

November 8, 1996

Ms. Cathleen Roughan
Regulatory Affairs Manager
Sentinel
Amersham Corporation
40 North Avenue
Burlington, MA 01803

Dear Ms. Roughan:

This letter is in reference to your letter dated May 24, 1996, and subsequent letters and telephone calls, regarding the Model 865 radiography camera (NR-0628-D-118-S). As we discussed, NRC's Region IV-WCFO has reported a concern that the source would be exposed during the maintenance procedures outlined in your users manual. To address this concern, we have amended the registration certificate, NR-0628-D-118-S, to include the following license review note:

REVIEWER NOTE: If authorizing a licensee to perform maintenance, note that at one point in the the maintenance section procedures in the Amersham users manual, the source is held in place by only the locking mechanism. If the locking mechanism should work incorrectly or fail, the source could possibly be removed from the device. Licensee's program should be reviewed to ensure that they have adequate training and procedures to perform this maintenance procedure.

If you have any questions, please contact me at (301) 415-5868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

151
Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: As stated

cc w/encl: SKimberley, LFDCB

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 17, 1996

Ms. Cathleen Roughan
Regulatory Affairs Manager
Sentinel
Amersham Corporation
40 North Avenue
Burlington, MA 01803

Dear Ms. Roughan:

This letter is in reference to your letter dated May 24, 1996, and subsequent letters and telephone calls, regarding the Model 865 radiography camera. As we discussed, NRC's Region IV-WCFO has reported a concern that the source would be exposed during the maintenance procedures outlined in your users manual, and we are in the process of evaluating the design of the device to determine whether that is the case. As of the date of this letter, we have still not received sufficient information to complete this evaluation. Therefore, please provide the following information within thirty (30) days of the date of this letter so that we may continue our evaluation:

1. Provide a drawing of the bottom of the actuator piston, which shows the keyhole slot.
2. Provide a drawing and description that illustrates how the four hex bolts hold the actuator assembly and the source holddown cap to the device.
3. It appears from the maintenance procedures that after completing step 12, the source is held in the device by only the source holddown cap. Based on the sketch of the source holddown cap supplied in your July 11, 1996, letter, it does not seem that the source is held in position at this point and that the source assembly could move forward and backward along the source tube inside the device, resulting in the source assembly not being properly locked in the shielded position after reinsertion of the locking mechanism. When the source holddown cap is removed in step 23, the source assembly could then be in an unlocked position, with nothing restricting its movement into an unshielded position. Please provide additional details to clarify this situation, demonstrating that the source will be maintained in a shielded position at all times during the maintenance, and that the source assembly will be locked in the shielded position upon completion of the maintenance procedures.
4. Your May 24, 1996, letter states that the piston limiter tool secures the source rod in the stored position during removal of the actuator assembly. From the drawings and maintenance procedures, it does not appear that this is correct. Please clarify.

9607260139

C. Roughan

-2-

5. The copy of the users manual that you sent with your May 24, 1996, is missing a portion of Section VII. Please provide a complete copy of Section VII.

If you have any questions, please contact me at (301) 415-5868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

Original Signed by

Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Distribution:

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NR-0628-S-118-S

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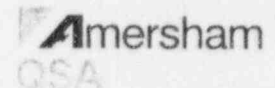
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SENTINEL

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



11 July 1996

Ms. Michele Burgess
Sealed Source Safety Section
Source Containment and Devices Branch
Division of Industrial of Medical Nuclear Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, DC 20555

RE: NR-628-D-118-S
NR-628-S-121-S

Dear Ms. Burgess:

Enclosed please find the information you requested concerning the model 865 device and the 86520 source rod.

The plating on the model 86520 source rod will not add any appreciable thickness to the rod, it is done through an electroplating process and will be less than 0.0005 inches thick. In addition the drawing has been updated to reflect the appropriate number of significant digits in the dimensions, based on importance to safety. This has resulted in some rounding off of dimensions, however no actual dimensions have been modified.

I have enclosed some sketches that show the view of the 865 during maintenance, depicting the removal of the actuator head, the method of securing the source and the specific tools used as described in our last letter. These depict the information given in the 865 manual, steps 3-29.

Should you have any questions regarding this information, please contact me at (617) 272-2000, extension *210.

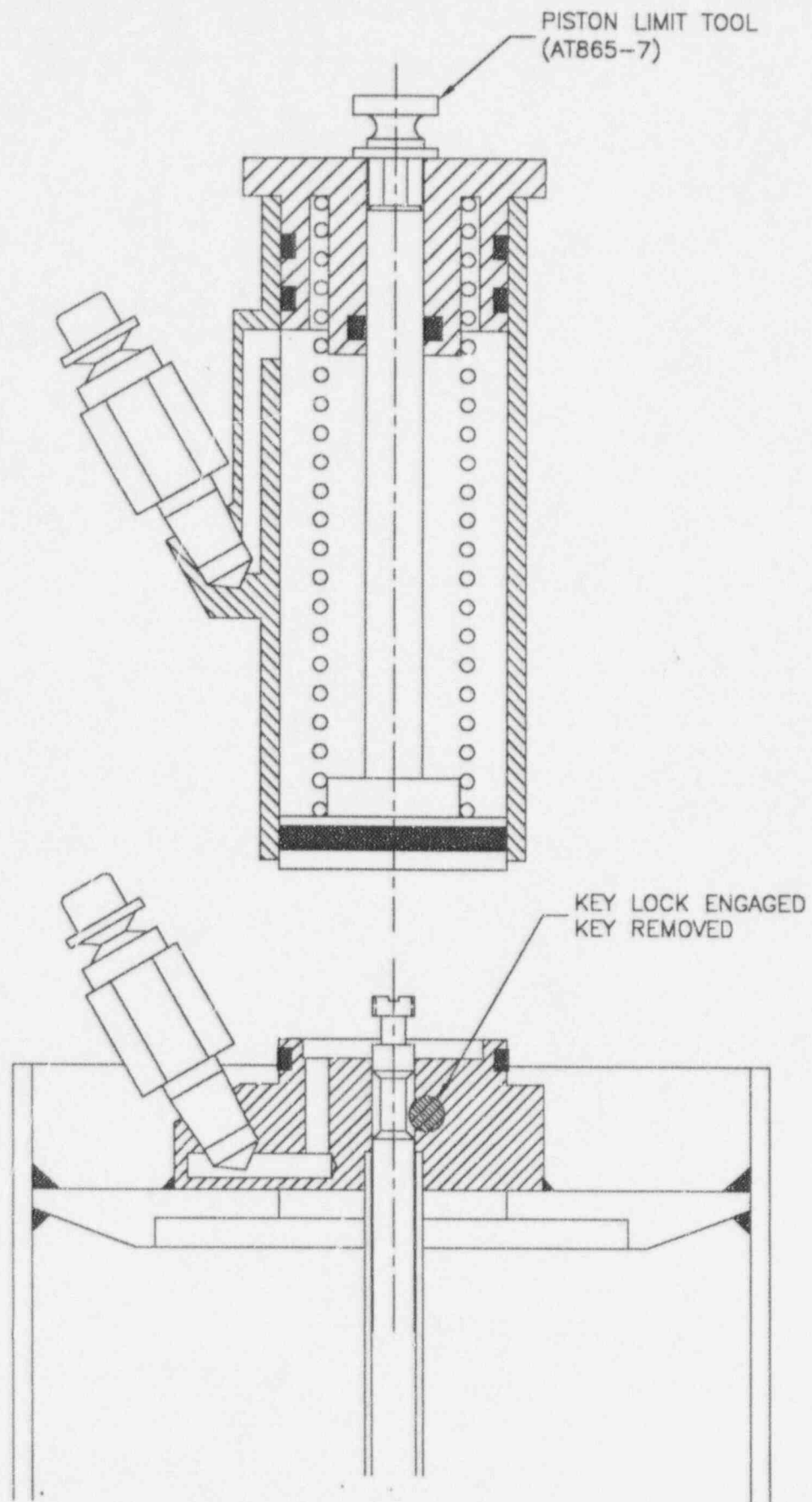
Sincerely,

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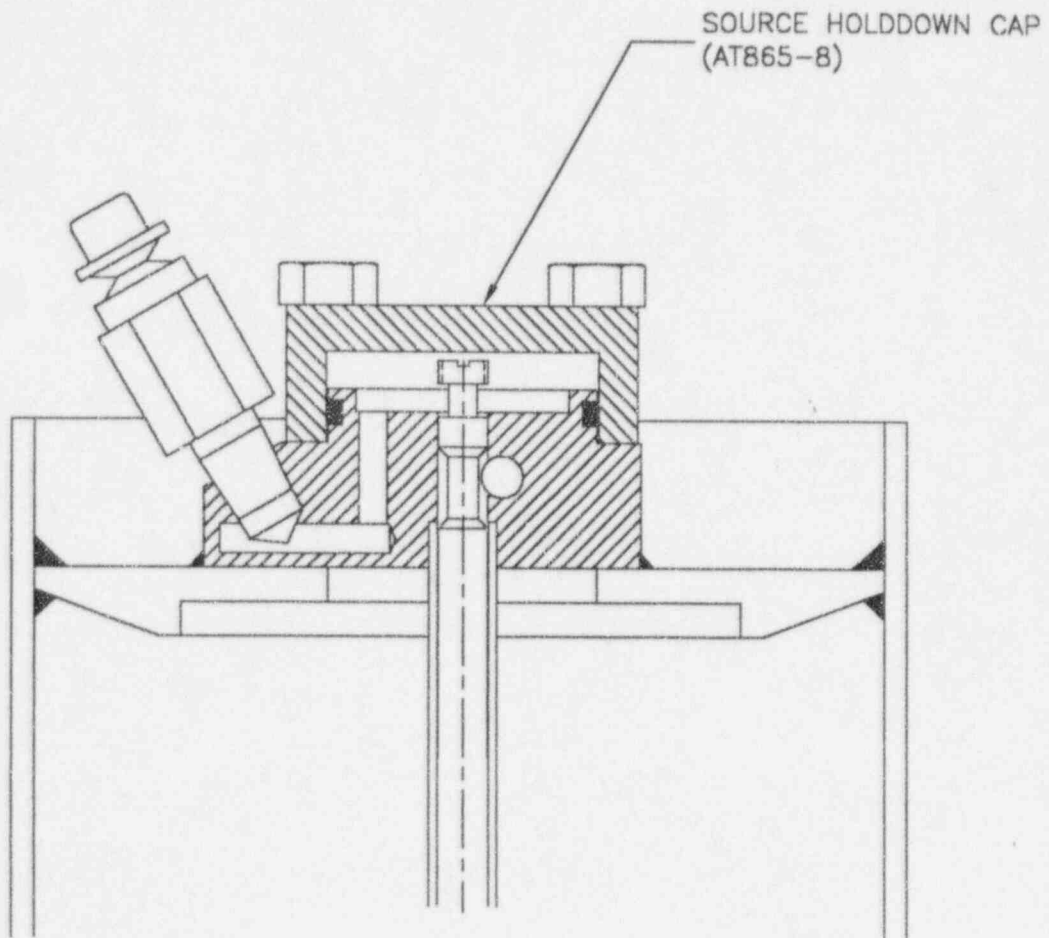
Cathleen Roughan
Regulatory Affairs Manager

Enclosure

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ACTUATOR MAINTENANCE



LOCK REMOVAL

rec'd 5/31/96

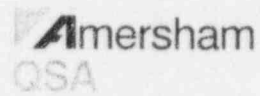
SENTINEL

24 May 1996

Ms. Michele Burgess
Sealed Source Safety Section
Source Containment and Devices Branch
Division of Industrial of Medical Nuclear Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, DC 20555

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

RE: NR-628-D-118-S



Dear Ms. Burgess:

Enclosed please find the information you requested concerning the model 865 device.

I have enclosed the most recent version of the operations manual for the 865. We recommend that maintenance be performed at the time of reloading at our facility, but provide instructions for users to perform their own when necessary. We have several users that perform this maintenance in the field.

The tools referenced for the performance of maintenance include a piston limiter tool, source holddown cap and a lock seal removal tool. The piston limiter tool is a screw that secures the source rod in the stored position while removing the actuator assembly. The piston limiter tool is a knurled thumb screw with 10/32 thread approximately 3/4 inch long.

The lock seal removal tool facilitates the removal of the lock seal while disassembling the lock housing, but is not required for removal. This tool is a steel rod approximately 3 inches long and 3/16 inch diameter.

The source holddown cap is installed over the source rod once the actuator assembly is removed from the device. The cap is approximately a 2 inch square and has holes to allow for the installation of screws through the cap and into the body of the device into the threaded holes for the actuator assembly. This keeps the source rod in the stored position while maintenance is performed.

Should you have any questions regarding this information, please contact me at (617) 272-2000, extension *210.

Sincerely,

A handwritten signature in cursive script, appearing to read "Cathleen Roughan".

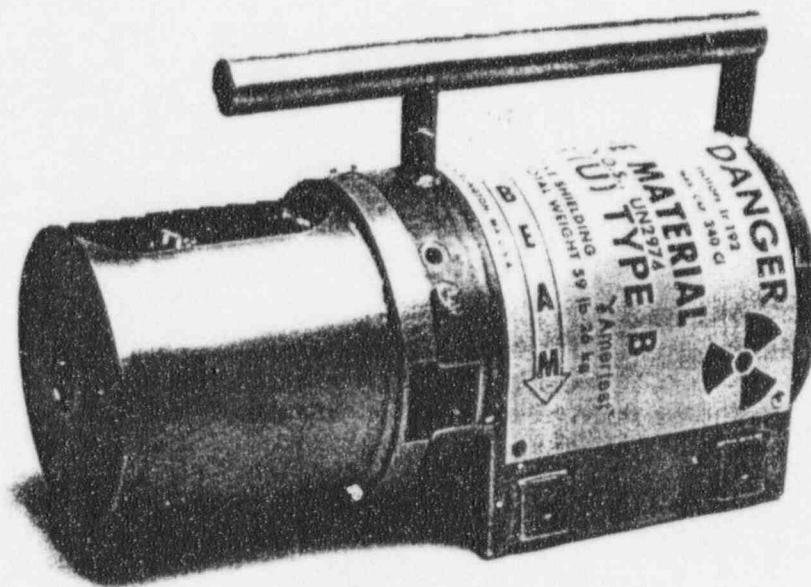
Cathleen Roughan
Regulatory Affairs Manager

Enclosure

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SENTINEL

**MODEL 865
RADIOGRAPHIC EXPOSURE DEVICE
AND TYPE B(U) PACKAGE**



**OPERATIONAL AND MAINTENANCE
INSTRUCTION MANUAL**

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Section I

1. General

The Model 865 is used as a radiographic exposure device and Type B(U) transport package for Amersham Corporation radioactive sources. **The user should become thoroughly familiar with the instruction manual before attempting operation of the equipment.**

In order to use this equipment, the user in the United States must be specifically licensed to do so. Applications for a license should be filed with the appropriate Regional Office of the U.S. Nuclear Regulatory Commission or with the appropriate Agreement State office.

Prior to the initial use of the exposure device as a transport package in the United States, the user must:

- a. If performing transportation activities with an NRC Regulated State, you must have an approved Quality Assurance Program and comply with its conditions. This must be applied for with an application fee to the:

Transportation Branch
Division of Safeguards and Transportation
Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

- b. Register as a user of the Type B package with the Transportation Branch of the U.S. Nuclear Regulatory Commission.
- c. Maintain on file a copy of the Certificate of Compliance Number 9187, issued by the Nuclear Regulatory Commission, including all copies of all applicable drawings referenced on this certificate and the operational and Maintenance Manual for the package.
- d. Maintain on file a copy of the U.S. Department of Transportation Certificate of Competent Authority for the special form source transported in the radiographic exposure device.
- e. Prepare this package for transport, as shown in the applicable drawings and as described in the Operational and Maintenance Manual.

Prior to the first shipment of this radiographic exposure device from the United States, the user must also register with:

Office of Hazardous Materials Technology
Research and Special Programs Administration
400 Seventh Street SW
U.S. Department of Transportation
Washington, DC 20590

The user must have in his possession a copy of IAEA Certificate of Competent Authority Number USA/9187/B(U) issued for this radiographic exposure device. Users of this equipment outside of the United States must comply with the regulatory, licensing and transportation rules and regulations of their respective countries.

2. Warranty and Limitation of Liability

Amersham Corporation, warrants its products which it manufactures and sells to be free of defects in material and workmanship for a period of one year from the date of shipment. This warranty shall not apply to any product or parts which have been subjected to misuse, improper installation, repair, alteration, neglect, accident, abnormal conditions of operation, or use in any manner contrary to instructions.

The manufacturer's liability under such warranty shall be limited to replacing or repairing, at its option, any parts found to be defective in such respects, which are returned to it transportation prepaid; or, at its option, to returning the purchase price thereof.

The exposure device is equipped with a key operated lock to prevent operation of the device by unauthorized personnel. The unit can only be locked when the source assembly is in the shielded storage position.

The exposure device incorporates a positive visual indication of source position. A rod emerges from the actuating cylinder as the source is exposed. The emergent length of the rod indicates the position of the source. When the source is in its fully shielded storage position, the rod is no longer visible.

b. Model 86550 Control Unit

The Model 86550 Control Unit is a pneumatic control designed for use with the Model 865 Exposure Device. The control unit is designed to pressurize the actuating mechanism of the exposure device through the use of a hand pump or through the use of an auxiliary air supply.

The control unit is equipped with a pressure gauge to monitor operating pressure.

The standard control unit is equipped with a 7.5 meter (25 feet) long control hose for attachment to the exposing side of the actuator and a similar control hose for attachment to the storing side of the actuator. Control units with longer hoses are available on an optional basis.

The control unit is equipped with a lock which prevents operation of the unit by unauthorized personnel.

3.4 Radioactive Source Assembly

The Model 865 Exposure Device is used in conjunction with Amersham Model 86520 Source Assembly. This source assembly contains either Amersham Model 90004 or Amersham Model 90005 source capsule. These source capsules are fabricated from stainless steel and are seal welded.

Each of these source capsules have been designed and tested to comply with the criteria for classification C43515 in accordance with International Standard ISO 2919 - 1980 and American National Standard N542 -1977. Additionally, these source capsules have been certified as special form radioactive material in accordance with IAEA Safety Series No. 6, 1985, (as amended 1990).

The Model 865 exposure device will contain a maximum of 240 curies of Iridium-192.

The source in the Model 865 may only be changed by a user licensed to do so. Source changing of this device requires the use of a shielded cell and specially designed tools. Because of this, Amersham recommends that all devices be returned to the manufacturer for source replacement. During this source replacement the device will be completely inspected and maintained.

4. Technical Data

4.1 Exposure Device

Length:	310 mm (12.25 inches)
Diameter:	127 mm (5.0 inches)
Shipping Weight:	27 kg (59 pounds)
Capacity:	240 Ci, Ir-192
Shielding:	Depleted Uranium 18 kg (40 pounds)
Transport Status:	Type B(U) Package USA/9187/B(U) Special Form Certification USA/0179/S
Sources approved for Use with Model 865:	86520

The radiographer or radiographer's assistant must guard against unauthorized entrance into these areas at all times. No personnel should be allowed into the restricted area without a direct reading pocket dosimeter and either film badge or TLD.

Section III

1. Receiving Radioactive Material

The consignee of a package of radioactive material must make arrangements to receive the package when it is delivered. If the package is picked up at the carrier's terminal, 10 CFR Part 20.1906 requires that this be done expeditiously upon notification of arrival.

Amersham Model 865 portable gamma radiography system is normally shipped in one crate. Inspect the crate for signs of external damage. If damage is evident, the carrier's agent should be present while unpacking. Survey the exposure device with a survey meter as soon as possible, preferably at the time of pickup and no more than three hours later if it was received during working hours, or no more than 18 hours later if it was received after normal working hours. Radiation level should not exceed 200 milliroentgens per hour at the surface of the exposure device nor 10 milliroentgens per hour at a distance of 1 meter (40 inches) from the surface. Actual radiation levels should be recorded on the receiving report. If the radiation levels exceed these limits, the container should be secured in a Restricted Area, and the appropriate personnel notified. Visually inspect the 865 for signs of damage and assure that the seal wire has not been tampered with.

The radioisotope, activity, model number and serial number of the source and the package model number and serial number should be recorded in the receiving report.

Section IV

1. Principles of Operation

The source holder assembly, which contains the radioactive source capsule, is positioned such that the source capsule is located in the shielded storage position in the exposure device. This source assembly is attached to the piston in the actuating cylinder. When the cylinder is pressurized, the piston moves the source from its shielded storage position to the beam port. In this exposing position, the emergent beam is 60° wide and 30° high. The radiation intensity in all directions outside the primary beam is reduced by a factor of 10,000 by the built in beam limiter. The radioactive source assembly never leaves the exposure device during normal operation.

When the air pressure is reduced on the exposing side of the piston, a spring causes the source assembly to move to the shielded position. An additional optional air line is available to pressurize the storing side of the piston to assist the spring return. This additional air line is mandatory for underwater and underwater habitat applications.

2. Safety Precautions

This system may be operated only by a qualified radiographer. The radiographer must be physically present and in direct surveillance at all times when the exposure device is being used.

Since the source emits high levels of radiation, it is good practice to operate the system from as great a distance as practicable and, if possible, from behind a radiation shield such as a heavy steel or concrete object or the corner of a building.

Radiography must only be performed in a Restricted Area which is marked with the appropriate radiation signs, and secured against unauthorized entrance. While assembling the system, it is important to keep the exposure device locked at all times except when operating. The radiographer and radiographer's assistant must at all times have a pocket dosimeter, either a film badge or TLD, and a survey meter capable of measuring from 2 mR/hr to at least 1000 mR/hr.

6. Disassembly

- a. Assure that the exposure device is locked. Remove the key.
- b. Disconnect the control hoses from the exposure device.
- c. Install the outer protective cover and install the four 6 mm x 1 mm bolts.
- d. Survey the external surfaces of the device to assure that the radiation levels do not exceed 200 mR/hr. Survey at one meter from the external surfaces of the device to assure that the radiation levels do not exceed 10 mR/hr.

7. Source Changing

The source in the Model 865 may only be changed by a user licensed to do so. Source changing of this device requires the use of a shielded cell and specially designed tools.

Therefore, we recommend that all devices be returned to Amersham for source replacement. During this source replacement, the device will be completely inspected and maintained.

Section V

1. Shipment of Radioactive Material

The Model 865 meets the requirement for a Type B(U) shipping container under the regulations of the U.S. Nuclear Regulatory Commission, the U.S. Department of Transportation and the International Atomic Energy Agency. The container has been assigned USNRC Certificate of Compliance Number USA/9187/B(U) for domestic shipments and IAEA Certificate of Competent Authority Number USA/9187/B(U) for international shipments.

2. Shipment of Radioactive Source

Prior to shipment assure the package and its contents meet the following requirements:

- a. The contents are authorized for use in the package.
- b. The package is in good physical condition for transport.
- c. All locks are secured.
- d. All conditions of the certificate of compliance are met.

Assure that the source is locked into place in its proper shielded storage position. To check this, the source position indicator rod should be in the down position, and the key operated lock should be engaged. Install the outer cover using four, 6 mm x 1 mm bolts. Seal wire two of these bolts and attach a tamperproof seal with an identification mark.

If the exposure device is to be shipped inside outer packaging or barrel, mark the outside package "INSIDE PACKAGE COMPLIES WITH PRESCRIBED SPECIFICATIONS USA/9187/B(U) Type B." If an outer barrel is used as an over pack, it must be fastened with seal wire.

Survey all exterior surfaces of the package to assure that the radiation level does not exceed 200 mR/hr at the surface.

Measure the radiation level at one meter from all exterior surfaces to assure that the radiation level is less than 10 mR/hr. The maximum radiation level measured one meter from any exterior surface is the Transport Index. Example: with a maximum radiation level of 2.2 mR/hr, the transport index (T.I. is 2.2).

NOTE: If the device is to be shipped without an overpack, the radiation survey should be made of the outer surfaces of the device. If the device will be shipped inside of an overpack, the radiation survey should be from the outer surfaces of both the device and the overpack with the device packaged for shipment inside the overpack.

- e. Category of label applied to container (Radioactive Yellow II or Radioactive Yellow III).
- f. Transport Index.
- g. Type B identification number - USA/9187/B(U) Type B(U)
- h. Shippers certification stating:

"This is to certify that the above named materials are properly classified, described, packaged, marked and labeled and are in proper condition for transport according to the applicable regulations of the Department of Transportation."

NOTE:

1. For air shipments, the following shipper's certification may be used:

"I hereby certify that the contents of this consignment are fully and accurately described by proper shipping name and are classified, packed, marked and labeled and are in proper condition for carriage by air according to applicable national governmental regulations."
2. For air shipments, the package must be labeled with a "CARGO AIRCRAFT ONLY" label and the shipping papers must state: "THIS SHIPMENT IS WITHIN THE LIMITATIONS PRESCRIBED FOR CARGO AIRCRAFT ONLY."
- i. The shipping papers must indicate an emergency phone number for the shipper. This phone number must have 24 hour coverage in case of an emergency during transport of your package. The emergency phone number must be clearly visible on the shipping papers.

Return the container to Amersham Corporation according to proper procedures for transporting Radioactive material as established in Title 49 Code of Federal Regulation parts 172-178.

NOTE: The U.S. Department of Transportation, in 49 CFR 173.22(c) requires each shipper of Type B quantities of radioactive material to provide prior notification to the consignee of the dates of shipment and expected arrival.

3. Shipment of an Empty Package

Perform a radioactive contamination wipe test of the outer shipping package. This consist of rubbing filter paper or other absorbent material, using heavy finger pressure, over an area of 300 cm² (46.5 in²) of the package surface. The activity on the filter paper should not exceed 0.00001 uCi/cm² of removable contamination.

NOTE: If the device is to be shipped without an overpack, the radioactive contamination wipe should be made of the outer surfaces of the device. If the device will be shipped inside of an overpack, the radioactive contamination wipe test should be made of both the outer surfaces of the device and the overpack with the device packaged for shipment inside the overpack.

Survey the container and prepare the package depending upon the radiation levels obtained, as given below.

- a. If the radiation level is below 0.5 mR/hr at the surface and there is no measurable radiation level at one meter from the container, no label is required. Mark the outside of the package with the proper shipping name (Radioactive Material, articles manufactured from depleted uranium UN 2910). Mark the outside of the package:

"Exempt from specification packaging, shipping paper and certification, marking and labeling and exempt from the requirements of part 175 per 49 CFR 173.421 and 49 CFR 173.426."

Additionally, a notice must be enclosed in or on the package included with the packing list, otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement:

"This package conforms to the conditions and limitations specified in 49 CFR 173.426 for excepted radioactive materials, articles manufactured from depleted uranium, UN 2910."

If the vehicle is transporting a package bearing a "Radioactive Yellow III" label, 49 CFR Part 172.504 requires that the vehicle be posted on all four sides with a "Radioactive" placard. It should be noted that operation of a vehicle which is required to be placarded requires compliance with the Federal Motor Carrier Safety Regulations, 49 CFR Parts 390 to 397.

5. Hand Carrying

In order to minimize radiation exposure, it is recommended that care be taken when hand carrying the unit. A direct reading pocket dosimeter and film badge or TLD should be worn on the side of the body closest to the exposure device. If more than one person is present, it is good practice to alternate the hand carrying between them to minimize radiation doses to any one individual. Likewise, no person should be permitted to sit on or lounge against the exposure device.

6. Storage

When storing the system, the exposure device must be kept physically secure to prevent tampering or removal by unauthorized personnel. The storage area must be secured such that no unauthorized personnel are allowed entrance where radiation exposure levels exceed 2 millirem in any one hour. 10 CFR Part 34.22 and 34.23 require that the exposure device be kept locked and secured during storage.

Section VI

1. Leak Testing

The source assembly used in the Model 865 should be leak tested for removable radioactive contamination at intervals not to exceed six months. This can be accomplished using Amersham Model 518 Leak Test Kit.

This test must be performed in a properly secured Restricted Area. The individual performing this test should wear a direct reading pocket dosimeter and either a film badge or thermoluminescent dosimeter (TLD). The individual should also use a properly calibrated and operable radiation survey instrument.

- a. Assure that the exposure device is locked. Assure that the source assembly is in the proper shielded storage position by surveying the exposure device at the surface and at one meter (40 inches) from the surface. The radiation levels should not exceed 200 mR/hr at the surface nor 10 mR/hr at one meter (40 inches) from the surface when the device is loaded to its capacity.
- b. Moisten the wipe test swab with EDTA solution. Wipe the point on the device where the source position indicator emerges. Wipe the air inlets on the actuator assembly. Wipe the areas near each end of the locking rod. Wipe the end fittings of the control hoses.
- c. Place the wipe test swab in the plastic envelope.
- d. Set the survey meter on its most sensitive range and place the meter in a low background area. Move the wipe test swab towards the meter and observe the radiation level indication.
- e. If there was no indicated increase in the background radiation level, place the plastic envelope in the mailing box and send to Amersham. Be sure to complete and return the identification sheet.
- f. If the meter indicates an increase in the background radiation level, **DO NOT MAIL THE WIPE TEST PATCH**. Contact Amersham for further instructions.

Section VII

1. Maintenance

It is recommended that inspection and maintenance of the Model 865 exposure device and Model 86550 control unit be performed at intervals not to exceed three months.

10. Remove the piston, spring and top flange from the actuator assembly.

NOTE: If removal of the lock assembly is necessary, the procedure of steps 11 through 19 should be followed. Otherwise proceed to step 20. Assure that the source holddown cap is properly installed.

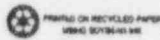
11. Remove the end cap of the locking rod and the cap screw which holds the lock body in the lock housing.
12. Insert the key into the lock. Rotate the key 90° and pull the lock and locking rod assembly from the lock housing. The locking rod has two seals. One seal should remain with the locking rod and one seal should remain in the lock housing. This seal can be removed using the lock seal removal tool.
13. Inspect the lock and locking rod. Replace shaft seal.

NOTE: To replace shaft seal located near the lock body, it is necessary to remove the pin nearest the seal. When reassembling the lock and locking end assembly, the end cap and its associated shaft seal must be assembled last.

14. Lightly grease the shaft seal, insert the return springs and spring guide pins into the lock body.
15. Depress the plunger on the side of the lock body so it clears the hole in the lock housing and insert the locking assembly into the housing.
16. Align the screw hole in the lock body with the slot in the housing and secure the lock with its cap screw.
17. Lightly grease the second shaft seal and place it on the locking rod.
18. Attach end cap to locking rod so that the cap is flush with the end of the rod.
19. Insert key in lock and check that lock works freely.
20. Replace shaft seal and "O" ring on the rear flange, lightly grease the seal and "O" ring and insert the flange into the actuator housing.
21. Replace and lightly grease the piston seal and install the piston and return spring in the actuator housing.
22. Thread piston limit tool into end of source position indicator shaft.
23. Assure that the key operated lock is engaged and the key is removed. Remove the source holddown cap.
24. Replace and lightly grease the base "O" ring seal.
25. Connect the source rod to the keyhole slot in the actuator piston. Assemble the actuator to the base being sure to align the air line connectors.
26. Fasten actuator assembly to base with the four tie rod bolts.
27. Safety wire the tie rod bolts.
28. Remove the piston limit screw.
29. Attach the actuator guard.
30. Assure that the exposure device operates properly by performing the operation in Section IV.

Figure 2

SHIPPER'S DECLARATION FOR DANGEROUS GOODS



AMERICAN LABELMARK CO. — CHICAGO, IL 60646

299075-DH

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline.)

Shipper SENTINEL AMERSHAM CORPORATION 40 NORTH AVENUE BURLINGTON, MA 01803 USA				Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number (optional)							
Consignee SENTINEL AMERSHAM CORPORATION 40 NORTH AVENUE BURLINGTON, MA 01803											
Two completed and signed copies of this Declaration must be handed to the operator				WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.							
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (delete non-applicable) <table border="1"> <tr> <td><input checked="" type="checkbox"/> PASSENGER</td> <td><input type="checkbox"/> CARGO</td> </tr> <tr> <td><input checked="" type="checkbox"/> AIRCRAFT</td> <td><input type="checkbox"/> AIRCRAFT ONLY</td> </tr> </table>				<input checked="" type="checkbox"/> PASSENGER	<input type="checkbox"/> CARGO	<input checked="" type="checkbox"/> AIRCRAFT	<input type="checkbox"/> AIRCRAFT ONLY	Airport of Departure Airport of Destination:			
<input checked="" type="checkbox"/> PASSENGER	<input type="checkbox"/> CARGO										
<input checked="" type="checkbox"/> AIRCRAFT	<input type="checkbox"/> AIRCRAFT ONLY										
				Shipment type: (delete non-applicable) <input checked="" type="checkbox"/> RADIOACTIVE							
NATURE AND QUANTITY OF DANGEROUS GOODS (see Subsections 6.6 and 6.1 of IATA Dangerous Goods Regulations)											
Dangerous Goods Identification											
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization				
RG RADIOACTIVE MATERIAL SPECIAL FORM MOS	7	UN2974			SOLID METAL IRIDIUM-192 74.0 CURIES 2738.0 GBq	II YELLOW	SPECIAL FORM CERT. USA/ 0179/S ***** T.1. TYPE B(U) 0.6 PACKAGE CERT. USA/ 9587/B(U)				
					1 TYPE B(U) PACKAGES 13 X 20 X 31 CMS						

Ms. Cathleen Roughan
 Regulatory Affairs Manager
 Sentinel
 Amersham Corporation
 40 North Avenue
 Burlington, MA 01803

Dear Ms. Roughan:

This letter is in response to your application dated February 19, 1996, requesting an amendment to the registration of the Model 86520 radiography source assembly and our telephone conversation on March 14, 1996, requesting additional information in order to continue our evaluation of your request. To date, the requested information has not been received. If we do not receive the requested information within forty-five (45) days of the date of this letter we will have considered your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-5868 or Mr. Thomas Rich at (301) 415-7893.

Sincerely,

Original Signed by

Michele L. Burgess, Mechanical Engineer
 Sealed Source Safety Section
 Medical, Academic, and Commercial
 Use Safety Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

cc ~~w/enc1~~: SKimberley, LFDCB

Distribution:

SSSS r/f

SSD-96-10

NE01

DOCUMENT NAME: C:\SSSS\WORKSSD\AM86520\NR628121.VOI

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	IMAB	<input checked="" type="checkbox"/> C	IMAB	<input checked="" type="checkbox"/> C					
NAME	MBurgess/mb		TRich						
DATE	04/ /96		04/ 22 /96						

OFFICIAL RECORD COPY

9604240245 Suppls 01 & 02

NRC FORM 567

U. S. NUCLEAR REGULATORY COMMISSION

(8-93)

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

Kn

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.

NOTE: Retain a copy of this request with the application and background files.

REQUESTER <i>Michele Burgess</i>		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB	
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)	
APPLICANT'S NAME <i>Amersham</i>		<input type="checkbox"/> SOURCE REVIEW <input checked="" type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)	
MAIL CONTROL NUMBER(S)		<input type="checkbox"/> DEVICE REVIEW	
LETTER/APPLICATION DATE	LICENSE NUMBER(S)	<input type="checkbox"/> CUSTOM REVIEW <i>NR 628 51185</i>	
COMMENTS: <i>review maintenance procedures to determine if source is exposed to user during maintenance</i>			
FOR SSSS USE ONLY			
REVIEWER <i>M. Burgess</i>	MODEL NUMBERS <i>865</i>	NUMBER ASSIGNED <i>96-64</i>	
DATE RECEIVED	DATE ASSIGNED <i>7/17/94</i>	DATE TO FEES <i>7/29/94</i>	
TYPE OF ACTION (Indicate the number of each type)			
<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		<input type="checkbox"/> USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input checked="" type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN	
<input type="checkbox"/> OTHER (Specify)		<input type="checkbox"/> YES <input type="checkbox"/> NO	
TOTAL NUMBER OF REVIEW HOURS		NOTES <i>also see 96-10 (was tied to that action for processing purposes) no fees</i>	
NUMBER OF DEFICIENCY LETTERS			
NUMBER OF DEFICIENCY CALLS			
FOR BILLING PURPOSES ONLY			
<input type="checkbox"/> NAME CHANGE	<input type="checkbox"/> ADDRESS CHANGE	<input type="checkbox"/> NEW REGISTRATION - ADD TO BILLING	<input type="checkbox"/> PRODUCT INACTIVE - REMOVE FROM BILLING
FOR FEE USE ONLY			
TYPE OF FEE <i>N/A</i>	FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D		
AMOUNT RECEIVED <i>Admin Charge</i>	CHECK NUMBER	<input type="checkbox"/> MATANN UPDATED AS REQUIRED	
DATE OF CHECK <i>No Fee Required</i>	LOG <i>Aug 96' SS+0</i>	<input type="checkbox"/> MATSYS UPDATED AS REQUIRED	
APPROVED BY <i>M</i>	DATE RETURN	DATE <i>8/5/96</i>	
COMMENTS			

NOTE: Retain a copy of this request with the application and background files.

NRC FORM 567 (8-93)

ORIGINATORS COPY

Kim,

Sandy

8/1

Here's what happened.

We recieved the fax from Beth Frange ^{RIVUCPO} dated 2/6/96. It raised the question of whether the design of the device allowed access to the source when following the maintenance procedures.

It was logged as an action to track ~~the~~ the work. Right now it is an administrative action that we initiated, so no fees due.

Michelle

NRC FORM 386 (7-82)		U.S. NUCLEAR REGULATORY COMMISSION		DATE 2/6/96
TELECOPIER TRANSMITTAL				TIME 3:00pm
WARNING: Most facsimile machines produce copies on thermal paper. The image produced is highly unstable and will deteriorate significantly in a few years. Reproduce copies onto plain paper prior to filing as a record.				
TO				
NAME Tom Rich			TELEPHONE	
NAME AND LOCATION OF COMPANY (if other than NRC) HQRS; NRC				
TELECOPY NUMBER (301)415- 227 5369		VERIFICATION NUMBER		
FROM				
NAME Beth Prange		TELEPHONE (510)975-0250	MAIL STOP RIV; WCFO	
TELECOPY DATA				
NUMBER OF PAGES THIS PAGE + 10 PAGES = 11 TOTAL		PRIORITY IMMEDIATE OTHER (Specify)		
SPECIAL INSTRUCTIONS Per NMSS call on 2/6/96. Here is the info. from CTI which came in 1988. Also enclosed is info. from Arctic Slope, submitted 1/26/96. They are <u>very</u> similar! On 5/18/88, I had discussed this matter with Dixie Matson (not B.J. Holt, as I thought), Steve Baggett, and Mike Lamstra. Didn't expect to see it again! Thanks for you,				
PROBLEMS If any problems occur or if you do not receive all the pages, call: help on this matter.		DISPOSITION OF ORIGINAL After telecopy has been sent, process the original as requested below. (If none are checked, the original will be discarded.) RETURN TO SENDER CALL AND SENDER WILL PICK UP DISCARD		
TELEPHONE		VERIFIED BY (INITIALS)		
PROCESSED BY (INITIALS)		VERIFIED BY (INITIALS)		

NRC FORM 218
(4-78)
NRCM 0240

U.S. NUCLEAR REGULATORY

MISSION

DATE

MD-10

5/17/88

TIME

4:35

☐ A.M.
☒ P.M.

TELEPHONE OR VERBAL CONVERSATION RECORD

☐ INCOMING CALL

☐ OUTGOING CALL

☐ VISIT

PERSON CALLING

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

PERSON CALLED

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

Sandy Watson

CTI, Inc., RSO

(907) 452-1788

CONVERSATION

SUBJECT

Deficiency Telecon

SUMMARY

1. Does the maintenance procedure involve exposing the source?
 No. Closing off the expose hose prevents a hazardous condition.

2. Does removing the actuator and then removing the locking pin leave the source free to fall from the unit?
 This is the Tech/Ops procedure. Mr. Watson will contact them for further information.

3. What are the responsibilities of John McGlynn, Radiation Safety Mgr.? He is really the Asst. RSO. Watson will send a resume. McGlynn has been involved with radiation safety in industrial radiography for a number of years.

- B.O. Riedinger

REFERRED TO:

ACTION REQUESTED

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

NRC FORM 218
(4-76)
NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

DATE

3/18/88

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

☐ A.M.
☒ P.M.☒ INCOMING CALL☐ OUTGOING CALL☐ VISIT

PERSON CALLING

Sandy Watson

OFFICE/ADDRESS

CTI Inc.

PHONE NUMBER | EXTENSION

(907)452-1788

PERSON CALLED

OFFICE/ADDRESS

PHONE NUMBER | EXTENSION

CONVERSATION

SUBJECT

Maintenance Procedure for Tech Ops Model 865

SUMMARY

1. The personnel at Amersham / Tech Ops agree that the maintenance procedure could cause problems for persons in the field. CTI will end their procedure at 13.3.2.
2. Mr. Watson will send photos + back-up to show how the first portion of the maintenance procedure can be conducted without exposing the source.
3. He will also forward a resumé for John McGlynn.

- B.A. Riedlinger

REFERRED TO:

ACTION REQUESTED

ACTION TAKEN

☐ ADVISE ME OF
ACTION TAKEN.

INITIALS

DATE

INITIALS

DATE