

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 12-12836-01/79-02; No. 12-12836-02E/79-01; No. 12-12836-03MD/79-01
No. 12-12836-04G/79-01; No. 12-836-05MD/79-01; and No. SNM-1125/79-01

Licensee: Amersham Corporation
2036 South Clearbrook Drive
Arlington Heights, IL 60005

Facility Name: Amersham Corporation

Inspection At: Arlington Heights, Illinois Facility

Inspection Conducted: November 14-16, 1979

Inspector: *C. J. Paperiello*
B. B. Dicey

Approved By: *C. J. Paperiello*
C. J. Paperiello, Chief
Materials Radiological
Protection Section 1

12/11/79
12/11/79

Inspection Summary

Inspection November 14-16, 1979 (Report No. 12-12836-01/79-02;
12-12836-02E/79-01; 12-12836-03MD/79-01; 12-12836-04G/79-01;
12-12836-05MD/79-01; and No. SNM-1125/79-01)

Areas Inspected: Routine, unannounced inspection of activities conducted under the above referenced licenses, including: action on previously identified enforcement matters; review of previously unresolved matters; radiation protection procedures; audits; employee training program; facilities and equipment; receipt of radioactive materials; transfer of radioactive materials; customer license verification program; shipping incidents; exposure control; posting, labeling, and control; surveys; radioactive effluent control; waste disposal; notifications and reports; environmental monitoring; emergency preparedness; unusual occurrences; and confirmatory measurements. The inspection involved 19 inspector-hours onsite by one NRC inspector and four man-hours onsite by one NRC Region III Supervisor.

Results: Of the 20 areas inspected, no apparent items of noncompliance were identified in 19 areas; one apparent item of noncompliance was identified in one area (Deficiency; Failure to submit report required by 10 CFR 32.20 in a timely manner - License No. 12-12836-02E - Paragraph 18, Details).

DETAILS

1. Persons Contacted

*John L. Castello, President
*Terry E. Gibson, Director of Operations
*Al Westerfield, Manager of Regulatory Affairs
*David J. Fischer, Distribution Manager
*Daniel P. Be'grair, Radiation Safety Officer
Linda Bagby, Safety Officer
Roger Ferris, Manufacturing Manager, Liquid Scintillation and
Source Products
Albert C. Walters, Manager, Materials Management
Rick Powers, Order Processing and Traffic Supervisor

The inspector also interviewed several nonsupervisory personnel during the course of the inspection.

*Denotes those present at the exit interview on November 16, 1979.

2. General

A review of various aspects of the licensee's operations was carried out during this inspection, including the scope of operations, operating practices, incidents or unusual occurrences, and other items. Emphasis was placed on a review of the licensee's customer verification program to ensure that transfers of licensed material are made only to properly authorized recipients.

The results of this review indicate that with the exception listed below the licensee appears to be performing in accordance with regulations, its operating procedures, and the conditions of the several licenses. A review of the licensee's inventory and use records indicate that licensed material possessed under the license appeared to be used in quantity and kind as authorized.

Inspection of five small, licensed programs was also completed (12-12836-02E-Distribution to Persons Exempt from Licensing; 12-12836-03MD-Distribution under Groups I and II, 10 CFR 35; 12-12836-04G-Distribution of I-125 Kits under 10 CFR 31.11 General License; 12-12836-05MD-Medical Distribution of Sealed Sources; SNM-1125-Possession, Storage, and Distribution of Products Containing Special Nuclear Material). Of these, License No. SNM-1125 had been incorporated into License No. 12-12836-01 by amendment dated September 28, 1979. Programs under the remaining licenses appeared to be in accordance with the respective licenses, license applications, and applicable regulations except that a material transfer report required by 10 CFR 32.20 to be submitted for activities under License No. 12-12836-02E, had not been submitted in the prescribed manner. Details of this are included in paragraph 18, below (Notifications and Reports).

Except when specifically annotated to the contrary, all subsequent paragraphs in this report refer to activities conducted under License No. 12-12836-01.

3. Licensee Action on Previously Identified Enforcement Matters

(CLOSED) Infraction 1 (03004261/79-01): Transfer of material to person not authorized to receive such material (10 CFR 30.41(b)(5)). The licensee has developed and implemented detailed procedures for verification of the licensure status of customers, as stated in the licensee's letters to Region III dated March 23 and February 20, 1979.

(CLOSED) Infraction 2 (03004261/79-01): Transfer of material without verifying that the transferee's license was current (10 CFR 30.41(c) and 10 CFR 30.41 (d)). Licensee corrective action with respect to this item was the same as that for Infraction 1, above.

(CLOSED) Infraction (03004261/78-03): Inadequate survey of packages for contamination with tritium (10 CFR 20.201(a) to demonstrate compliance with 10 CFR 20.205(b)(2)). The licensee had modified the package survey procedures so that packages containing tritium are surveyed for contamination using instrumentation capable of detecting tritium.

(CLOSED) Infraction 1 (03004261/78-02): Failure to calibrate survey instruments at six month intervals (License Condition #15). This infraction was corrected as described by the licensee in a letter dated November 29, 1978. A review of records indicated that there had been no recurrence of this item.

(CLOSED) Deficiency 2 (03004261/78-02): Failure to complete posting as required by 10 CFR 19.11(a) and (b). This deficiency was corrected prior to completion of the inspection conducted September 29, October 3, 4, and 6, 1978. A review of facilities showed that there had been no recurrence of this item.

4. Review of Previously Unresolved Matter

The previous routine inspection (Report No. 12-12836-01/78-02) identified as unresolved the question of whether bioassay alone was acceptable to demonstrate compliance with 10 CFR 20.103. In resolution of this matter, it was determined that, bioassay may be used to supplement direct measurements of concentrations of radioactive materials in air, for purposes of demonstrating compliance with 10 CFR 20.103, but that bioassay may not be used as a substitute for such measurements. The licensee has one area (Fibrinogen Manufacturing Area) where airborne radioactivity could occur. Paragraph 16, Radioactive Effluent Control, describes the licensee's program for demonstrating compliance with 10 CFR 20.103 in this area.

This item is closed.

5. Radiation Protection Procedures

The licensee's radiation protection procedures are documented in a "Radiation Protection Policy Manual". This manual was revised in May, 1978 and the revision was submitted to the Commission with an application for renewal dated May 31, 1978. Aspects of these written operating and emergency procedures were reviewed during this inspection.

No items of noncompliance or deviations were identified.

6. Audits and Management Controls

Management control over licensed activities is accomplished by a Radiation Safety Committee and by a full time Radiation Safety Officer (RSO). The Committee meets at least quarterly, often more frequently. Responsibilities and membership of the Committee are as specified in the Radiation Protection Policy Manual.

In addition, the RSO conducts routine audits of licensed activities, documenting the results of these audits. An annual Health Physics Report is submitted to the parent corporation in England describing the Radiation Safety Program.

A review of records of the Radiation Safety Committee and of audits conducted by the RSO indicate that the audit function is accomplished in a manner appropriate to the scope of licensed activities being conducted.

No items of noncompliance or deviations were identified.

7. Employee Training Program

The licensee's program for training and qualification of personnel for both new and existing employees was reviewed during this inspection and found to be in accordance with Section 2.7 of the Radiation Protection Policy Manual. In addition to the formal training program for radiation workers, the RSO participates in a formal new employee orientation program provided to all new employees regardless of whether they are radiation workers. Also, female radiation workers are given instruction concerning prenatal radiation exposure with reference to USNRC Regulatory Guide 8.13. Documentation of training provided is maintained by the RSO.

No items of noncompliance or deviations were identified.

8. Facilities and Equipment

There had been no major facility use changes since the last routine inspection.

Significant equipment changes include installation July, 1979 of an Eberline Model IM-1B "Cart Mounted Radioactive ¹²⁵I Monitoring

System" in the Fibrinogen production area. This system provides constant air monitoring of the Fibrinogen production area, with a strip chart record that is annotated by the production workers to indicate the beginning and the end of a production operation.

No items of noncompliance or deviations were identified.

9. Receipt of Radioactive Materials

All incoming radioactive material is surveyed upon receipt for damage and evidence of radioactive contamination caused by leakage of the radioactive contents. Wipe tests are evaluated by counting techniques appropriate to the isotopic contents of the package. Records are maintained and random samples were reviewed by the inspector.

No items of noncompliance or deviations were identified.

10. Transfer of Radioactive Materials

Control of transfers of radioactive material is by a formal Customer Verification Program, discussed in greater detail in the next paragraph.

Licensed material for distribution is packaged, labeled, and surveyed by the Shipping Department. Transport index information is recorded on the shipping package using an Eberline mini-scaler with GM probe. Interviews with licensee representatives, reviews of documents, and observation of shipping operation indicated that, with the exception of the shipping incident discussed in Report No. 12-12836-01/79-01, no problems had been encountered since the last routine inspection.

No items of noncompliance or deviations were identified.

11. Customer License Verification Program

The licensee has established a computer assisted procedure for verification of the licensure status of proposed transferees. This system is describe in detail in the licensee's letters to Region III dated February 20 and March 23, 1979.

The inspector conducted a 100% review of the 376 transfer documents generated on a randomly selected date (November 6, 1979). This review was conducted using both the licensee's computer and the licensee's file of customer license documents. No variations from the written procedures were noted. Based on this review, it appears that the licensee's Customer License Verification Program is operating substantially in the way it was designed.

No items of noncompliance or deviations were identified.

12. Shipping Incidents

According to a licensee representative, one shipping incident involving licensed material occurred since the last routine inspection.

This incident, involving receipt by a customer of a broken container of tritium, was reviewed during a special inspection conducted November 14, 1978. (Report No. 12-12836-01/78-03)

A review of licensee corrective action with respect to this matter indicated that supplemental training of shipping personnel and changes in packaging procedures have been effective in preventing a recurrence of this problem.

No items of noncompliance or deviations were identified.

13. Exposure Control

External

Section 2.5 of the licensee's Radiation Protection Policy Manual describes the Personnel Monitoring System.

Whole body film badges and finger TLD rings supplied by G. D. Searle, Inc. are used for monitoring external radiation exposures. The licensee employs two exchange frequencies: weekly and monthly. Shipping personnel are assigned to weekly exchange frequency, all other radiation workers are assigned to a monthly exchange frequency.

Film badge and TLD reports were reviewed for the first nine months of 1979. Maximum exposures for the full nine month monitoring period were as follows:

20 Alpha Workers	-	177 mR
49 General Workers	-	422 mR
10 Shipping Workers	-	973 mR (whole body)
		1,331 mR (ring)

The licensee maintains NRC Forms 4 and 5 or equivalent for all badged personnel. Randomly selected records were reviewed during this inspection with no problems noted. The licensee provided all accumulated personnel exposure information, including film, TLD, and bioassay data, to all terminating personnel. These records were reviewed during this inspection and were found to be in accordance with 10 CFR 20.408.

Internal

Fibrinogen production and testing personnel are monitored by means of a weekly thyroid counting program. These counts, over three locations in the thyroid and a summed count, are compared with a NBS traceable I-125 standard counted in an Abbott/Orins Thyroid Phantom.

A review of 1979 weekly thyroid counts for 21 individuals showed that 19 of the 21 had no thyroid uptake greater than 10% of a body burden. Two individuals showed single uptake values of approximately

15% of a body burden. These two uptakes were explained as being due to a glove box leak in April, 1979. No recurrence was noted and essentially all thyroid counts conducted were at background levels. Nine special tritium urinalyses were conducted as a result of a spill on July 31, 1979 of 2 curies of tritium in the waste storage area. Based on these urinalyses, the maximum uptake by any one individual was 0.13% of a body burden (13/100ths of one percent). All others were found to have no detectable tritium uptake.

No items of noncompliance or deviations were identified.

14. Posting, Labeling and Control

The licensee's practices with respect to posting and labeling and controls on access to radioactive material were reviewed. Posting and labeling practices were found to be in accordance with 10 CFR 19.11 and 10 CFR 20.203.

No items of noncompliance or deviations were identified.

15. Surveys

Radiation surveys conducted by the licensee include exposure rate measurements of surface contamination, and personnel monitoring for contamination. A review of survey records and discussions with personnel indicated that there had been no major surface contamination problems since the previous routine inspection and that the smear and area survey programs were being conducted as described in the Radiation Protection Policy Manual.

No items of noncompliance or deviations were identified.

16. Radioactive Effluent Control

Gaseous Effluents

The licensee conducts a program of continuous air monitoring in the fibrinogen production area. This is accomplished by use of an Eberline Model IM-1B "Cart Mounted ¹²⁵I Monitoring System". Sample collection location appeared to be in a typical breathing zone for the fibrinogen production workers. The constant air monitoring system was installed in July, 1979. A review of strip chart data collected since installation of the system indicated that there had been no occurrence of airborne concentrations of ¹²⁵I which exceeded 10% of the Part 20 limits for unrestricted areas.

Prior to July, 1979, the licensee demonstrated compliance with 10 CFR 20.103 and with 10 CFR 20.106 by means of a routine air sampling program which included both general area samples and portable breathing zone samplers worn by the fibrinogen production workers. Results of these discrete samples also showed no concentrations of ¹²⁵I which exceeded 10% of the Part 20 limits for unrestricted areas.

Room air from the fibrinogen production area passes through an activated charcoal filter and four "HEPA" absolute filters before entering the building stack for exhaust to the environment.

The inspector concluded from this review of the Gaseous Effluent Control Program, that the licensee is demonstrating compliance with both 10 CFR 20.103 and 10 CFR 20.106.

Liquid Effluents

Prior to June 6, 1979, the licensee collected waste water from laboratory sink drains in four 1000 gallon tanks. Liquid in the tanks was sampled daily and analyzed to identify and quantify any isotopes which might be present. Results of the analyses were recorded and the tank contents were pumped to the sanitary sewer provided concentrations were below Appendix B, Table II, Column 2, 10 CFR 20 limits or if adequate volumes of dilution water were available to reduce concentrations to below these limits. A review of records indicated that most samples required no dilution and, for the few requiring dilution, the gallons required to effect dilution were exceeded by the volumes actually used for dilution by several thousand gallons per day.

Subsequent to June 6, 1979, the licensee has adopted a policy that no radioactive material is to be discharged to the sanitary sewage system. Monthly liquid effluent samples since that date have confirmed that the policy has been effectively implemented.

No items of noncompliance or deviations were identified.

17. Waste Disposal

Radioactive waste generated at the licensee's facility is collected, stored for decay, and is packaged for shipment to a licensed radioactive waste disposal site. At the time of this inspection, the licensee was utilizing the services of the Nuclear Engineering Company (NECO) for radioactive waste disposal. A review of all shipping records since the last routine inspection indicated that no problems had been encountered.

On August 10, 1979, the licensee was mailed a copy of IE Bulletin No. 79-19, "Packaging of Low-Level Radioactive Waste for Transport and Burial". The licensee replied to this Bulletin with a letter dated September 24, 1979 detailing the radioactive waste disposal program and responding to specific questions in the Bulletin. Observation of radioactive waste disposal practices during this inspection confirmed the accuracy of the licensee's September 24, 1979 letter.

No items of noncompliance or deviations were identified.

18. Notifications and Reports

It was noted during this inspection that, reports to the Commission and notices to workers were made by the licensee as required by 10 CFR 19.13, 10 CFR 20.407 and 10 CFR 20.409.

During the inspection of license number 12-12836-02E, it was noted that the Material Transfer Report for the period July 1, 1978-June 30, 1979 was not submitted until September 26, 1979. 10 CFR 32.20 requires that this report be filed within 30 days after June 30. This failure to submit a report in a timely manner is in noncompliance with 10 CFR 32.20.

One item of noncompliance was identified.

19. Environmental Monitoring Program

The licensee does not maintain an environmental monitoring program and none is required by the license.

No items of noncompliance or deviations were identified.

20. Emergency Preparedness Program

The licensee has a formal radiation emergency procedure which is administered by the Safety Officer.

Unannounced drills of the emergency plan were conducted July 26 and September 26, 1979. The Safety Officer stated that no significant problems were identified during either of the two drills.

No items of noncompliance or deviations were identified.

21. Unusual Occurrences

No unusual occurrences were identified that had not previously been revised by the Commission.

No items of noncompliance or deviations were identified.

22. Confirmatory Measurements

An area survey of the radioactive waste storage areas made using an end window G-M Survey Instrument showed results consistent with surveys made by the RSO.

No items of noncompliance or deviations were identified.

23. Unresolved Items

Unresolved items are matters about which more information is required in order to ascertain whether they are acceptable items, items of

noncompliance, or deviations. Discussion of a previously unresolved matter is included in paragraph 4 of this report.

No new unresolved items were disclosed during this inspection.

24. Management Exit Interview

Those subjects inspected during this inspection as outlined in the Details of this report were discussed with personnel denoted by an asterisk in paragraph 1 during an exit interview November 16, 1979. The exit interview was also attended by a representative of the NRC Region III Supervisory Staff, who had observed portions of the inspection.

The following items were specifically discussed at this meeting:

- a. The item of noncompliance identified during the inspection of License No. 12-12836-02E.
- b. License action with respect to previously identified enforcement matters.
- c. Review of a matter previously unresolved.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

SEP 24 1979

Minnesota Mining and Manufacturing
Company
ATTN: Mr. Robert G. Wissink
Chairman
Radioisotope Committee
3M Center
St. Paul, MN 55101

License No. 22-00057-06
License No. 22-00057-34G
License No. 22-00057-37E
License No. 22-00057-55E
Authorization No. 22-00057-56MA ✓

30-10822

Gentlemen:

This refers to the inspection conducted by Mr. B. B. Dicey accompanied by Miss N. A. Nicholson of this office, on August 20-24, 1979, of activities at the Minnesota Mining and Manufacturing Company authorized by the above referenced licenses and authorization and to the discussion of our findings with you at the conclusion of the inspection.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC's Public Document Room, except as follows. If the enclosures contain information that you or your contractors believe to be proprietary, you must apply in writing to this office, within twenty days of your receipt of this letter, to withhold such information from public disclosure. The application must include a full statement of the reasons for which the information is considered proprietary, and should be prepared so that proprietary information identified in the application is contained in an enclosure to the application.

During this inspection, one of your activities with respect to License No. 22-00057-06 appeared to be in noncompliance with NRC requirements, as described in the enclosed Appendix A. No items were identified with respect to License No. 22-0057-34G, 22-0057-37E, 22-0057-55E, and Authorization No. 22-00057-56MA.

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The inspection report also identifies as unresolved the matter of releases of I-125 to the unrestricted area from your recently established production facilities in Building 675. Information required to enable an adequate evaluation of this matter was not available for review at the time of this inspection. This will be further reviewed during a subsequent inspection.

This notice is sent to you pursuant to the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Section 2.201 requires you to submit to this office within twenty days of your receipt of this notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved.

With respect to the identified apparent item of noncompliance, we note that the failure to conduct required surveys was an isolated occurrence and that there was no evidence of recurrence. Consequently, your reply should be limited to (1) and (2), above.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

A. B. Davis, Chief
Fuel Facility and
Materials Safety Branch

Enclosures:

1. Appendix A, Notice of Violation
2. IE Inspection Report
No. 22-00057-06/79-01,
22-00057-34G/79-01,
22-00057-37E/79-01,
22-00057-55E/79-01
and 22-00057-56MA/79-01

cc w/encls:

Central Files

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Appendix A

NOTICE OF VIOLATION

Minnesota Mining and Manufacturing
Company

License No. 22-00057-06
22-00057-34G
22-00057-37E
22-00057-55E
22-00057-56MA

Based on the inspection conducted on August 20-24, 1979, it appears that certain of your activities were in noncompliance with NRC requirements, as noted below. This item is a deficiency.

Condition 21 of License No. 22-00057-06 incorporates by reference your Surface Contamination Assessment Program as described in Section IV, Paragraph II(D)(4) of the Health Physics Manual. This section specifies, among other requirements, that the Health Physics Group conducts a wipe test survey in all Green, Yellow, and Red areas at least once a week.

Contrary to this requirement, no such survey was conducted by the Health Physics Group in Green areas of Building 575 during the period July 26 through August 7, 1979, inclusive, a period in excess of one week.

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 22-00057 06/79-01 Priority 1 Category B
22-00057-34G/79-01 Priority 7 Category K
22-00057-37E/79-01 Priority 4 Category E
22-00057-55E/79-01 Priority 4 Category E
22-00057-56MA/79-01 Priority 7 Category K

Licensee: Minnesota Mining and Manufacturing Company
3M Center
St. Paul, MN 55101

Inspection At: 3M Center, St. Paul, MN and Twin Cities
Army Ammunition Plant, Arden Hills, MN

Inspection Conducted: August 20-24, 1979

Inspector: B. B. Dicey

Bruce B. Dicey 9/21/79

Accompanied By: N. A. Nicholson

*Bruce B. Dicey
for N. A. Nicholson 9/21/79*

Approved By: C. J. Paperiello, Chief
Materials Radiological
Protection Section 1

C. J. Paperiello 9/21/79

Inspection Summary

Inspection August 20-24, 1979 (Report No. 22-00057-06/79-01;
22-00057-34G/79-01; 22-00057-37E/79-01; 22-00057-55E/79-01
and 22-00057-56MA/79-01)

Areas Inspected: Licensee action on previously identified enforcement matters; Radiation protection procedures; Audits; Employee training program; Facilities; Equipment; Receipt of radioactive materials; Transfer of radioactive materials; Shipping incidents; Exposure control; Posting, labeling, and control; Surveys; Radioactive effluent control; Solid waste; Notification and reports; Environmental monitoring; Confirmatory measurements. The inspection involved 74 inspector-hours on site by two NRC inspectors and 12 man-hours on site by one representative of NRC Region III management.

DUPLICATE DOCUMENT

Entire document previously
entered into system under:

ANO 7911070582

No. of pages: 18