial Products,  
P.O. Box 6300,  
Postal Station "J",  
OTTAWA, Ontario, CANADA  
K2A 3W3

7. Nature of Non-Compliance

AECL-CP undertook to provide a Model F-131 transfer and shipping flask to General Electric Company (our Representatives in the USA), Medical Systems Division, Brooklyn Heights, Ohio, 4431. The flask was used to remove an active radiation source with source drawer from Model Theratron C-II, Serial No. 4, sited at this location. The radiation source in flask was shipped to AECL-CP in Ottawa for disposal.

On examination of the source and drawer in our hot cells, evidence was discovered which leads us to strongly suspect that a non-compliant condition has been in existence on this equipment from early 1973 up to the time of source removal by General Electric (Richard Miller, Service Technician, GE, Toledo office) in September, 1977.

The AECL-CP hot cell laboratory supervisor's report includes the following data:

- (a) The radiation source was not properly identified with the manufacturer's name or symbol.
- (b) The source serial number (engraved on surface of source capsule) was recorded as T-4247.
- (c) Source contained activity, as of August, 1977, was approximately 1200 curies of Cobalt 60.



The source drawer, located in the equipment, was clearly stamped on the front and with the identification mark "UNSHIELD". A simple visual and physical survey of the drawer indicated that it contained no uranium shielding components at all.

- (e) The origin of the radiation source and source drawer cannot be established from either of these components. The source drawer resembles an AECL-CP standard tungsten shielded source holder design, but the engraved identification normally present on these drawers has been deliberately erased.
- (f) This source and drawer were not installed in this equipment by AECL-CP. The identity of the installer is not known.

It is assumed that this source and drawer assembly was installed around March, 1973. From the facts available to us, we estimate that the contained activity at the time of installation was approximately 2150 curies of Cobalt 60.

Our PQA radiation survey records indicate that the maximum radiation capacity of Theratron C-II, Serial No. 4, is =28 Rmm (ICRU) utilizing an AECL-CP standard tungsten drawer or =43 Rmm (ICRU) utilizing an AECL-CP optional uranium drawer.

Using our nominal source content-to-output ratio of 67 curies of Cobalt 60/Rmm (ICRU) then the capacity outputs specified above translate to 1876 curies of Cobalt 60 and 2881 curies of Cobalt 60 respectively. We therefore conclude that, since an incorrectly marked tungsten drawer was evidently used to contain this source from the time of installation in 1973, then the sourcehead may have been used in an overloaded condition (in terms of head leakage) for up to one year of its useful life.

#### 8. Source of Information

AECL-CP hot cell supervisor's report, dated 30 November, 1977, and P.Q.A. radiation head survey records.

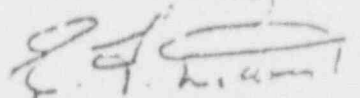
December, 1971

Remedial Action to Prevent Re-occurrence of This

None required by informant; this case is under USNRC jurisdiction and is subject to their confirmation of the facts presented.

The source and drawer under consideration have been impounded by AECL-CP pending the results of the USNRC investigation and notice of release for disposal.

Yours truly,



E.F. Ridout,  
Product Licensing Officer,  
Product Quality Assurance.

/cg

cc. Mr. James M. Howard, II,  
CEC, Milwaukee, Wisconsin