



RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

NURDOCS

NRC FOIA REQUEST NUMBER(S) FOIA - 93-157	
RESPONSE TYPE	
<input checked="" type="checkbox"/> FINAL	<input type="checkbox"/> PARTIAL
DATE JUL - 6 1993	
DOCKET NUMBER(S) (if applicable)	

REQUESTER
Jeri L. Jones

PART I. AGENCY RECORDS RELEASED OR NOT LOCATED (See checked boxes)

<input type="checkbox"/>	No agency records subject to the request have been located.
<input type="checkbox"/>	No additional agency records subject to the request have been located.
<input type="checkbox"/>	Requested records are available through another public distribution program. See Comments section.
<input type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) _____, are already available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
<input checked="" type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) <u>A</u> are being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
<input type="checkbox"/>	The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and copying at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC, in a folder under this FOIA number.
<input type="checkbox"/>	Agency records subject to the request that are identified in Appendix(es) _____ may be inspected and copied at the NRC Local Public Document Room identified in the Comments section.
<input type="checkbox"/>	Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, N.W., Washington, DC.
<input checked="" type="checkbox"/>	Agency records subject to the request are enclosed. [Appendix A documents are enclosed.]
<input type="checkbox"/>	Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.
Fees	
<input type="checkbox"/>	You will be billed by the NRC for fees totaling \$ _____.
<input type="checkbox"/>	You will receive a refund from the NRC in the amount of \$ _____.
<input type="checkbox"/>	In view of NRC's response to this request, no further action is being taken on appeal letter dated _____, No _____.

PART II. A INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

Certain information in the requested records is being withheld from public disclosure pursuant to the exemptions described in and for the reasons stated in Part II, B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 2120 L Street, N.W., Washington, DC in a folder under this FOIA number.

COMMENTS

Some records relating to the Amersham Corporation were provided in response to your previous FOIA request, 93-154.

9404270251 930706
PDR FOIA PDR
JONES93-157

SIGNATURE, DIRECTOR, DIVISION OF FREEDOM OF INFORMATION AND PUBLICATIONS SERVICES

Carl A. Harris for

APPENDIX

Documents to be Released in their Entirety

<u>No.</u>	<u>Date</u>	<u>Description</u>
1.	1/12/93	Combined Inspection No.s 030-29300/92-001; 030-32596/92-001; and 040-08917/92-001 (3 pages)
2.	10/21/92	Routine Inspection Nos. 030-29300/92-001, 030-32596/92-001, and 040-08917/92-001 (8 pages)

JAN 12 1993

Docket Nos. 030-29300
030-32596
040-08917

License Nos. 20-12836-01
20-12836-02E
SUB-1485

Amersham Corporation
ATTN: William McDaniel
Facility Manager
40 North Avenue
Burlington, Massachusetts 01803

Dear Mr. McDaniel:

Subject: Combined Inspection Nos. 030-29300/92-002; 030-32596/92-001; and
040-08917/92-001

This refers to your letter dated December 9, 1992, in response to our letter dated
October 21, 1992.

Thank you for informing us of the corrective and preventive actions documented in your
letter. These actions will be examined during a future inspection of your licensed program.

We also appreciate the corrections to our report and apologize for the errors.

Your cooperation with us is appreciated.

Sincerely,

001
Original Signed By:
Francis M. Costello

Francis M. Costello, Chief
Industrial Applications Section
Division of Radiation Safety
and Safeguards

9301200105

ASHAM OFFICIAL RECORD COPY Pg 1 January 6, 1993
RETURN ORIGINAL TO IE:07
REGION I

Al/1

Amersham Corporation
40 North Avenue
Burlington, Massachusetts 01803
Telephone (617) 272-2000

December 9, 1992

Mr. Francis Costello, Chief
Industrial Application Section
Division of Radiation Safety and Safeguards
US Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Costello;

We have received a copy of inspection report Nos. 030-29300/92-001, 030-32596/92-001 and 040-08917/92-001.

We would like to clarify a couple of inaccuracies that appear in the inspection report.

1. The facility manager is William McDaniel
2. Lab supervisor is Edward Shaffer
3. On page 11 it states that area monitors are calibrated annually. These are inspected during the monthly audits to assure they are operational, and are activated approximately once a year for a radiation drill.
4. On page 6 of the inspection report it states that the radiological technician are reaudited; while we have proposed this policy it has not been completely implemented. The inspectors may have been reviewing records on the actual qualification reviews performed on the technician.

9301200170

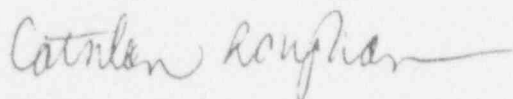
DEC 14 1992

Amersham

The notice of violation issued concerned the nonperformance of one of our required monthly audits. Amersham has had an excellent record in performing all the required license commitments, including the monthly audits. We did not perform the actual physical audit ie wipe tests and radiation surveys as cited in the NOV, however the required records audit was performed. In addition the routine daily contamination wipes and radiation surveys performed in the radioisotope laboratory during this time period did not indicate any unusual results. Amersham will continue to maintain its good safety record by performing the monthly audits as required on a monthly basis. As noted in your inspection report, Amersham has hired a full time QA Manager which will allow the safety office to appropriately focus more attention on radiation safety issues. This will assure that license commitments are met as required.

I trust this contains the information necessary to address your inspection findings. If you require any additional information, please contact me.

Sincerely,



Cathleen Roughan
Regulatory Affairs Manager

cc: W. McDaniel, Facility Manager

OCT 21 1992

Docket Nos. 030-29300
030-32596
040-08917

License Nos. 20-12836-01
20-12836-02E
SUB-1485

Amersham Corporation
ATTN: William McDonald
Facility Manager
40 North Avenue
Burlington, Massachusetts 01803

Dear Mr. McDonald:

Subject: Routine Inspection Nos. 030-29300/92-001, 030-32596/92-001, and
040-08917/92-001

On September 16 and 17, 1992, Betsy Ullrich, Duncan White and Steven Baggett of this office conducted a routine safety inspection at the above address, of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and K. Roughan, at the conclusion of the inspection.

As discussed at the exit meeting on September 17, 1992, at your facility, it is our understanding that Amersham Corporation will take the following actions; 1) review inventory records to ensure that records have been updated to include any changes as a result of transfer or disposal of licensed material; 2) verify that all sealed sources have been leak tested within the last ten years; and 3) the calibration area currently located outside the Cobalt Room will be relocated to another area within the facility with a low ambient gamma radiation background. In addition to your response to this Notice of Violation, please advise this office the dates that these items will be completed. If our understanding of these items is different from yours, please contact our office immediately.

AMERSHA.NOV OFFICIAL RECORD COPY

Pg 1

October 20, 1992

A/2

9210291024

RETURN ORIGINAL TO
REGION I

IE:07

Amersham Corporation

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bcc:
Region I Docket Room (w/concurrences)

<i>W</i> RI:DRSS	<i>M</i> RI:DRSS	<i>FMC</i> RI:DRSS	<i>FCV</i> RI:DRSS
White/tp	Ulrich	Baggett	Costello
10/20/92	10/1/92	10/1/92	10/2/92

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Combined Report Nos. 030-29300/92-001
030-32596/92-001
040-08917/92-001

Docket Nos. 030-29300
030-32596
040-08917

License Nos. 20-12836-01
20-12836-02E
SUB-1485

Licensee: Amersham Corporation
40 North Avenue
Burlington, Massachusetts 01803

Facility: Amersham Corporation

Inspection at: 40 North Avenue
Burlington, Massachusetts

Inspection Conducted: September 16 and 17, 1992

Inspectors: *Duncan White* 10/20/92
Duncan White, Health Physicist date

Betsy Ullrich 10/21/92
Betsy Ullrich, Senior Health Physicist date

Steven L. Baggett 10/21/92
Steven L. Baggett, Acting Chief date
Research, Development and
Decommissioning Section

9210294432

DETAILS

1. Persons Contacted

- *W. McDonald, Facility Manager
- *K. Roughan, Radiation Safety Officer
- M. St. Ours, Distribution Group Leader
- E. Schaffer, Hot Cell Manager
- J. Price, Customer Service Supervisor
- A. Leonin, Radiological Technician, Distribution Group
- N. Poster, Customer Service Representative
- H. Kingsbury, Hot Lab Technician
- K. Soucy, Hot Lab Technician
- M. Wright, Hot Lab Technician

* indicates those present during exit interview

2. Licensee Action on Previous Violations, Licensee Event Reports and Preliminary Notifications

a. (Closed) Violation, Inspection Report 030-20300/91-001

During an NRC inspection conducted on April 22, 24-25, 1992, a violation was identified regarding the failure of the licensee to provide a written report within 5 days of the initial notification of a defect as required by 10 CFR 21.21(b)(2). In a letter dated July 8, 1991, the licensee's corrective action included the issuance of a preliminary report within the 5 days of the notification followed by a comprehensive evaluation at a later date. During the course of this inspection, the inspectors noted the licensee provided written notification to the NRC within 5 days for the two Part 21 events that occurred since the previous inspection (leaking source at QEST and the Model 920 front adaptor).

b. (Closed) PNO-III-91-43, Leaking source at QEST, Tulsa, Oklahoma

The events following the identification of contamination at the QEST facility in Tulsa, Oklahoma were reviewed at the Radiation Protection and General Safety Committee (RPGSC) meetings. Information was submitted to the Region I office in letters dated July 12, 1991 and January 16, 1992. The information

Approximately 39 employees work with licensed material; about one-half of these are radiation technicians who handle material on a daily basis. The performance of each job assignment involving licensed material (i.e. hot cell, shipping, etc.) requires the radiological technician to be qualified and approved by the licensee's Radiation Protection and General Safety Committee.

The licensee has imposed in-house dose restrictions on the facility, requiring investigations into methods of reducing doses to individuals at the facility. The workload of any individual who is expected to receive greater than 500 millirem dose in a year is reviewed. Such reviews have resulted in the re-design of the shipping/receiving area to provide additional shielding as well as automated and remote methods of handling devices containing radioactive sources. If any individual is expected to receive greater than one rem in a year, a special review is performed to determine if it is necessary that the work activities be performed by this individual. No individual is permitted by the licensee to receive a dose greater than two rem in any one year.

The licensee has recently hired a full-time quality assurance manager. This individual will assume all quality control and quality assurance duties. These changes in responsibilities are intended to provide more time to the Radiation Safety Officer and Assistant Radiation Safety Officer to address radiation safety.

No safety concerns were identified.

4. Radiation Protection and General Safety Committee (RPGSC)

Minutes of meetings were reviewed for the period of June 1991 through July 1992. Meetings were held at least quarterly as required. The RPGSC is comprised of the Facility Engineer, the Radiation Safety Officer, the Assistant Radiation Safety officer, the Engineering Manager, and the Hot Lab Supervisor. The Corporate Radiation Safety Officer is frequently present at these meetings. Minutes included reports of discussions of items to be followed up from the past meeting; periodic summaries of personnel monitoring and other survey results; licensing and regulatory issues; and reportable incidents. During review of other records, the inspectors noted that some corrective actions by the licensee had been taken for incidents which were not required to be reported to the NRC, and these incidents were not recorded in the RPGSC minutes or in the Incidents file. Licensee representatives agreed that, whenever significant follow-up actions were taken, e.g. a suspected intake in which an individual was sent for a whole-body count, the incident should be reviewed by the RPGSC even though the follow-up to the incident identified no problem.

No safety concerns were identified.

The inspectors observed the hot cell operations. The radiological technicians complete a daily and weekly checklist for operability of equipment, radiation levels, and air handling flow. Interlocks, alarms, and lights were tested and functioned as required by 10 CFR 20.203(c). The air handling and sampling equipment built into the cells are used to demonstrate compliance with 10 CFR 20.106(a). Each cell has three air sampling positions which are analyzed daily. A review of the air sampling results over the last year indicated that daily concentrations were on the average less than $1\text{E-}11$ microcuries per cubic centimeter of air ($\mu\text{Ci/cc}$). The highest concentration noted by the inspectors was $2.81\text{ E-}11\ \mu\text{Ci/cc}$.

The inspectors noted that copies of the licensee's procedures were readily available throughout the facility. A list of authorized individuals was posted at the entrance to the hot cell area. Appropriate caution signs and postings were visible throughout the entire facility.

No safety concerns were identified.

8. Materials

The licensee is required to conduct an inventory of licensed material every six months. During the inspection, the inventories for August 1991, February 1992 and September 1992 were reviewed. A summary of these inventories is listed below:

<u>Material</u>	<u>August 1991</u>	<u>February 1992</u>	<u>September 1992</u>
Encapsulated Ir-192	21,842 Ci	14,280 Ci	26,323 Ci
Bulk Ir-192	16,688 Ci	1,029 Ci	25,013 Ci
Yb-169	1.96 Ci	9 Ci	3 Ci
Co-60	2,863 Ci	5,250 Ci	3,681 Ci
Cs-137	50.44 Ci	49 Ci	67 Ci
Depleted Uranium	17,433 kg	21,395 kg	17,712 kg
Sr-90	--	16 mCi	16 mCi

The inventory identifies material in six areas within the facility: Hallway I; Hallway II and III; Range Room; Cutting Room; Shipping; and Hot Lab and Waste Room. The depleted uranium, in the form of shields for exposure devices, is maintained by model number as received from the vendor. The licensee also maintains a monthly total of licensed material with high turnover (i.e. iridium, cobalt and cesium).

The inspectors identified a dozen sources or lots of bulk material located on the licensee's inventory for physical identification. All sources were located in the areas identified on the inventory.

The inspectors reviewed the licensee's procedures for customer license verification. Orders are processed by a customer service department which maintains the customers' files. These files contain the packing list, shipping check list, bill of lading, and receiving/receipt report. The licensee also maintains copies of their customers' NRC or Agreement State licenses to confirm that (1) the customer is authorized for the licensed material, and (2) the address matches that on the licensee or the customer is authorized for temporary job sites.

The inspectors also reviewed the transfer of exempt quantities of Cs-137 under the licensee's exempt distribution license. During the period April 1991 through July 1992, a total of 16 exempt sources were shipped.

No safety concerns were identified.

10. Personnel Monitoring for External Exposure

Dosimetry records were reviewed for the period of January, 1991 through July 1992. Dosimeters are issued monthly to workers, and are provided to the licensee by a NVLAP-certified company. Thirty-nine individuals have been monitored using whole-body film dosimeters. In addition, 16 of these individuals also wear left and right-hand TLD ring dosimeters, and nine individuals also wear left and right-wrist dosimeters as well as a film dosimeter at head level. In 1992, the maximum monthly dose measured by the whole body badges was 150 millirem, and the maximum monthly exposure measured by the ring dosimeters was 440 millirem. In 1991, the maximum annual whole body dosimeter measured 1090 millirem (maximum of 340 millirem in a quarter); the maximum ring dosimeter measured 3180 millirem (maximum of 750 millirem in a quarter); the maximum wrist dosimeter measured 340 millirem; and the maximum head dosimeter measured 1200 millirem (maximum of 410 millirem in a quarter).

In 1992, workers in the Hot Lab received a range of 670 to 1200 millirem on their whole body and head dosimeters, and 50 to 1020 millirem on the ring and wrist monitors. Workers in Quality Control received zero to 660 millirem whole-body and zero to 3180 millirem to the ring dosimeters. Workers in Shipping/Receiving received 880 to 1070 millirem to the whole body. The licensee stated that these workers are not issued extremity dosimeters as past monitoring has indicated that little or no dose is received to their hands, and that the whole body dose is due to the high ambient levels in the area. However, the licensee also stated that they expect to see these doses decrease beginning with the August dosimeters, due to the implementation of the new shielding and handling systems. The range of whole body doses for all other workers was zero to 430 millirem in 1991.

Pocket dosimeters are calibrated annually and tested for leakage. All pocket dosimeters in use were observed to be calibrated. Records of calibration and testing were maintained. Dosimeters taken out of service and the reason for failure were noted in the records.

The licensee is required to calibrate most radiation survey instruments every six months. Area monitors are calibrated annually. All instruments and monitors observed in use were calibrated. The inspectors reviewed records from April 1991 to August 1992.

The inspectors noted that the sampling pumps and the flowmeters used in the hot cells had not been calibrated. The licensee representatives agreed to calibrate this equipment at least annually because it is used for demonstrating compliance to NRC regulations.

The licensee calibrates its own survey instruments and those for its customers utilizing an Amersham Model 773 calibration device located in the hall outside the Cobalt Room in the hot cell area. The inspectors measured ambient radiation levels in this area in the range from 0.5 to 1 milliroentgens per hour. The licensee acknowledged that increases in the ambient radiation levels could affect their ability to calibrate the low range of the survey instruments. The licensee agreed to relocate the instrument calibration device to an area in the facility where the ambient gamma radiation background was low.

No safety concerns were identified.

13. Area Surveys

The licensee is required to conduct monthly surveys for radiation and contamination of area where licensed material is either used or stored. The inspectors reviewed monthly survey results from April 1991 through August 1992. The inspectors determined that the licensee did not perform a radiation survey in March 1992.

The failure to conduct a survey for radiation and contamination in March 1992 is a violation of the licensee's procedures in Part A, Section 9 of the Radiation Safety Manual.