

U. S. NUCLEAR REGULATORY COMMISSION  
REGION I

Report No. 030-29300/90-01

Docket No. 030-29300

License No. 20-12836-01 Priority 1 Category B

Licensee: Amersham Corporation  
40 North Avenue  
Burlington, Massachusetts 01803

Facility Name: Amersham Corporation

Inspection At: Burlington, Massachusetts

Inspection Conducted: September 13, 1990

Inspectors:

[Signature] 11/15/90  
date  
for Thomas K. Thompson,  
Senior Health Physicist

[Signature] 11/15/90  
date  
John R. White, Chief, Nuclear Materials  
Safety Section C

Approved by:

[Signature] 11/15/90  
date  
John R. White, Chief, Nuclear Materials  
Safety Section C

Inspection Summary: Routine Unannounced Inspection conducted September 13, 1990  
(Inspection Report No. 030-29300/90-01).

Areas Inspected: Routine unannounced inspection covering use of materials;  
facilities and equipment; exposure control external; exposure control-internal;  
shipping; training; and a review of the Licensee's actions from the March, 1990,  
Korean source incident.

Results: No violations were identified.

## DETAILS

### 1. Persons Contacted

\*William McDaniel - Corporate Manufacturing Manager  
\*Cathleen Roughan - Radiation Safety Officer (RSO)  
John Graziadei - Radiation Safety Specialist

\*Present at exit interview.

### 2. Use of Materials

The Licensee's inventories of Ir-192, Co-60, and Cs-137 are up to date and indicate that possession limits have not been exceeded.

No violations were identified.

### 3. Facilities and Equipment

The Licensee's facilities are unchanged. Plans are to reorganize the shipping and receiving area to lower exposures to personnel who work in the area.

Equipment problems and defect reports to NRC were discussed with the (RSO). The licensee provided the following information:

The Licensee has completed all actions proposed in their September 27, 1989 telefax to NRC with regard to the Genesis Chain defect in the Model 920 exposure devices. The Licensee believes they understand the failure mechanism; and that through careful inspection utilizing dye penetrant test and the establishment of a useful life for the device, further failures will be prevented. All domestically distributed chains have been inspected to date.

The Licensee has proposed modification to the 899 Model source assembly which was reported to have had a defect in a letter to NRC dated June 30, 1989. On June 18, 1990 the Licensee requested a revision to the NRC source and device registry for the Model 899 source assembly to increase the hardness of the connector and to increase the wall thickness of the connecting pin. The Licensee no longer manufactures the 899 source assembly in its original design. New assemblies are manufactured with the revisions. The Licensee has also distributed "go-no-go gauges" to their customers with instructions for checking the wear on the connector assemblies prior to use. Gauges were distributed by June 19, 1990.

The Licensee has not completed their evaluation of the Model 861 connector defect reported to NRC in their letter dated March 7, 1990. The Licensee indicated that they are considering the machining of this connector rather than the present method of casting. The Radiation Safety Officer committed to send a written followup report upon determining an effective corrective measure.

A review of actions taken by the Licensee to assure proper swaging of sources to their cables as described in their letter to NRC dated April 7, 1989 was completed. The Licensee's color coding of swaging dies was verified and the procedure was observed.

No violations were identified.

4. Exposure Control External

No records of overexposures were noted for the years 1989 and 1990 through July. In 1989 the highest total whole body exposures was 2060 millirem. In 1990 through July the highest whole body exposure was 1400 millirem. Six individuals exceeded 1000 millirem whole body exposure as a total in 1989.

The source fabrication general area measured approximately 5 millirem per hour with an NRC Ludlum Model 14C GM meter. The waste storage area adjacent to the source fabrication area measured 40-50 millirem per hour in the general area. The area was posted and controlled in accordance with regulatory requirements.

No violations were identified.

5. Exposure Control Internal

Protective clothing were observed to be properly worn in the source fabrication area. The Licensee continues to maintain their contamination monitoring equipment at the exit to the fabrication area. The Licensee indicated wipe testing of sources and the laboratory area continues to be performed as previously described. No loose surface radioactivity was apparent. Air sampling protocols appeared to be adequate.

No violations were identified.

6. Shipping

The Licensee's procedures for preparation of shipping containers were observed. The RSO indicated that two individuals check each prepared package following the checklist (see Enclosure 1). A third individual from the quality assurance staff audits the procedure. Packages prepared that day appeared to include all the required information, including proper posting and labelling.

No violations were identified.

## 7. Training

The Licensee has increased the number of individuals qualified to perform source fabrication. A point system is utilized to assess level of achievement that individual technicians have attained (see Enclosure 2). Individuals observed and interviewed in the source fabrication area were knowledgeable of the radiological hazards associated with the task and took proper precautions, and adhered to operating procedures.

No violations were identified.

## 8. Review of Licensee Actions Resulting from Korean Source Incident

### Background

On March 8, 1990, the Licensee received a shipment of fourteen Model AI 500 SU source changers that were being returned from their product distributor, NDI Corporation, Seoul, Korea. The shipment was identified as containing only empty source changers. However, an iridium-192 source capsule (about 3 curies) was inadvertently included in one of the source changers. On receipt of the shipment, Amersham personnel detected the presence of excessive radiation from one of the source changers, determined that a sealed source was the cause, and took actions to recover the material and place it in safe storage. Subsequently, the event was investigated by the NRC. The findings were published in May 1990 as NUREG-1405, "Inadvertent Shipment of a Radiographic Source from Korea to Amersham Corporation, Burlington, Massachusetts".

No regulatory deficiencies, directly contributing to the event, were identified by NRC Region I relative to Amersham Corporation. However, in a letter dated June 18, 1990, the NRC identified certain corrective measures to Amersham to prevent recurrence. These included recommendations to:

- (1) Review and amend instructions to shippers, as necessary, to assure that complete and accurate directions are provided for all shipping situations and packaging configuration that could be reasonably expected; and,
- (2) Review and amend instructions provided to shippers, as necessary, to require a physical verification that source changers are empty prior to shipment.

Further, while not a contributing factor to the event, it was noted in NUREG-1405 that the Certificate of Compliance (CoC) for the Model AI 500 SU source changer (CoC No. 9006, described a device design that was slightly different than the source changers that were then distributed by the Amersham Corporation. The differences were that (1) none of the devices in use contained a lock box mechanism to secure source assemblies as described by the CoC, and (2) some devices in use had different physical dimensions than specified in the CoC.

### Review of Licensee Actions

The inspector reviewed the licensee's response dated August 6, 1990, to the NRC's letter dated June 18, 1990. The inspector confirmed that the Licensee had reviewed and amended instructions to shippers relative to directions for all shipping situations and packaging configurations. Adequate directions were contained in the Operation Manual that the licensee supplies with each source changer device. The directions accurately described the International Atomic Energy Agency and United States Department of Transportation requirements that pertain to both loaded and empty packages, including shipping specifications for packages containing depleted uranium as shielding material.

At the time of the inspection, the licensee had submitted package renewal applications for several types of packages, including the Model AI 500 SU source changer (submitted April 26, 1990). The inspector verified that the renewal applications addressed the different dimensions exhibited by some units of the model type, and described the lock box mechanism design change that is planned for all units.

On July 18, 1990, the licensee met with the NRC Nuclear Materials Safety and Safeguards, Transportation Branch. The requirement of direct determination of actual package status, i.e., empty versus loaded, was discussed. As a result, as part of the package renewal process, the licensee committed to design a teflon probe (gauge) to physically determine if source tubes were empty; and include such probe and instructions for use with each device that could be used as a Type B package (including Model AI 500 SU source changers). The licensee has committed to distribute such gauges by December 31, 1990, providing that no major design changes are necessary.

The inspector reviewed the licensee's package renewal submittal for CoC 9006 and verified that:

- (1) the CoC accurately described each type of Model AI 500 SU source changer that was currently in use relative to physical dimensions and with regard to the design change involving the addition of a locking mechanism; and,
- (2) the Operating Procedure for each device type (with and without lock mechanism) provided accurate and clear directions for the use, preparation, and shipment of the Model AI 500 SU as a Type B and empty package.

No violations were identified.

9. Exit Interview

The findings of the inspection were discussed with the licensee representatives denoted in Section 1 of this report.

Enclosure 1

SHIPPING CHECKLIST

SALES ORDER NUMBER: \_\_\_\_\_ TECHNICIAN: \_\_\_\_\_

	<u>YES</u>	<u>NO</u>
(1) HOLD DOWN BLOCK IS SECURED AND SEAL WIRED	_____	_____
(2) SHIPPING PLUGS ARE PROPERLY SECURED AND SEAL WIRED	_____	_____
(3) ID TAG AND DECAY CHART IS ATTACHED	_____	_____
(4) SUPPLEMENTAL WIPE TEST INFO INCLUDED IF NAVY OR NEWPORT NEWS SHIPMENT	_____	_____
(5) RETURN INSTRUCTIONS INCLUDED	_____	_____
(6) PADLOCK/BOLT IS PROPERLY SECURED ON OUTSIDE OF PACKAGE	_____	_____
(7) OUTSIDE OF PACKAGE IS PROPERLY SEAL WIRED AND CRIMPED	_____	_____
(8) CONTAINER IS IN GOOD CONDITION	_____	_____
(9) PROPER INSERTS ARE USED IN OVERPACKS	_____	_____
(10) PROPER SHIPPING NAME ON OUTSIDE	_____	_____
(11) PROPER DOT LABELS FILLED OUT ENTIRELY AND AFFIXED TO BOTH SIDES	_____	_____
(12) SURFACE READING, T.I., CATEGORY OF LABELS APPLIED AND RESULTS OF EXTERNAL WIPE TEST RECORDED ON SALES ORDER	_____	_____
(13) "FOR CARGO AIRCRAFT ONLY" LABEL ON	_____	_____
(14) RQ STICKER ATTACHED	_____	_____
(15) TYPE B CERTIFICATE NUMBER ON PACKAGE	_____	_____
(16) GROSS WEIGHT MARKED ON PACKAGE	_____	_____
(17) TEXAS SHIPMENTS HAVE PROPER NAMEPLATE (80015)	_____	_____
(18) ALL ITEMS ON SALES ORDER ARE INCLUDED IN SHIPMENT	_____	_____

COMMENTS: IF ANY DEFICIENCIES ARE NOTED, DESCRIBE CORRECTIVE ACTION TAKEN PRIOR TO APPROVAL.

JWG109

APPROVED \_\_\_\_\_

Shipping Super approved

# RAD TECH QUALIFICATION POINTS

*Enclosure 2*

9/7/90

*Employee's initials*

QUALIFICATION	POINTS	Employee's initials				
		ES	RB	HK	MW	KS
UNLOADING IRIIDIUM						
ASSISTANT	4	4	4	4	4	
OPERATOR	12	12	12		0	
LOADING IRIIDIUM						
ASSISTANT	4	4	4	4	4	
WELDING	4	4	4	4	0	
REGULAR	8	8	8	0		
SPECIALS	4	4	4			
SOURCE TRANSFER						
CUTTING CELL	2	2	2	2	2	2
EXPOSURE ROOM	6	6	6	6	6	6
FIELD TRANSFER	2	2				
SOURCE DISPOSAL						
REGULAR IN CELL	6	6	6	6	6	6
SPECIALS	4	4	4	4	4	
WALL CUTTING	2	2	2	2	2	2
LOADING CALIBRATORS						
UNLOADING	3	3	3	0	0	
LOADING	6	6	6	6	0	
RECEIVING OF R.M.	4	4	4	4		
SHIPPING OF R.M.	9	9				
DISPOSAL OF RAD WASTE						
LOW LEVEL	3	3	3			
HIGH LEVEL	3	3	3			
SHIPMENT	3					
METER CALIBRATIONS	4	4				
DOSIMETER CALIBRATIONS	4	4				
CONT. MONITOR CALIBRATION	4	4	4	4	4	4
WELL COUNTER CALIBRATION	4	4	4	4	4	4
H. & S. MONITOR CALIBRATION	4	4	4	4	4	4
HANDLING D.U. SHIELDS	1	1	1	1	1	1
CARRIAGE OF R.M.	1	1				
LEAK TESTING SOURCES	4	4	4	4	4	4
MAINTENANCE & INSPECTION						
CONTROLS	3	3				
REGULAR GRPs	3	3				
SPECIALS	3	3				
RADIOGRAPHY	4	4	4		4	4
COBALT ASSEMBLY						
RECIEVING	4	4	4			
COU SERIES	8	8	8			
OBSOLETE	4	4				
SOURCE CALIBRATION						
REGULAR SOURCES	3	3	3	3	3	
PIPELINERS	3	3	3	3	3	
CALIBRATORS	3	3	3	3	3	
CONTAMINATION SURVEYS	4	4	4	4	4	4
DECONTAMINATION	9	9	9	9	9	
GAMMA PIPELINER LOADING	9	9	9			
SOURCE RETRIEVAL	16					
PROFILES	9					

<b>TOTALS:</b>	200	172	139	81	71	41	504	<b>TEAM</b>
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