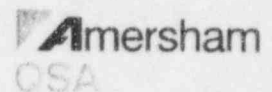


# SENTINEL

Amersham Corporation  
40 North Avenue  
Burlington, MA 01803  
tel (617) 272-2000  
tel (800) 225-1383  
fax (617) 273-2216



18 Feb 97

Mr. John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

Docket Nos. 030-29300  
040-08917

## Reply to a Notice of Violation

Dear Mr. Kinneman:

The following is submitted in response to inspection letter containing a notice of violation dated 13 Feb 97. Both actions referenced in the violation were investigated at the time of occurrence and corrective actions implemented prior to the NRC inspection on the 14 & 15 Jan 97. Both occurrences although effecting a similar regulatory requirement occurred for different reasons and each was addressed as described in the attached occurrence reports. These reports state the reasons for the violations and the corrective steps that were taken to avoid recurrence. No recurrence of these violations has occurred since corrected and compliance was achieved for the first occasion by 02 Oct 96 (receipt of returned package at Burlington facility) and for the second occasion by 30 May 96 (effected staff informed of situation and reminded of regulatory requirements for such shipments).

Should you have any questions regarding any of this information please contact me at (617) 272-2000, ext. 200 or Lori Podolak at ext. 298.

Sincerely,

A handwritten signature in dark ink, appearing to read "William McDaniel", written over a circular stamp.

William McDaniel  
Site Manager

Enclosures

9702270012 970218  
PDR ADDCK 03029300  
C PDR

cc: U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555

TEC 1/1

## OCCURRENCE REPORT: 96-12

CLASSIFICATION: Regulatory Compliance

DATE OF OCCURRENCE: 24 May 96

REPORT DATE: 17 July 96

### DESCRIPTION:

Radiation Safety Staff became aware during a facility production meeting on 30 May 96 of the transfer of ten empty 660 radiography devices containing depleted uranium to a packaging facility in Woburn, MA. The packaging firm was being used to apply shrinkwrap around the shipment components, re-crated the components then returned the newly crated shipment to Burlington prior to their shipment overseas via ocean transport.

The packaging firm did not possess a radioactive material license to receive depleted uranium. This shipment could not legally be received by the packaging company under any existing general license authorizations in the NRC regulations. The shipment was released without license verification review sign-off. This shipment violated the regulations contained in 10 CFR 30.41 and requirements contained in internal procedures SOP-R022-01 and WI-R05-02 which address shipping requirements for radioactive materials. The packaging firm was not told prior to shipment that they were re-packaging radioactive materials.

### RESOLUTION:

Radiation Safety and shipping staff from Burlington went out to the packaging company to make sure that the return shipment to us, after completion of re-packaging, complied with the Department of Transportation regulations regarding package marking, labeling and identification for radioactive material shipments. (All previously applied DOT labeling had been covered by the wrapping/crating process and the packaging company had no knowledge regarding the shipping requirements related to radioactive material transport.)

As the shrink wrap was being applied over the existing shipping configuration, and the items were shipped as an excepted package, the dose rates on contact were less than 0.5 mR/hr and not distinguishable above background at a meter away from the package surfaces. Even assuming contact exposure of a packaging company employee for 8 hours a day for the 8 days the package was at their facility, the maximum external exposure to an individual from this shipment would have been 32 mrem. (A more realistic calculation of exposures received would be assuming a 4 hour exposure time producing a dose of 2 mrem.) The conservative estimate is less than 50% of the maximum exposure allowed under the regulations for members of the general public.

### FOLLOW-UP:

Discussions were held with Marc St. Ours and his supervisor regarding why the shipment was released without the required license sign-off. He stated that he had considered the packaging company as a "freight forwarder" and thought they would be exempt from license verification. Marc stated that this is an unusual operation and it had possibly only been done once before for a shipment shrinkwrapped prior to transport to Batan in Indonesia. He stated that this occurred 4-5 years ago and that this was the only similar shipment made that he could remember. No other shipments to packagers or suppliers/vendors had been made, that he knew of, without proper license verifications.

Marc was advised that (1) freight forwarders were not allowed to change the physical configuration of a package after shipment, their function is to aid in moving/processing the shipment along in transport in as packaged condition and (2) freight forwarders are not exempted from the license requirements. Although they do not need a specific radioactive material license to facilitate package transport, they are issued a general license in the regulations which allows common and contract carriers, freight forwarders, warehousemen and the U.S. Postal Service to transport or store radioactive material in the regular course of carriage for another or storage incident thereto (10 CFR 30.13 and 40.12). In this situation, the packaging company did not meet these requirements.

Training was provided to the shipping department by Marc St Ours during May 1996 covering clarification on the requirements for license verifications for all shipments not released to carriers or destined for freight forwarders.

The shipping paperwork as well as the Customer Service file for this transaction was reviewed and copies are attached. Regarding the shipment to the packaging company, the bill of lading was completed noting the proper shipping name and exemption statements for excepted packages, however, (1) no license sign-off information, (2) no record of contamination wipe results, and (3) no record of the final package survey results were noted on the shipping paperwork as required by WL-R05-2.

To ensure that all individuals qualified for radioactive material shipment were reminded of the requirements for license verification prior to transfer and that no similar confusion existed on status of packaging companies, vendors, suppliers, etc., a memo was issued to all such individuals on 30 May 96 describing this occurrence and providing additional clarification on these issues.

The CS file was reviewed and additional discrepancies were noted related to requirements for export of radioactive material under 10 CFR 110. No documentation from the customer was supplied/maintained on file which specified the country of destination for this shipment. Although SENTINEL generated correspondence indicated that China was the country of destination, this was not supported by a signed customer statement and the specific final destination of the material in China was unknown. Although a signed copy of the P.O. notes that the shipment will be sent overseas via ocean freight, there is no commitment to final destination. Without this information, compliance with the general license requirements in 10 CFR 110.22(a) regarding ensuring that the material was not exported to an embargoed destination could not be verified.

It is assumed that Laurel Industrial Company (the customer) was acting as a freight forwarder for us for this shipment from California to China. Although Laurel is assumed to be the end-user in China, no final destination other than "China" is listed on the shipping paperwork or the CS file and we have no mechanism in place to confirm that the shipment reaches its end destination after arriving at the freight forwarders in San Bruno, California.

This material was exported by SENTINEL under conditions of a general license covered in 10 CFR 110.22(a). By regulatory definition, export means to "physically transfer...material to a person or an international organization in a foreign country". Individual shipments under these regulations mean "a shipment consisting of one lot of freight tendered to a carrier by one consignor at one place at one time for delivery to one consignee on one bill of lading". This implies the shipment should reflect point of origin as well as the final destination even if it will be transported through interim locations where freight forwarders, carriers, etc. will temporarily receive the shipment incident to transport to its final destination.

Regardless, it remains the exporter's ultimate responsibility (in this case SENTINEL) for ensuring the shipment's proper transport from the point of origin to its final destination in the foreign country. If SENTINEL is providing the shipment export as a service to customers for these types of shipments, then SENTINEL is responsible for ensuring compliance with all regulatory requirements associated with that export including Customs and Department of Commerce regulations.

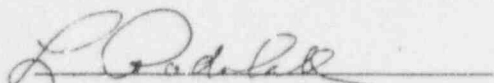
Working with Customer Service, a copy of the end user statement for the Laurel shipment was obtained prior to its release from the USA. In addition, the final destination address was also obtained prior to export from the states.

Customer service representatives were advised that end user statements and destination addresses were needed for future export shipments. Specific requirements for completion of supportive documentation to be provided by the Radiation Safety Office.

**CORRECTIVE ACTION:**

1. Review existing regulations concerning export and determine if additional programmatic changes are needed to ensure compliance.

Resp: L. Podolak



LORI PODOLAK, RADIATION SAFETY OFFICER

C O V E R

MEMO

S H E E T

To: All Radiological Technicians Qualified for Radioactive Material Shipment & Receipt  
Copy: R. Monroe, W. McDaniel, D. Thorpe, R. Barrett, K. Afeef, Occurrence File 96-12  
From: Lori Podolak *RLP*  
Subj: Illegal Transfer of DU to Unlicensed Persons  
Date: May 30, 1996

A shipment of empty 660 exposure devices was made to a packaging firm in Woburn, MA from our Burlington facility. The packaging firm applied shrinkwrap around the shipment components, re-crated the components then returned the newly crated shipment to Burlington.

The packaging firm does not possess a radioactive material license to receive depleted uranium. This shipment could not legally be received by the packaging company under any existing general license authorizations in the NRC regulations. The packaging firm was not told prior to shipment that they were re-packaging radioactive materials.

Our shipment to the packaging company was an illegal transfer of radioactive materials. The shipment was released without license verification review sign-off. This shipment violated the regulations contained in 10 CFR 30.41 and requirements contained in internal procedures SOP-R022-01 and WI-R05-02 which address shipping requirements for radioactive materials.

Radiation Safety and shipping staff from Burlington went out to the packaging company to make sure that the return shipment to us after completion of re-packaging did not violate the Department of Transportation regulations regarding package marking, labeling and identification for radioactive material shipments. (All previously applied DOT labeling had been covered by the wrapping/crating process and the packaging company had no knowledge regarding the shipping requirements related to radioactive material transport.)

This memo is a restatement of existing requirements and does not contain any modifications or additions to previous approvals, instructions or guidance related to radioactive material shipments.

Unless specifically exempted by the Radiation Safety Office, All Shipments of radioactive material require license verification and approval prior to release for shipment to ensure that the consignee is licensed under a specific, general or exempt license approval condition to receive the radioactive material.



The only routine specific exemptions from license verification requirements are:

- a. 10  $\mu$ Ci Cs-137 sources contained in Gammalarms which are distributed under our exempt distribution license 20-12836-02E to end users (no more than 10 sources distributed in any one shipment; name and address of end user documented and forwarded to NRC under a reporting requirement), and
- b. Shipments whose transport is coordinated through a freight forwarder (no re-packaging of shipment involved) under a general license provision in the regulations. However, license verification for the end recipient in these cases is still required prior to release of shipments approved through a freight forwarder.

Under no circumstances should radioactive material or devices containing radioactive material be shipped to vendors and/or suppliers without prior license verification or specific exemption from the Radiation Safety Office.

If you have any questions regarding the basic requirements for radioactive material shipments, or need clarification on any matters of compliance with the regulations or existing internal procedures designed to ensure compliance with the regulations, contact the Radiation Safety Office for guidance prior to release of any radioactive material shipment.

## OCCURRENCE REPORT: 96-20

CLASSIFICATION: Transportation

DATE OF OCCURRENCE: 01 Oct 96

REPORT DATE: 07 Oct 96

### DESCRIPTION:

At 2:30 pm on October 1, 1996 Jeanne Price notified me that SENTINEL-Burlington had made a shipment ordered by CBI, however, the destination address for the shipment as entered by Client Services was incorrect. Subsequently the shipment, an 865 exposure device with a 221.5 Ci Ir-192 source, had been delivered to and accepted at the incorrect address. Jeanne had been notified of this situation by Chuck Benson of CBI who stated that he had received notification of the situation from his West Coast RSO after the individual who signed for the shipment had contacted that CBI individual.

### RESOLUTION:

Jeanne stated that she had entered the order into the system, however, she could not explain how the incorrect address had been entered as all paperwork for the order reflected a final destination in Donaldsonville, LA. Later investigation in the MAPICS system showed that the Donaldsonville, LA address did not have an assigned ship-to in the computer, however, the Las Vegas address was the last assigned ship-to in the system. Further, although not an active CBI jobsite, the Las Vegas address appears to be a future jobsite for CBI. At the time of this occurrence, however, CBI had no staff on site or in the immediate vicinity of the delivery address. I had Jeanne contact Chuck Benson and request that he try to track down the name and phone number of the individual who signed for and received the shipment from Federal Express.

At 3:00 pm, I advised Bill McDaniel of the situation and we decided to contact Roy Parker from Federal Express around 3:15 pm. Roy also advised us to find out the contact person at that address. At 3:30 we received word from Chuck Benson that the contact person at that site was Roland Johnson who worked for a company called MMC (702) 491-2072. Bill and I contacted Mr. Johnson who confirmed that the package had not been opened, had not been damaged and that it had DOT hazardous materials shipping labels indicating the contents were radioactive. (Note: The shipment contained two packages, one radioactive the other not, confirmation of contents was necessary to ensure that Mr. Johnson had signed for the radioactive material package. The second package did not arrive with the 865.) We made arrangements with Federal Express to have the package picked up that night and returned to SENTINEL in Burlington.

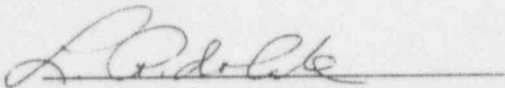
### FOLLOW-UP:

At 6:50 pm on 01 Oct 96 Roland contacted Bill and advised that Federal Express had picked up the package. On 02 Oct 96 the package was received by SENTINEL and inspected. The package was received as shipped (865 in a pelican case, within a wooden crate). The crate had not been opened as the lid was still nailed shut and metal banded together as it had left Burlington on 30 Sep 96. Inspection of the crate revealed no damage to the package.

CORRECTIVE ACTION:

1. Client Services staff will be advised of this occurrence and the problems which could have arose had the package been opened by an un-licensed, un-trained individual and the importance of confirming shipment destination addressed prior to release of sales orders for shipment.

Resp. L. Podolak

A handwritten signature in cursive script, appearing to read 'L. Podolak', is written over a horizontal line.

LORI PODOLAK, RADIATION SAFETY OFFICER



C O V E R

# MEMO

S H E E T

To: W. McDaniel, C. Roughan, G. Field, E. Shaffer, E. Okvist, R. Kelly, K. Afeef, R. Barrett, D. Evans, D. Thorpe, L. Cumbus, M. Doruff, W. London  
From: Lori Podolak *LKP*  
Subject: Occurrence Report 96-20  
Date: October 7, 1996

Attached is Occurrence Report 96-20 which describes resolution of an occurrence involving a radioactive material shipment which was delivered to an incorrect address. This shipment was subsequently received and signed for by personnel at this address before realizing they were signing for a radioactive material shipment.

Significant regulatory and potentially adverse safety impacts were averted in this case since the individual signing for the package immediately quickly realized he was dealing with a radioactive material package, and contacted the intended end user before doing anything else with the package. Had the package been opened by an untrained, inquisitive person, the individuals in that area could have been placed at significant health and safety risk and serious safety and regulatory repercussions would have resulted for the Amersham-SENTINEL business.

The importance of confirming accuracy of radioactive shipment information prior to order release cannot be stressed enough as we cannot assume that a future mis-directed shipment will be handled as safely in the future. Any questions or confusion on this memo or occurrence should be directed to Kate or myself ASAP in order to avoid any misunderstandings related to this issue. At a minimum, confirmation of the shipment information against the original order information must be made prior to release of the sales order for shipment to ensure that radioactive material shipments are entered for the valid end destination address.

From the desk of...

Lori Podolak  
Radiation Safety Officer  
Amersham/SENTINEL  
40 North Avenue  
Burlington, MA 01803

(617) 272-2000 ext \*298  
Fax: (617) 273-2216