November 15, 1988 SECY-88-320

For: The Commissioners

From: Victor Stello, Jr.
Executive Director for Operations

Subject: PROPOSED ACTION IN RESPONSE TO MINNESOTA MINING AND MANUFACTURING COMPANY'S (3M'S) SHOW CAUSE RESPONSE TO FEBRUARY 18, 1988 ORDER

Purpose: To inform the Commission of the staff's intent to issue a Confirmatory Order Modifying License Effective Immediately (Enclosure 1).

Discussion: In briefings on February 9, 1988 and February 18, 1988, the staff informed you of the widespread failure of polonium-210 (Po-210) static elimination devices (hereafter called either devices or static eliminators) that 3M manufactured and distributed to both specific and general licensees of the United States Nuclear Regulatory Commission (NRC) and Agreement States. These findings led NRC to issue a series of Orders to 3M on January 25, February 5, February 12, and February 18, 1988 (see Enclosures 2 to 5).

These Orders modified two of the several licenses issued to 3M. License No. 22-00057-06 (06 License) authorized, among other things, manufacture, testing, installation, and repair of Po-210 sources and the static elimination devices in which they are used, and the distribution of Po-210 devices to persons specifically authorized to receive them. License No. 22-00057-32G (32G License) authorized distribution of Po-210 static eliminators to persons generally licensed in accordance with 10 CFR Section 31.5.

Section V of the February 18, 1988 Order (Enclosure 5) required 3M to show cause, within 60 days of February 18 (i.e., by April 18, 1988), why the 32G License should not be revoked in its entirety and why the 06 License should not be revoked to the extent that it authorized manufacturing of Po-210 static eliminators. By letter dated April 5, 1988, 3M requested an extension from April 18 to July 18, 1988 as the date for filing the show cause response. 3M stated that the additional time would allow it to obtain the results of internal and contract studies and to determine

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whether to request authorization to resume manufacture and distribution of all or some of its Po-210 static eliminators to persons holding specific or general licenses that NRC or Agreement States issued to them. NRC granted the extension by letter dated April 13, 1988, and 3M filed its written response under oath on July 18, 1988 (Answer).

In its Answer, 3M requested:

- With regard to the 06 License, continuation of authority to manufacture the Po-210 devices for research and development (R&D) to evaluate whether the devices could be modified to permit resumed commercial distribution.

- With regard to the 32G License, continuation of the suspension until research and test data confirm that resumed distribution of the Po-210 devices is appropriate. In that case, 3M may seek an amendment of the 32G License to permit resumed distribution outside 3M.

The staff's proposed response is set out in Enclosure 1. The staff's views on the appropriate responses to the licensee's requests on the two licenses are outlined next.

The 06 License

The staff agrees that the licensee's request is appropriate and that the proposed partial revocation of the 06 License is not needed now. However, one commitment that 3M made in its Answer and its September 16, 1988 letter is so essential to the staff's agreement that the staff believes an Order should confirm the commitment.

Continued manufacturing authority must not result in commercial distribution and use outside 3M. Distribution within 3M would be limited to use of the devices in 3M production facilities to assess, as an R&D matter, whether long-term use of the devices is acceptable. The terms of the Order would prohibit distribution of Po-210 static eliminators to specific licensees outside 3M. (Note that if 3M wished, in the future, to distribute a Po-210 device to a specific licensee other than 3M, the staff could consider such a request under the general relief provisions of the Order.) The terms of the February 18, 1988 Order would continue to prohibit distribution to general licensees.

The 32G License

The staff agrees that the licensee's request for continued suspension of the 32G License is appropriate, because it precludes any public health and safety concern. It also would not foreclose to 3M a regulatory mechanism (i.e., amendment of the 32G License) to request resumed distribution of Po-210 static eliminators to general licensees, if 3M could convince NRC that it could conduct such distribution safely. Thus, the staff does not propose to revoke the 32G License now.

Additional Information Developed

Since the February 1988 Commission briefings, the staff has obtained additional information; namely, the results of an NRC contractor's evaluation of some 3M devices; the conclusions of an internal 3M team's evaluation; test results from the return of thousands of 3M devices; and the results of a series of inspections that NRC conducted at 3M.

At NRC's request, the Brookhaven National Laboratory (BNL) performed a failure investigation of 3M Model 908 static eliminators obtained from Ashland Chemical Company, Easton, Pennsylvania. BNL chose the devices it investigated from a total of 34 both used and new, unused devices. In its report (Enclosure 6), BNL concluded that the "breakdown of the epoxy binder appears to be a significant contributor to the contamination by loose microspheres or microsphere fragments." BNL indicated that the epoxy binder appears to suffer significant environmental and material damage even under ambient conditions. Conditions that may accelerate damage include solvents, heat, moisture, or vibration. For example, new, unused devices may be potential sources of contamination.

In its Answer, 3M reported that one of its internal task forces found several factors that contributed to leakage of the Po-210 devices. These factors (and the 3M devices affected by them) include:

1. Abuse of the devices, both by alteration of devices and by exposure to unsuitable environments (compressed air- and bar-type devices);

2. Variation of microsphere seating (compressed air-type devices);

3. Flaking of the epoxy overcoating (bar-type devices).

In response to NRC's Orders, 3M has recalled all models of its Po-210 static eliminators and has tested the returned devices for removable Po-210. Enclosure 7 summarizes the returns and test results to date.

Since January 1988, NRC staff has been conducting both an investigation at 3M and a series of inspections of 3M. The staff has not identified any other 3M sources or devices with actual or potential problems of the nature found with 3M's Po-210 static eliminators. Enclosure 8 summarizes the results of these inspections. In brief, the staff found apparent violations that indicate a need for 3M corporate management to improve its oversight of all licensed activities. In its Answer, 3M has recognized the need to make organizational and programmatic changes to improve management oversight and to increase its emphasis on quality assurance (QA). 3M appears to be in the process of making these changes, but has not submitted the specific details of, nor schedule for completing, these changes. In its review of 3M's response to the apparent violations identified in the 1988 NRC inspections, the staff will evaluate carefully 3M's planned corrective actions. The results of that review will determine whether additional action is needed to improve management oversight and attention to detail. The staff will consider further actions, including enforcement, as appropriate, after reviewing the completed inspection reports, planned corrective action, and the results of the pending Office of Investigations (OI) investigation.

Coordination: The Office of the General Counsel has no legal objection to this action. The Agreement States will be informed of the Commission's action.

Recommendation: The staff intends to issue the Order shown in Enclosure 1 two weeks from the date of this paper, unless the Commission directs otherwise.

Victor Stello, Jr.
Executive Director for Operations

Enclosures:
1. Proposed Order and Cover Letter
2. Order dated January 25, 1988
3. Order dated February 5, 1988
4. Order dated February 12, 1988
5. Order dated February 18, 1988
6. NUREG/CR-5145
7. Summary of Returned Devices and Test Results of 3M Po-210 Devices
8. Summary of Inspections of 3M

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Wednesday, November 30, 1988, that the Commission, by negative consent, assents to the action proposed in this paper.

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of Minnesota Mining and Manufacturing Company 3M Center 220-2E-02 St. Paul, MN 55144-1000	Docket No. 030-04951 License No. 22-00057-06

CONFIRMATORY ORDER MODIFYING LICENSE EFFECTIVE IMMEDIATELY

I

Minnesota Mining and Manufacturing Company (3M or Licensee) is the holder of byproduct material licenses issued by the Nuclear Regulatory Commission (the Commission or NRC). License No. 22-00057-06 (the 06 License) was issued on February 17, 1964, was most recently amended on May 6, 1987, and expires on May 31, 1992. This license authorizes the Licensee to use a variety of radionuclides, including polonium-210 (Po-210), and to conduct a variety of activities with these materials including the manufacture, testing, installation, and repair of radioactive sources, and the devices in which they are used, and the distribution of sources and devices to those specifically licensed to receive them.

Enclosure 1

License No. 22-00057-32G (the 32G License) was issued on July 12, 1965, most recently amended on May 5, 1987, and expires on July 31, 1990. This license authorizes the Licensee to transfer Po-210 sources for use in static elimination devices to persons generally licensed in accordance with the provisions of 10 CFR Section 31.5. These licenses were modified by Orders on January 25, 1988, February 5, 1988, February 12, 1988, and February 18, 1988.

II

In the Order of January 25, 1988, NRC had determined that the use of certain models of static elimination devices had resulted in significant alpha contamination on worker clothing and in a number of facilities. The facts then known demonstrated an immediate potential for radiological hazards to persons working with those models of static eliminators and to other persons present in the area of use. Accordingly, the Commission found that the public health, safety, or interest required that the January 25, 1988 Order be made effective immediately. The Order modified the 06 and 32G Licenses and, among other things, suspended authority to distribute Model Nos. 902, 902F, 906, and 908 Po-210 static elimination devices.

In the Order of February 5, 1988, NRC stated that it subsequently learned of multiple instances of failures of Model Nos. 902, 902F, 906, and 908 devices. Many of these failures occurred at facilities where general licensees manufactured products, or packages for products, such as food, beverages, pharmaceuticals, cosmetics, medical products, and other items which are to be

consumed by, or applied to, human beings. On February 5, 1988, the Licensee issued a letter to all of its customers using the above-specified models of the devices, directing such users to remove the devices from applications related to the packaging of food, beverages, pharmaceuticals, or cosmetics and to return them to 3M. The Licensee's action was confirmed by the Order of February 5, 1988 modifying the 06 and 32G Licenses.

In the Order of February 12, 1988, NRC stated that it subsequently learned of failures of devices identified by model numbers not specified in the prior Orders. These failures included both blown air and bar-type static eliminators that are used in plants that manufacture products and packages, or package materials for products, which would constitute a direct pathway for human exposure if contaminated. The cause of these failures was not then known. In view of the wide use of these devices for products intended for human consumption or application, the increasing number of failed devices of various model numbers, the uncertainty as to the failure mechanisms, and the potential for contamination and consequent exposure to human beings, the Commission found that the public health, safety, or interest required that the February 12, 1988 Order be made effective immediately. The Order modified the 06 and 32G Licenses to require, among other things, that 3M inform all users of all models of 3M's Po-210 static eliminators involved in the production or packaging of food, beverages, pharmaceuticals, or cosmetics that 3M had withdrawn them from service and they were to be returned to 3M by March 2, 1988.

In the Order of February 18, 1988, NRC stated that, beginning in late January 1988, it had performed an inspection at 3M, and NRC, the Agreement States, and

the Food and Drug Administration had performed follow-up visits at customers' sites. During this period and through these activities, the following information came to light. 3M's static eliminators were used in a variety of industries and there were continuing reports of failures of devices in industries not affected by the January 25, 1988 Order. These failures could cause not only exposure of persons working with the devices as well as other persons in the area of use, but also contamination of products that were manufactured with the assistance of 3M's static eliminators and which were then widely distributed to members of the public. Based on this information, NRC found that the public health, safety, and interest required that Section IV of the February 18, 1988 Order modifying the 06 and 32G Licenses be made effective immediately. Among other things, Section IV of this Order suspended 3M's authority to transfer any Po-210 static elimination devices to persons generally licensed except as may be specifically authorized in writing by NRC.

Section V of the February 18, 1988 Order stated that, within 60 days of the date of the Order, 3M was to show cause, pursuant to 10 CFR 2.202(b), why the 32G License should not be revoked in its entirety and why the 06 License should not be revoked to the extent that it authorizes manufacturing of Po-210 static eliminators.

III

By letter dated April 5, 1988, 3M requested an extension from April 18, 1988 to July 18, 1988 as the date for filing the show cause response to the February 18, 1988 Order. 3M stated that the additional time would allow 3M

to obtain the results of internal and contract studies and then determine whether to request authorization to resume manufacture and distribution of some or all of its static eliminators to persons holding general or specific licenses issued by NRC or the Agreement States. The extension was granted by letter dated April 13, 1988. 3M filed its written response under oath on July 18, 1988 (Answer).

In its Answer, 3M requested the continuation of its authority under the 06 License to manufacture static elimination devices for research and development purposes to evaluate whether the devices could be modified to permit resumed commercial distribution. 3M further requested that the suspension of the 32G License be continued until research and test data confirm that resumed distribution of static elimination devices is appropriate. In that case, 3M may, in the future, seek an amendment of the 32G License to permit resumed distribution outside of 3M.

NRC agrees that continued suspension of the 32G License is appropriate in that continued suspension precludes any concern regarding public health and safety and would not foreclose to 3M a regulatory mechanism, i.e., amendment of the 32G License, to seek to again distribute static elimination devices as a commercial item to general licensees, should 3M be able to convince NRC that such distribution could be conducted safely. NRC considers, then, that the Licensee has shown cause why the 32G License should not be revoked in its entirety at this time. NRC notes that this License is due to expire on July 31, 1990.

NRC also agrees that continued authority to manufacture static elimination devices containing Po-210 is appropriate under the 06 License. Such manufacturing authority is needed by the Licensee in its continuing efforts to determine whether it could develop a device which would be suitable for commercial use at some future date. Essential to NRC's finding is the commitment 3M made in its Answer not to distribute static elimination devices under the 06 License outside of 3M, a commitment which NRC has determined should be confirmed by this Order. Continued manufacturing authority would not result in any current commercial distribution and use of the devices outside of 3M. Distribution to general licensees is prohibited by NRC's Order to 3M of February 18, 1988. Distribution to specific licensees other than 3M is prohibited by the terms of this Order. Distribution within 3M would be limited to use of the devices in its own commercial production facilities to assess, as a research and development matter, the acceptability of the devices for long-term use. Consequently, continued authority to manufacture static elimination devices containing Po-210 would be for research and development purposes only and would not result in distribution and use outside 3M.

NRC also concludes that the Licensee has the ability to safely manufacture and test static elimination devices containing Po-210 for research and development purposes without undue risk to its employees. This conclusion is based on the results of NRC's four inspections of 3M's various licensed activities during 1988. Although NRC identified apparent violations and areas of concern and 3M will have to describe to NRC its corrective action, NRC did not identify significant violations related to in-plant worker safety in that portion of 3M's program in which Po-210 static eliminators will be manufactured and tested for research and development purposes.

With the added restriction imposed by this Order and agreed to by 3M, NRC considers that the Licensee has shown cause why the 06 License should not be revoked to the extent that it authorizes the manufacture of static elimination devices containing Po-210. NRC notes that this License is due to expire on May 31, 1992.

3M, in its Answer dated July 18, 1988, committed not to distribute static elimination devices outside of 3M. 3M has confirmed this commitment to NRC by letter dated September 16, 1988. NRC has determined to confirm 3M's commitment by this Order. Because of 3M's assent to the terms of this Order, prior notice need not be provided and this Order shall be effective immediately.

IV

Accordingly, in view of the foregoing and pursuant to Sections 81, 161b, and 161i of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, specifically in 10 CFR Section 2.204 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NUMBER 22-00057-06 IS MODIFIED AS FOLLOWS:

> The authority to transfer any Po-210 static elimination device to a specific licensee other than 3M is suspended. Such devices used within 3M shall be for research and development purposes only.

The Director, Office of Nuclear Material Safety and Safeguards, may in writing relax or rescind any of the above conditions for good cause shown by the Licensee.

V

Pursuant to the Atomic Energy Act of 1954, as amended, any person other than the Licensee who may be adversely affected by this Order may request a hearing within 30 days of the date of this Order. Any request for a hearing shall be submitted to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with copies to the Assistant General Counsel for Enforcement at the same address, and to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. If a person requests a hearing, that person shall set forth with particularity in accordance with 10 CFR Section 2.714 the manner in which the person's interest is adversely affected by this Order. A request for a hearing shall not stay the immediate effectiveness of this Order.

If a hearing is requested, the Commission shall issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such a hearing is whether this Order should be sustained.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety
and Safeguards

Dated at Rockville, Maryland
this day of 1988

Docket No. 030-04951

License No. 22-00057-06

Minnesota Mining and Manufacturing Company (3M)
ATTN: Mr. Robert G. Wissink
Chairman, Isotope Committee
3M Center 220-2E-02
St. Paul, Minnesota 55101-1000

Subject: CONFIRMATORY ORDER MODIFYING LICENSE EFFECTIVE IMMEDIATELY

Enclosed is a Confirmatory Order Modifying License Effective Immediately. This Order suspends your authority under License No. 22-00057-06 to transfer Po-210 static elimination devices to specific licensees other than 3M.

Note that License No. 22-00057-32G remains suspended, as you requested.

We note that in Section IV., Subsection B of "Minnesota Mining and Manufacturing Company's Response to Order to Show Cause," dated July 18, 1988, you indicated that 3M planned to make organizational and programmatic changes to improve management oversight and to place increased emphasis on quality assurance (QA), product reliability, and adherence to procedures and regulatory requirements. However, some of your statements appeared to apply to only portions of 3M's organization, and you did not provide a detailed description of these changes nor a schedule for implementation. Please be advised that, when we review your responses to the apparent violations identified in the 1988 NRC inspections, we will expect a functioning, corporate-wide program that improves management oversight and increases 3M staff's attention to detail with respect to all NRC-licensed activities.

In addition, as you try to develop a new or modified design for your static eliminators, you must ensure that the resulting devices comply with all applicable regulations. For example, if you should wish to distribute such devices to general licensees, you will need to demonstrate that, "Under ordinary conditions of handling, storage and use of the device, the byproduct material contained in the device will not be released, or inadvertently removed from the device...." See 10 CFR Section 32.51, copy enclosed.

Note also that, in order to approve any request to distribute Po-210 static eliminators outside of 3M, we will need a detailed description of your QA program. Your QA program should be sufficient to ensure that there will be no repetition of the problems experienced earlier this year.

In accordance with 10 CFR Section 2.790 of the U.S. Nuclear Regulatory Commission's (NRC's) "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosed Order will be placed in the NRC's Public Document Room.

A response to this letter or the accompanying Order is not subject to the clearance procedures of the Office of Management and Budget, as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,

Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Confirmatory Order
   Modifying License
   Effective Immediately
2. 10 CFR Part 32

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[Docket Nos. 030-04661 and 030-04671; Licenses Nos. 22-00057-06 and 22-00057-32C]

Notice of Orders Served; Minnesota Mining and Manufacturing Co.

In the matter of Minnesota Mining and Manufacturing Company, 3M Center 220-2E-02, St. Paul, MN 55144-1000.

This Notice is made to inform the public of three Orders which were served on the Minnesota Mining and Manufacturing Company (3M) on January 25, February 8, and February 12, 1988. Copies of those Orders are an Appendix to this Notice.

For the Nuclear Regulatory Commission.

Robert M. Bernero,

Deputy Director, Office of Nuclear Material Safety and Safeguards.

Appendix:
3M Orders

Dated at Rockville, Maryland this 19th day of February 1988.

Order Modifying License, Effective Immediately

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Minnesota Mining and Manufacturing Company (3M; licensee) is the holder of several byproduct material licenses issued by the Nuclear Regulatory Commission (the Commission or NRC) pursuant to 10 CFR Part 30. License No. 22-00057-06 was issued on February 17, 1964, was most recently amended on May 8, 1987, and expires on May 31, 1992. This license authorizes the licensee to use a variety of radionuclides, including polonium-210 (Po-210), and to conduct a variety of activities with these materials including manufacturing, testing, installing and repairing radioactive sources, and the devices in which they are used.

License No. 22-00057-32C was issued on July 12, 1965, was most recently amended on May 8, 1987, and expires on July 31, 1990. This license, issued pursuant to 10 CFR Part 30 and § 32.51, authorizes the licensee to distribute Po-210 sources for use in static elimination devices to persons generally licensed in accordance with the provisions of 10 CFR 31.5. The authorized devices

include Model Numbers 902, 902F, and 905–909, inclusive (the 900 series).

II

Ashland Chemical Company (ACC), Easton, Pennsylvania, uses Po-210 static elimination devices under the general license provisions of 10 CFR 31.5 and thus is a general licensee. ACC's Po-210 devices were manufactured and distributed by 3M.

On January 22, 1988, ACC's radiation safety consultant notified NRC's Region I office that he had detected alpha contamination on worker clothing at its electronic chemicals packaging plant in Easton, Pennsylvania. (These clothes are worn by ACC employees while working in the ACC plant and are not worn to and from work.) Contamination was also detected in the plant areas in the vicinity of 3M series 900 high pressure static elimination air guns, the apparent source of the contamination. ACC uses the series 900 static elimination air gun to remove dust particles from packaging bottles. These 3M air guns, which incorporate a radioactive source containing from 10 to 40 millicures of Po-210, showed significant levels of alpha contamination. Po-210 decays by emission of a 5.3 MeV alpha particle, has a physical half-life of 138 days, and, in these sources, is in the form of ceramic microspheres attached to an epoxy backing and overcoated with an epoxy binder.

ACC had engaged the services of a radiation safety consultation after one of its customers inquired about possible alpha contamination in [illegible] supplied by ACC. The customer's representative had visited ACC on January 12, 1988, identified the presence of alpha contamination at ACC's Easton plant, and reported low-level alpha contamination on his person and clothing as a result of his visit to ACC.

ACC also uses 3M static elimination air guns at its plants in Columbus, Ohio, Dallas, Texas, and Newark, California. As a result of the findings at its Easton plant, ACC had these plants surveyed. The Newark and Columbus plants were found not to be contaminated, but the Dallas plant was contaminated and six of its twelve 3M series 900 static elimination air guns showed evidence of leakage. ACC plans to test ACC employees at its Easton and Dallas plants for the presence of Po-210.

NRC inspectors arrived at the Easton plant on January 22, 1988, confirmed the presence of the radioactive contamination, and are assessing the adequacy of ACC's and 3M's responses to this event. The Texas Bureau of Radiation Control was informed of the findings at the Dallas plant and its inspectors will assess ACC's response to that event.

As of January 25, 1988, the root causes of these contamination incidents have not been identified. These causes could be related to manufacturing defects, environment and conditions of use, and/or other unknown factors. The devices of concern appear to be Model Nos. 902, 902F, 906, and 908 that use compressed air, rather than ambient blown air. The total number of these static elimination devices being used by general licensees is not presently known to NRC. The facts demonstrate an immediate potential for radiological hazard to personnel working with the static eliminators and others present in the area of use. Accordingly, the Commission finds that the public health, safety, or interest requires this Order to be made effective immediately.

III

Accordingly, in view of the foregoing and pursuant to sections 81, 161b, 161c, 161i, 161o, and 182 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR Parts 30, 31, and 32, *it is hereby ordered, effective immediately, that the license numbers 22–00067–08 and 22–00067–32C are modified as follows:*

A. The authority to distribute Model Nos. 902, 902F, 906, and 908 polonium 210 static elimination devices (the devices), is suspended until the Regional Administrator, Region III has approved your response to paragraph E.

B. Immediately inform users or persons to whom the devices have been distributed, including NRC and Agreement State licensees, persons in the United States exempted from the NRC licensing requirements, e.g. the Department of Energy, and distributors outside the United States, of:

(1) The incidents identified in Part II of this Order;

(2) Any appropriate information thus far developed related to the possible cause of the leakage/contamination (device failure);

(3) Instructions to promptly notify 3M if there is any reason to believe or suspect the devices in their possession might also have failed; and

(4) The requirements of 10 CFR 31.5(c)(5).

C. A copy of the information notice in paragraph B above shall be sent to the Regional Administrator, Region III, along with a list of users or persons to whom the notice is sent (unless the list has been previously supplied to the Administrator). Should reports of potential or suspected device failure from users or other persons be received, 3M shall notify the Regional Administrator, Region III of the report within 24 hours.

D. Immediately commence testing of the devices presently in use sufficient to define the potential scope of the device failure problem and, based on the data acquired along with any other relevant information developed through analysis, submit within 14 days to the Regional Administrator, Region III, a plan for approval of an expanded test and user information program which provides a high degree of assurance that additional failed devices, if any, will be identified. The plan should be accompanied by the results of test data developed during the 14 day period, any other relevant information and a justification for the plan.

E. Analyze the causes of device failure described in Part II of this Order and any other device failures subsequently identified, as a result of implementing the plan in paragraph D above and report to the Regional Administrator, Region III, the detailed technical results of the analysis and the corrective actions proposed including any limitations on devices already distributed.

The Regional Administrator, Region III, may relax or rescind any of the above conditions or requirements upon good cause shown.

IV

Pursuant to 10 CFR 2.204, the licensee or any other person adversely affected by this Order may request a hearing within 20 days of the date of this Order.

Any request for a hearing shall be submitted to the Director of the Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the Assistant General Counsel for Hearings at the same address. A copy of any request shall be sent to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137. If a person other than the licensee requests a hearing, that person shall set forth with particularity in accordance with 10 CFR 2.714 the manner in which the petitioner's interest is adversely affected by this Order. A request for a hearing shall not stay the immediate effectiveness of this Order.

If a hearing is requested by the licensee or a person whose interest is adversely affected, the Commission shall issue an Order designating the time and place of any hearing. If a hearing is held the issue to be

considered at such hearing is whether this Order should be sustained.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 25th day of January 1988.

Hugh L. Thompson, Jr.,

Director, Office of Nuclear Materials Safety and Safeguards.

Confirmatory Order Modifying License. Effective Immediately

I

Minnesota Mining and Manufacturing Company (3M; licensee) is the holder of several byproduct material licenses issued by the Nuclear Regulatory Commission (the Commission or NRC) pursuant to 10 CFR Part 30. License No. 22-00067-08 was issued on February 17, [illegible] was most recently amended on [illegible] 6, 1987, and expires on May 31, 1992. This license authorizes the licensee to use a variety of radionuclides, including polonium-210 (Po-210), and to conduct a variety of activities with these materials including manufacturing, testing, installing and repairing radioactive sources, and the devices in which they are used.

License No. 22-00067-32G was issued on July 12, 1966, was most recently amended on May 5, 1987, and expires on July 31, 1990. This license, issued pursuant to 10 CFR Parts 30 and 32.51, authorizes the licensee to distribute Po-210 sources for use in static elimination devices to persons generally licensed in accordance with the provisions of 10 CFR 31.5. The authorized devices include Model Numbers 902, 902F, and 906-909, inclusive (the 900 series).

On January 25, 1988, these licenses were modified by an immediately effective Order.

II

As more fully described in the Order Modifying License, Effective Immediately, dated January 25, 1988, the NRC determined that the use of the above-described static elimination devices has resulted in significant alpha contamination on worker clothing and in a number of facilities. As of January 25, 1988, the root causes of these contamination incidents had not been identified. These causes could be related to manufacturing defects, environment and conditions of use, and/or other unknown factors. The devices of concern appear to be Model Nos. 902, 902F, 906, and 908 that use compressed air, rather than ambient blown air. The total number of these static elimination devices being used by general licensees is not presently known to NRC. The facts demonstrate an immediate potential for radiological hazard to personnel working with the static eliminators and others present in the area of use. Accordingly, the Commission found that the public health, safety, or interest required that the January 25, 1988 Order be made effective immediately. The Order modified 3M's license as follows:

A. The authority to distribute Model Nos. 902, 902F, 906, and 908 polonium 210 static elimination devices (the devices), is suspended until the Regional Administrator, Region III has approved your response to paragraph E.

B. Immediately inform users or persons to whom the devices have been distributed, including NRC and Agreement State licensees, persons in the United States exempted from the NRC licensing requirements, e.g. the Department of Energy, and distributors outside the United States, of:

(1) The incidents identified in Part II of this Order;

(2) Any appropriate information thus far developed related to the possible cause of the leakage/contamination (device failure);

(3) Instructions to promptly notify 3M if there is any reason to believe or suspect the devices in their possession might also have failed; and

(4) The requirements of 10 CFR 32.5(c)(5).

C. A copy of the information notice in paragraph B above shall be sent to the Regional Administrator, Region III, along with a list of users or persons to whom the notice is sent (unless the list has been previously supplied to the Administrator). Should reports of potential or suspected device failure from users or other persons be received, 3M shall notify the Regional Administrator, Region III of the report within 24 hours.

D. Immediately commence testing of the devices presently in use sufficient to define the potential scope of the device failure problem and, based on the data acquired along with any other relevant information developed through analysis, submit within 14 days to the Regional Administrator, Region III, a plan for approval of an expanded test and user information program which provides a high degree of assurance that additional failed devices, if any, will be identified. The plan should be accompanied by the results of test data developed during the 14 day period, any other relevant information and a justification for the plan.

E. Analyze the causes of device failure described in Part II of this Order and any other device failures subsequently identified, as a result of implementing the plan in paragraph D above and report to the Regional Administrator, Region III, the detailed technical results of the analysis and the corrective actions proposed including any limitations on devices already distributed.

The Regional Administrator, Region III, may relax or rescind any of the above conditions or requirements upon good cause shown.

III

Subsequent to issuing the January 25, 1988 Order, the staff received a list from 3M of general licensees which possess static eliminator devices affected by the Order. Included in the list were general licensees which appear to be manufacturing products or packages for products such as food, beverages, pharmaceuticals, cosmetics, medical products and other products which are to be consumed by or applied to humans. NRC inspectors reviewing records during the week of January 24, 1988 at the 3M Center in St. Paul, Minnesota also determined that there were indications of a number of failed devices during the previous year, including devices used at facilities which manufacture products for human consumption. Further inspection and investigation at general licensee facilities conducted by 3M, NRC and State personnel revealed additional instances of device failure including some located at beverage and food processing plants.

Because of the large number of general licensees which use the affected static eliminators and the variety of products for which these devices are used in the manufacturing process, the full dimensions of the potential radiological risk resulting from device failure cannot be fully established until further inspections, investigations, analyses and assessment are conducted. However, the failure of such devices at such plants can result in contamination of products which constitutes a direct pathway for human exposure. In order to permit the completion of the requisite evaluations and to avoid possible contamination of products intended for human consumption, we have determined that certain static elimination devices should be recalled by the licensee.

On February 5, 1988, the licensee issued a letter to all of its customers using the specified models of the device, directing such users to remove the devices from applications related to the packaging of food, beverages, pharmaceuticals, or cosmetics and to return them to 3M. The licensee's action was confirmed to the Commission by letter dated February 5, 1988. We have determined to confirm 3M's action by this Order.

IV

Accordingly, in view of the foregoing and pursuant to sections 81, 161b, 161c, 161i, 161o, and 182 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR Parts 30, 31, and 32, *It is hereby Ordered, effective immediately, that license numbers 22-*

Enclosure 3

00057-06 and 22-00057-32C are modified as follows:

In accordance with its letter dated February 5, 1988, the licensee shall inform all users of its Model 982, 983F, 984, and 986 static eliminators involved in the packaging of food, beverages, pharmaceuticals, and cosmetics that it is withdrawing these devices from service and that such devices are to be returned to the licensee as instructed in the licensee's notice to customers dated February 5, 1988.

The Director, Office of Nuclear Materials Safety and Safeguards, may relax or rescind any of the above conditions for good cause shown by the licensee.

V

Any person other than the licensee adversely affected by this Order may request a hearing within 20 days of the date of this Order. Any request for a hearing shall be submitted to the Director of the Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the Assistant General Counsel for Enforcement at the same address, and to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137. If such person requests a hearing, that person shall set forth with particularity in accordance with 10 CFR 2.714 the manner in which the petitioner's interest is adversely affected by this Order. A request for a hearing shall not stay the immediate effectiveness of this Order.

If a hearing is requested by a person whose interest is adversely affected, the Commission shall issue an Order designating the time and place of any hearing. If a hearing is held the issue to be considered at such a hearing is whether this Order should be sustained.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Director, Office of Nuclear Materials Safety and Safeguards.

Dated at Rockville, Maryland this 5th day of February, 1988.

(Po-210), and to conduct a variety of activities with these materials including manufacturing, testing, installing, and repairing radioactive sources, and the devices in which they are used.

License No. 22-00057-32G was issued on July 12, 1965, was most recently amended on May 5, 1987, and expires on July 31, 1990. The license authorizes the Licensee to transfer Po-210 sources for use in static elimination devices to persons generally licensed in accordance with the provisions of 10 CFR 31.5. The authorized devices include, among others, Model Numbers 902, 902F, and 906–909, inclusive (the 900 series).

On January 25, 1988, these licenses were modified by an immediately effective Order. These licenses were further modified by an immediately effective Confirmatory Order on February 5, 1988.

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As more fully described in the Order Modifying License, Effective Immediately, dated January 25, 1988, the NRC had determined that the use of the above-described static elimination devices has resulted in significant alpha contamination on worker clothing and in a number of facilities. As of January 25, 1988, the root cause of these contamination incidents had not been identified. These causes could be related to manufacturing defects, the environment and conditions of use, and/or other unknown factors. The devices initially of concern appeared to be Model Nos. 902, 902F, 906, and 908 which use compressed air. The total number of these static elimination devices being used by general licensees was not then known to NRC. The facts then known demonstrated an immediate potential for radiological hazards to personnel working with the static eliminators and others present in the area of use. Accordingly, the Commission found that the public health, safety, or interest required that the January 25, 1988 Order be made effective immediately. The Order modified 3M's licenses and, among other things, suspended the authority to distribute Model Nos. 902, 902F, 906, and 908 polonium-210 static elimination devices.

As more fully described in the Confirmatory Order Modifying License, Effective Immediately, dated February 5, 1988, NRC subsequently learned of multiple instances of failures of Model Nos. 902, 902F, 906, and 908 devices. Many of these failures occurred at facilities where general licensees manufacture products, or packages for products, such as food, beverages, pharmaceuticals, cosmetics, medical products, and other items which are to be consumed by, or applied to, humans.

On February 5, 1988, the Licensee issued a letter to all of its customers using the specified models of the device, directing such users to remove the devices from applications related to the packaging of food, beverages, pharmaceuticals, or cosmetics and to return them to 3M. The Licensee's action was confirmed by Order dated February 5, 1988. The February 5, 1988 Confirmatory Order modified 3M's license to require 3M to inform all users of its Model 902, 902F, 906, and 908 static eliminators involved in the packaging of food, beverages, pharmaceuticals, and cosmetics that it is withdrawing these devices from service and that such devices are to be returned to the Licensee.

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Subsequent to issuing the February 5, 1988 Confirmatory Order, the staff has received reports of additional failed devices. Some of the newly reported failures are identified by model numbers not specified in the prior Orders. For example, Model No. 907 static elimination devices, which utilize blown rather than compressed air, have been found leaking in at least 3 cases. In addition, bar-type static eliminator devices, specifically Model No. 210, have been reported to have leaked. Some of these blown air and bar-type devices are used in plants that manufacture products and packages, or package materials for products, which would constitute a direct pathway for human exposure if contaminated. At this time, the cause(s) of the failures of these devices is not known.

On February 8, 1988, 3M submitted a brief report of its work under the Order of January 25. The staff met with 3M at Region III offices on February 11, 1988, to discuss these results and to hear 3M's proposed plan of action. Among other things, 3M senior executives indicated that 3M planned to voluntarily withdraw all static eliminators (regardless of model number) used in the packaging of food, beverages, pharmaceuticals, and cosmetics.

In view of the wide use of these devices, the increasing number of failed devices of various model numbers, the current uncertainty as to the failure mechanisms and the potential for contamination and the consequent exposure of humans, the Commission finds that the public health, safety, and interest requires that all such devices, regardless of model number, be withdrawn from use by general

Order Modifying Licenses, Effective Immediately

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Minnesota Mining and Manufacturing Company (3M or Licensee) is the holder of several byproduct material licenses issued by the Nuclear Regulatory Commission (the Commission or NRC). License No. 22-00057-06 was issued on February 17, 1984, was most recently amended on May 6, 1987, and expires on May 31, 1992. This license authorizes the Licensee to use a variety of radionuclides, including polonium-210

licensees engaged in the production and/or packaging of food, beverages, pharmaceuticals and cosmetics and that such action be ordered, effective immediately.

IV

Accordingly, in view of the foregoing and pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR Parts 30 and 32, it is hereby ordered, effective immediately, that license numbers 22-00057-06 and 22-00057-32C are modified as follows:

A. 3M is required to inform all users of all models of 3M Po-210 static eliminators involved in the production or packaging of food, beverages, pharmaceuticals, or cosmetics that it is withdrawing these devices from service and that such devices are to be returned to 3M not later than March 2, 1988, in accordance with its instructions.

B. Not later than March 4, 1988, 3M shall submit to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, a written report describing the extent to which it has complied with this Order and the February 5, 1988 Order. The report shall include the names, addresses, and telephone numbers of all users who were not notified and all users who have failed to return devices by this date.

The Deputy Director, Office of Nuclear Material Safety and Safeguards, may relax or rescind any of the above conditions for good cause shown by the licensee.

IV

The Licensee and any other person adversely affected by this Order may request a hearing within 20 days of the date of this Order. Any request for a hearing shall be submitted to the Deputy Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the Assistant General Counsel for Enforcement at the same address, and to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. If a person other than the Licensee requests a hearing, that person shall set forth with particularity in accordance with 10 CFR 2.714 the manner in which the petitioner's interest is adversely affected by this Order. A request for a hearing shall not stay the immediate effectiveness of this Order.

If a hearing is requested, the Commission shall issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such a hearing is whether this Order should be sustained.

For The Nuclear Regulatory Commission.

Robert M. Bernero,

Deputy Director, Office of Nuclear Material Safety and Safeguards.

Dated at Rockville, Maryland, this 12th day of February, 1988.

[FR Doc. 88-4016 Filed 2-24-88; 8:45 am]

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[Docket Nos. 030-04961 030-04971; License Nos. 22-00057-06 22-00057-32C]

Order Modifying Licensee Effective Immediately and Order To Show Cause; Minnesota Mining and Manufacturing Co.

In the Matter of Minnesota Mining and Manufacturing Company, 3M Center (220-2E-02) St. Paul, MN 55144-1000.

I

Minnesota Mining and Manufacturing Company (3M or Licensee) is the holder of byproduct material licenses issued by the Nuclear Regulatory Commission (the Commission or NRC). License No. 22-00057-06 was issued on February 17, 1964, was most recently amended on May 6, 1987, and expires on May 31, 1992. This license authorizes the Licensee to use a variety of radionuclides, including polonium-210 (Po-210), and to conduct a variety of activities with these materials including manufacturing, testing, installing, and repairing radioactive sources, and the devices in which they are used.

License No. 22-00057-32C was issued on July 12, 1985, most recently amended on May 5, 1987, and expires on July 31, 1990. This license authorizes the Licensee to transfer Po-210 sources for use in static elimination devices to persons generally licensed in accordance with the provisions of 10 CFR 31.5. These licenses were modified by an immediately effective Order on January 25, 1988, an immediately effective Confirmatory Order on February 5, 1988, and a third immediately effective Order on February 12, 1988.

II

As more fully described in the Order Modifying License, Effective Immediately, dated January 25, 1988, the NRC had determined that the use of the above-described static elimination devices had resulted in significant alpha contamination on worker clothing and in a number of facilities. As of January 25, 1988, the root causes of these contamination incidents had not been identified. These causes could be related to manufacturing defects, the environment and conditions of use, and/or other unknown factors. The devices initially of concern appeared to be Model Nos. 902, 902F, 906, and 908 that use compressed air. The total number of these static elimination devices being used by general licensees was not known to NRC. The facts then known demonstrated an immediate potential for radiological hazards to persons working with the static eliminators of those models and other persons present in the area of use. Accordingly, the Commission found that the public health, safety, or interest required that the January 25, 1988 Order be made effective immediately. The Order modified 3M's licenses and, among other things, suspended authority to distribute Model Nos. 902, 902F, 906, and 908 polonium-210 static elimination devices.

As more fully described in the Confirmatory Order Modifying License, Effective Immediately, dated February 5, 1988, NRC subsequently learned of multiple instances of failure of Model Nos. 902, 902F, 906, and 908 devices. Many of these failures occurred at facilities where general licensees manufacture products, or packages for products, such as food, beverages, pharmaceuticals, cosmetics, medical products, and other items which are to be consumed by, or applied to, humans.

On February 5, 1988, the Licensee issued a letter to all of its customers using the above-specified models of the device, directing such users to remove the devices from applications related to the packaging of food, beverages, pharmaceuticals, or cosmetics and to return them to 3M. The Licensee's action was confirmed by Order dated February 5, 1988. The February 5, 1988 Confirmatory Order modified 3M's license to require 3M to inform all users of its Model Nos. 902, 902F, 906, and 908 static eliminators involved in the packaging of food, beverages, pharmaceuticals, and cosmetics that it was withdrawing these devices from service and that such devices should be returned to the Licensee.

As more fully described in the Order Modifying License, Effective Immediately, dated February 12, 1988, NRC subsequently learned of failures of devices identified by model numbers not specified in the prior Orders. These failures included both blown air and bar-type static eliminators that are used in plants that manufacture products and packages, or package materials for products, which would constitute a direct pathway for human exposure if contaminated. The cause of these failures was not then known.

On February 8, 1988, 3M submitted a brief report of its work under the Order

of January 25. The staff met with 3M at Region III offices on February 11, 1988 to discuss these results and to hear 3M's proposed plan of action.

Among other things, 3M senior executives indicated that 3M planned to voluntarily withdraw all static eliminators (regardless of model number) used in the processing of food, beverages, pharmaceuticals, and cosmetics.

In view of the wide use of these devices for products intended for human consumption or application, the increasing number of failed devices of various model numbers, the uncertainty as to the failure mechanisms, and the potential for contamination and consequent exposure to humans, the Commission found that the public health, safety or interest required that the February 12, 1988 Order be made effective immediately. The Order modified 3M's licenses to require that 3M inform all users of all models of 3M's Po-210 static eliminators involved in the production or packaging of food, beverages, pharmaceuticals or cosmetics that 3M has withdrawn them from service and they are to be returned to 3M by March 2, 1988. The Order further required 3M to submit a report to the Regional Administrator, Region III, not later than March 4, 1988, describing the extent to which it has complied with the February 5 and February 12 Orders.

III

During its inspection of 3M, the NRC staff reviewed 3M's records of leak tests and observations of static elimination devices that have been returned from general licensees. 3M's records indicate that many devices showed measurable contamination and/or evidence of exposure to environments which may be unsuitable for the devices (e.g., solvents, moisture), but which are often typical of the workplace and the processes in which they are used. Based upon a review of 3M's records and follow-up by NRC or Agreement State staff at these customers' sites, it appears that 3M has failed to notify most, if not all, general licensees, whose returned devices were found to be leaking and/or exposed to an unsuitable environment. Furthermore, 3M has failed to perform effective follow-up of these reports and observations. During their inspections of these general licensees, NRC and Agreement State staff have found, in many instances, that static eliminators now in use at customers' sites (where 3M had knowledge of earlier leaking devices) were also leaking and causing contamination of the work place.

Based on information reviewed to date, static eliminators have experienced frequent failures in what appear to be normal and customary industrial environments (i.e., under ordinary conditions of use). Such failures are in direct conflict with the licensing basis for these devices including the requirements of 10 CFR 32.51(a)(2)(i) which states, in part, that "[u]nder ordinary conditions of handling, storage and use of the device, the byproduct material contained in the device will not be released * * *." In neither the February 8, 1988, report submitted by 3M nor the February 11, 1988 meeting with NRC did 3M submit a meaningful plan of action required by Section III, Paragraph D, of the January 25 Order, which required such a plan in 14 days of the date of the Order (i.e., by February 8). At the February 11 meeting, 3M indicated that it would need an additional two weeks to prepare such a plan of action.

Based on the information presented above (i.e., reports of failures of devices not affected by the January 25, 1988 Order; 3M's failure to notify customers; 3M's failure to take effective corrective actions after determining that a returned device was leaking and/or exposed to an unsuitable environment; 3M's failure to adequately respond to Section III, Paragraph D., of the January 25, 1988 Order; the frequency of failures in ordinary conditions of use), the NRC no longer has confidence that any of the Po-210 static elimination devices authorized for distribution to general licensees by License No. 22-00067-32C currently meet the original licensing basis including the requirements of 10 CFR 32.51.

The data available thus far includes analyses in the field by NRC, State and 3M staff showing the release of radioactive material from these generally licensed devices. The data available also include the results of many analyses by the Food and Drug Administration (FDA), State agencies and producers of products involving the use of static eliminators for food, beverage, cosmetic and pharmaceutical use as well as in many other industrial and commercial applications of the devices. The preponderance of these data indicates that, although the Po-210 appears to remain tightly bound in nondigestable and nonrespirable microspheres in accordance with the design basis, the particles are released from the devices in ordinary conditions of use. Such releases are not in accordance with the licensing basis nor in accordance with the requirements of 10 CFR 32.51. Given the broad use of these devices, the evolving number of failed devices being reported, the lack of effective actions by the Licensee in this matter, the pervasive potential for exposure of personnel working with these devices as well as other persons in the area of use, and the potential for contamination of products manufactured with the assistance of 3M static eliminators of all types and widely distributed to members of the public, the NRC finds that the public health, safety, and interest require that the actions specified in Section IV of this Order be made effective immediately.

The NRC has been informed that some of these Po-210 static eliminators are used in industrial or commercial service where suppression of static electricity is needed for workplace safety such as where significant fire or explosion hazards might otherwise exist. Therefore, in exercising the necessary radiological safety precaution of removing these devices from use, the NRC recognizes the need to consider the possibility of at least temporarily approving continued use where competing safety risks are involved and process surveillance is sufficient.

IV

Accordingly, in view of the foregoing and pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 2.204 and 10 CFR Parts 30 and 32, *It is hereby ordered, effective immediately, that license numbers 22-00067-08 and 22-00067-32C are modified as follows:*

A. The authority to transfer any Po-210 static elimination device to persons generally licensed is suspended except as may be specifically authorized in writing by the NRC.

B. 3M shall immediately notify by First Class Mail (1) all general licensees using static elimination devices containing Po-210 and manufactured by 3M and (2) all distributors outside the United States that the NRC has issued an immediately effective Order modifying the general license provided by 10 CFR 31.5 to suspend use of such devices. The notification shall include a copy of this Order and a copy of the Order Modifying General License which is attached hereto.

C. 3M shall instruct users of the devices to return them to 3M as soon as feasible but within 90 days of the date of this Order, except as provided by the Order of February 5 and 12, 1988. 3M shall also furnish its customers with shipping instructions and packaging materials as may be necessary for the safe return of the devices to 3M.

D. Upon receiving the returned devices from its customers, 3M shall

promptly test the devices for detectable leakage. When detectable leakage is found, 3M shall notify its customers of the potential contamination of their workplace and also notify the NRC or Agreement State, as appropriate, of the leaking device.

E. 3M shall submit to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, written reports describing the extent to which it has achieved compliance with Paragraphs A, B, C, and D above, including the names, addresses, and telephone numbers of all users who were not notified as required, and the reasons therefore, and all users who failed to return the devices by the dates specified in Paragraph C. Reports shall be submitted at intervals not to exceed 30 days, with the first report due not later than March 21, 1988.

The Director, Office of Nuclear Material Safety and Safeguards, may in writing relax or rescind any of the above conditions for good cause shown by the Licensee.

V

Within 60 days of the date of this Order pursuant to 10 CFR Section 2.202(b), the Licensee shall show cause why License No. 22-00057-32G should not be revoked in its entirety and why License No. 22-00057-06 should not be revoked to the extent it authorizes manufacturing of static elimination devices containing Po-210. The Licensee shall show cause by filing a written answer under oath or affirmation setting forth the matters of fact and law on which the Licensee relies. The answer shall be submitted to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555.

VI

The Licensee and any person other than the Licensee adversely affected by this Order may request a hearing within 20 days of the date of this Order. Any request for a hearing shall be submitted to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the Assistant General Counsel for Enforcement at the same address, and to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. If a person other than the Licensee requests a hearing, that person shall set forth with particularity in accordance with 10 CFR 2.714 the manner in which the petitioner's interest is adversely affected by this Order. A request for a hearing shall not stay the immediate effectiveness of the actions called for by Section IV of this Order.

If a hearing is requested, the Commission shall issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such a hearing is whether this Order should be sustained.

For the Nuclear Regulatory Commission.

Robert M. Bernero,

Deputy Director, Office of Nuclear Material Safety and Safeguards.

Dated at Rockville, Maryland, this 18th day of February, 1988.

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Failure Investigation of 3M Series 900 Static Eliminators

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ABSTRACT

Numerous instances of facility contamination by polonium-210 microspheres have been reported. These contamination events appear to be caused by leakage or ejection of the radioactive material from static elimination devices manufactured by the Minnesota Mining and Manufacturing Company (3M). The Ashland Chemical Company (Easton, Pennsylvania) was the first facility determined to be contaminated and was subsequently subjected to a comprehensive review by the U. S. Nuclear Regulatory Commission (USNRC). Therefore, devices from this facility were chosen for examination.

A failure investigation has been performed on six static eliminators. The investigation consisted of visual inspection, sectioning and scanning electron microscopy of six devices. It is concluded that non-uniform and imperfect microspheres appear to have been manufactured and installed in devices. Rough handling may induce loosening of the microspheres. The epoxy binder used in device manufacture may not be suitable for the varied service conditions.

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1. INTRODUCTION

On January 25, 1988, the U. S. Nuclear Regulatory Commission (USNRC) issued an order to the Minnesota Mining and Manufacturing Company (3M) suspending the distribution of certain static eliminating devices containing polonium-210. This suspension of distribution was prompted in part by the fact that Ashland Chemical Company reported (to the NRC) radioactive polonium-210 contamination at its facilities in Easton, Pennsylvania and Dallas, Texas, stemming from leakage of these devices. Devices affected by the NRC order are Model Numbers 902, 902F, 906, and 908. The Model 908 devices were those used at the Ashland Chemical facilities.

Static eliminators of this type contain radioactive polonium-210 which is fused into small (30-35 μm diameter) spheres, sometimes referred to as microspheres. These microspheres are composed of a zirconium pyrophosphate (ZrP_2O_7) ceramic. The polonium-210 is purified [1] and adsorbed on the outer layers of the microspheres which are then fired at 700°C to form a ceramic bead containing polonium-210. After firing, the microspheres are plated with a nickel coating of approximately 1 μm. These microspheres are then incorporated into an epoxy binder. The epoxy is then installed into the metal tube used as the static eliminator. The release of alpha particles ionizes compressed air blown through the device which reduces the static charge on surfaces onto which the ionized air is directed (Figure 1).

In order to independently ascertain potential failure modes of the 900 series 3M static eliminators, the USNRC contracted with Brookhaven National Laboratory (BNL) for a failure investigation of a sample of the eliminators used at the Ashland Chemical, Easton, Pennsylvania facility. This failure investigation was to encompass the following:

1. Receipt and visual inspection of new and failed devices;
2. Wipe surveys of new and failed devices to check radioactivity levels;
3. Selection of two new and at least one failed device from each use environment (6 total).

For each of these six devices, the following examination protocol was adhered to:

a. Conduct visual examination/optical photography
b. Disassemble/section devices
c. Optical microscopic examination of device internals/photography
d. Scanning electron microscopic (SEM) examination of device internals.

This report is the documentation of the failure investigation.

2. RECEIPT/VISUAL INSPECTION/WIPE SURVEY/TAP TEST

A total of thirty-four type 908 series 3M static eliminators were sent to BNL from the Ashland Chemical Company. A thirty-fifth (as yet unboxed) specimen was sent to BNL after the investigation was complete. Twelve of the static eliminators received were new, unused devices (samples 1-12, Table 1). Two of these new devices D74465 and D74471 were chosen at random for sectioning. The remainder of the devices (other than 12 new ones) had seen service at the Easton, Pennsylvania facility. Samples "B," "I," D64601, and D74410 were also chosen by the BNL investigator to be reasonably representative of the Ashland Chemical's service environment (Table 1: Nos. 14, 21, 29, and 30).

Samples "B" and "I" (ID #14 and 21 in Table 1) were used in Ashland's automatic bottle washing facility. The service conditions were compressed air blown through the devices at 90 psi in a moist air environment at 140°F (60°C).

Samples D64601 and D74410 were used at Ashland's manual filling station and had been exposed to dry compressed air blown through the devices (5-65 psi) and ambient temperature and moisture conditions.

The six specimens chosen as the BNL samples were photographed (Figures 2-7). Five of the devices appeared to be jacketed in stainless steel while D64601 (Figure 4) gave the appearance of being made from a copper alloy (probably brass).

Three of the devices appeared to have scratches on them from service (Figures 4, 6, and 7) with device "B" having gouges on the outside surface similar to those which pliers might produce (Figure 6).

Each of the devices was dry wiped (smeared) on the exterior surface. The wipes were counted in an alpha scintillator. The results of this survey are shown in Table 1. Eleven of the thirty-four devices were contaminated including six of the twelve new devices. The highest recorded contamination level was attributed to specimen D74469 - a new, unused device that was still sealed in the original 3M plastic bag.

Since it was apparent that normal handling could possibly loosen the polonium microspheres from the devices; D74465 and D74471 were subjected to a "TAP TEST." The test consisted of taping over both openings of the static eliminator (male and female threaded ends), then giving a single sharp tap on each end of the device against a hard surface. The intent was not to damage the device but only to ascertain if rough handling could loosen the microspheres from the epoxy matrix.

The resultant four pieces of tape were then counted in the alpha scintillator. Specimen D74465 displayed no measurable activity on either tape sample while D74471 had an activity of 339,100 cpm (916,486 dpm) on the female end tape specimen (the male end showing no activity). This activity (916,486 dpm) equates to approximately 0.4 microcuries deposited on the tape. This appeared to be a clear indication that rough handling of the devices might be contributing to the contamination problem.

Table 1 Results of Wipe (Dry) Tests Air Ionizers Received at BNL

Sample	Identification	Gross cpm	Net cpm	dpm
1. D74464	(loose)	0	-	-
2. D74465	(packaged)	0	-	-
3. D74466	(packaged)	1	1.0	2.7
4. D74467	(loose)	0	-	-
5. D74468	(packaged)	0	-	-
6. D74469	(packaged)	142	142	383.8
7. D74470	(loose)	1	.8	2.2
8. D74471	(packaged)	0	-	-
9. D74472	(packaged)	2	2.0	5.4
10. D74473	(loose)	4	3.8	10.3
11. D74474	(loose)	2	1.8	4.9
12. D74475	(loose)	0	-	-
13. A		0	-	-
14. B		0	-	-
15. C		1	1.0	2.7
16. D		0	-	-
17. E		0	-	-
18. F		0	-	-
19. G		0	-	-
20. H		0	-	-
21. I		0	-	-
22. J		0	-	-
23. K		0	-	-
24. L		0	-	-
25. M		0	-	-
26. N		0	-	-
27. D62253		0	-	-
28. D62251		7	6.8	18.4
29. D64601		0	-	-
30. D74410		Not recorded		72
31. Bag 4 - Label Torn		11	10.8	29.2
32. Bag 4 - Unmarked		0	-	-
33. Bag 4 - Unmarked		0	-	-
34. Box 3 - Unmarked		Not received		
35. D62256 (air gun)		13	12.8	34.6

3. EVALUATION OF EPOXY AND NON-RADIOACTIVE MICROSPHERES

Samples of two types of epoxy (black and amber) and a vial of non-radioactive microspheres (fused and nickel coated but no polonium-210) were received at BNL and examined by scanning electron microscopy (SEM).

The epoxy blanks were sputter coated prior to examination by the SEM.

Note:

> Insulating materials or nonconducting particles build up a space charge region by accumulation of absorbed electrons which deflect the incident beam of the scanning electron microscope. This deflection produces intense image distortion. These charging effects can be minimized by applying conductive coatings to the specimens. This coating ideally should be thick enough to provide a conductive path, yet thin enough not to mask any fine details of the specimen. Various materials can be applied, e.g., carbon, gold, palladium, platinum, silver, aluminum, or copper by either high vacuum evaporation or cathode sputtering. For the purposes of this investigation, a gold/palladium alloy was used to cathode sputter the samples to a thickness of approximately 300A.

Figures 8 through 11 are SEM photographs of the two blanks examined (black and amber epoxy). Both of the blanks appeared to be continuous in nature with no cracks visible. Discussions with USNRC personnel disclosed that the addition of 2% carbon black was the only difference between the compositions of the two epoxies.

A small sample of some of the non-radioactive microspheres was poured out onto a strip of masking tape, sputter coated and then examined by the SEM. Figures 12 through 15 are typical areas examined. It is apparent from the photographs that a significant number of the microspheres are in a cracked, split or otherwise damaged condition. Figures 13 and 15 are higher magnification fractographs of the types of cracking found on the microspheres.

An energy dispersive spectrographic (EDS) scan was performed on these microspheres which confirmed that they had indeed been nickel coated.

4. SECTIONING/MACROPHOTOGRAPHY/SEM STUDIES

The six sample static eliminators were sectioned by hand cutting the devices lengthwise with a mini-hacksaw until the jacketing material was penetrated. A single edged straight razor blade was then used to cut the epoxy tape in order to open the various devices' internals for inspection.

The devices were then evaluated under a stereo microscope. During this study, it was determined that the depth of field on the curved surfaces of the devices was limited to the extent that meaningful optical photomicrographs could not be taken without removal and flattening of the epoxy tape. In lieu of flattening the tape, it was decided to perform macrophotography of the devices' internals and rely on scanning electron microscopy of the specimens' features. After visual inspection and macrophotography, one half of each cut device was sputter coated to a thickness of 300A and then evaluated with the SEM.

Examination of Device D74465

The first static eliminator sectioned and evaluated was the new (manufactured 1/12/88) device identified as D74465. It is clear in Figure 16 that the black epoxy appeared to be intact with no obvious degradation of the epoxy binder or the polonium-210 microspheres (grey circle in black matrix). Optical microscopy revealed small portions of the polonium-210 circle to have discrete areas where no adhesion of the microspheres appeared to have occurred. Figure 17 is a low magnification SEM photograph of a typical area of the specimen. In the upper left side of the photograph there is an area with no microspheres evident. This appeared to be one of the areas where no adhesion had taken place. There were various cracked and broken microspheres observed on this specimen (Figures 18 and 19) and apparent areas of microsphere decohesion (Figure 20) were also seen.

Examination of Device D74471

Figure 21 is a macrophotograph of the cut and opened static eliminator D74471. The device appeared to be intact, with no obvious visual defects or abrasions on either the epoxy or the area of polonium microsphere adhesion. Optical microscopy again revealed areas where the microspheres were absent from the epoxy.

SEM evaluation of the microspheres (after the "TAP TEST") confirmed that many areas of the epoxy circle were not uniformly covered with microspheres (Figure 22). Additionally, apparent areas of cracking (Figure 23) were revealed on the periphery of the circle of microspheres. Damaged microspheres (Figure 24) and microsphere decohesion were also noted on this device.

Examination of Device D64601

The brass jacketed device D64601 had a similar appearance visually (epoxy and polonium-210 microspheres) to that observed on samples D74465 and D74471. There did not appear to be gross defects or damage visible to the naked eye (Figure 25). The SEM showed (Figure 26) that the epoxy binder was intact, with no evidence of cracking outside the circle of polonium microspheres.

Further examination in the area of the microspheres, however, revealed cracked and broken microspheres, decohesion of the microspheres and cracking of the epoxy matrix surrounding the microspheres (Figures 27 and 28). This particular device had been used at the manual filling station where 5-65 psi dry compressed air is blown through the device and ambient temperature and humidity conditions are present.

Examination of Device D74410

The second device used at the manual filling station (D74410) had an area within the circle of polonium microspheres (Figure 29) which appeared to have missing material. Although this area may have been the result of the cutting/sectioning operations, it is believed that the area is characteristic of original manufacture, since no additional marring or disruption of the epoxy/microsphere matrix was found.

Optical microscopy revealed hairline cracks on the epoxy binder and microspheres positioned outside the circle where polonium-210 microspheres are normally affixed. Both of these conditions are documented on Figures 30 and 31. Additionally, there appeared to be areas where microspheres may have dislodged from the epoxy (Figure 30).

Examination of Device "B"

Static eliminator "B" was obtained from the automatic bottle washing facility at Ashland Chemical. The device was subject to compressed air at 90 psi, at temperature 140°F and moist air.

After sectioning, the visual examination of the inside surfaces of the device disclosed a significant discoloration in the epoxy material (Figure 32). This discoloration extended to the very edges of the epoxy material. Instead of the normal blackened appearance of the epoxy, this device had a bleached (wheat colored) appearance.

Optical microscopy disclosed large areas of apparently missing microspheres and a "reptile skin" like appearance to the epoxy material. Additionally, damaged and cracked microspheres were also observed.

Scanning electron microscopy revealed many areas of missing microspheres from the circle (Figures 33 and 34) with the "reptile skin" cracking of the epoxy very much in evidence (Figure 35). Some of the microspheres showed significant damage, as seen in Figures 36 and 37.

Various areas where the microspheres were missing were examined by the SEM. Figure 38 is a typical area showing the location of an absent microsphere. The absence of swelling or blistering in this area suggests that radiation damage to the epoxy (although a possible contributor) is not the prime method of microsphere dislodgement.

Examination of Device "I"

A second static eliminator (Device "I") from the bottle washing facility was examined and had the same discolored appearance (Figure 39) as Device "B."

In this specimen, however, the epoxy cracking ("reptile-skin effect") was clearly visible to the naked eye (arrows).

SEM pictures of this device (Figures 40-44) showed significantly more damage to the epoxy binder, i.e., holes are quite evident (Figures 40, 41, 43). The epoxy cracking appeared to continue under the polonium microspheres as shown in Figure 42. On this device, the epoxy seemed to have suffered greater separation (possibly shrinkage) in the cracks (Figures 43 and 44). The decohesion of microspheres and damage to microspheres was also quite evident on this device.

5. DISCUSSION

The potential safety health hazards from industrial use of static eliminations (polonium containing) have been examined in New Zealand [2]. This paper described various immersion tests performed on both rigid and flexible (the active surface being curved) type static eliminators. Various solvents were used (including water) in the testing. After the required immersion time had elapsed, the source was removed from the solvent, which was acidified and filtered. In the case of the sources in water (after 14 days), the measured filter activity (primarily discrete microspheres) was 100 nCi which shows that the adhesive which secures the microspheres in place was definitely affected by the water. The observations of this investigation appear to echo a need for a more careful look at the environmental conditions under which the static eliminators may be operated.

A previously mentioned report [1] stated that the microspheres themselves were sample tested in solutions of both 3N HCl (hydrochloric acid) and 1% EDTA (ethylenediamine tetraacetic acid). However, the epoxy binder may not have endured such rigorous testing.

The observations of cracked and damaged microspheres on non-radioactive samples and on new, unused devices/reinforces the hypothesis that quality control of microsphere manufacturing methods deserves closer scrutiny.

The deposition of 0.4 μCi on a tape sample after a "TAP TEST" suggests that rough handling of these devices may initiate a contamination incident.

The dry wipe tests performed on various new (still in the original plastic envelopes) devices is a clear indication that some of these devices may have been a source of contamination in the "as received" condition.

The observed cracks in the epoxy of the new device (D74471) point to the area of epoxy quality control. This coupled with the widespread cracking of the epoxy in three of the devices examined (1 at ambient conditions; 2 at 140°F and moist air) suggests that the epoxy binder may not be suitable for the current service conditions.

6. CONCLUSIONS

The previous discussion and report observations have led to the following conclusions:

1. The manufacture of the 3M microspheres do not consistently produce uniform and perfect spheres. There is evidence that cracked and broken microspheres are being produced and incorporated into static eliminating devices.

2. Rough handling of the devices may initiate polonium-210 leakage during or prior to service.

3. "As received" devices may be potential sources of contamination (exterior surfaces).

4. The epoxy binder appears to suffer significant environmental and material damage even under ambient conditions. The effect of solvents, heat, moisture or vibration may accelerate this damage. An evaluation of the "suitability for service" of this epoxy binder appears warranted. The breakdown of the epoxy binder appears to be a significant contributor to the contamination by loose microspheres or microsphere fragments.

7. REFERENCES

1. Kempf, C. R., Siskind, B., Barletta, R. E., and Dougherty, D. R., "Characterization of the Radioactive Waste Packages of the Minnesota Mining and Manufacturing Company," NUREG/CR-3844, BNL/NUREG-51787, July 1984.

2. Robertson, M. K., and Randle, M. W., Health Physics, Vol. 26, pp. 245-250, March 1974.

8. ACKNOWLEDGEMENTS

The author wishes to thank R. Racinella (BNL Health Physics) for the wipe tests, T. Skelaney for typing this report and BNL Technical Photography for their normal excellent work.

SKETCH COURTESY OF USNRC

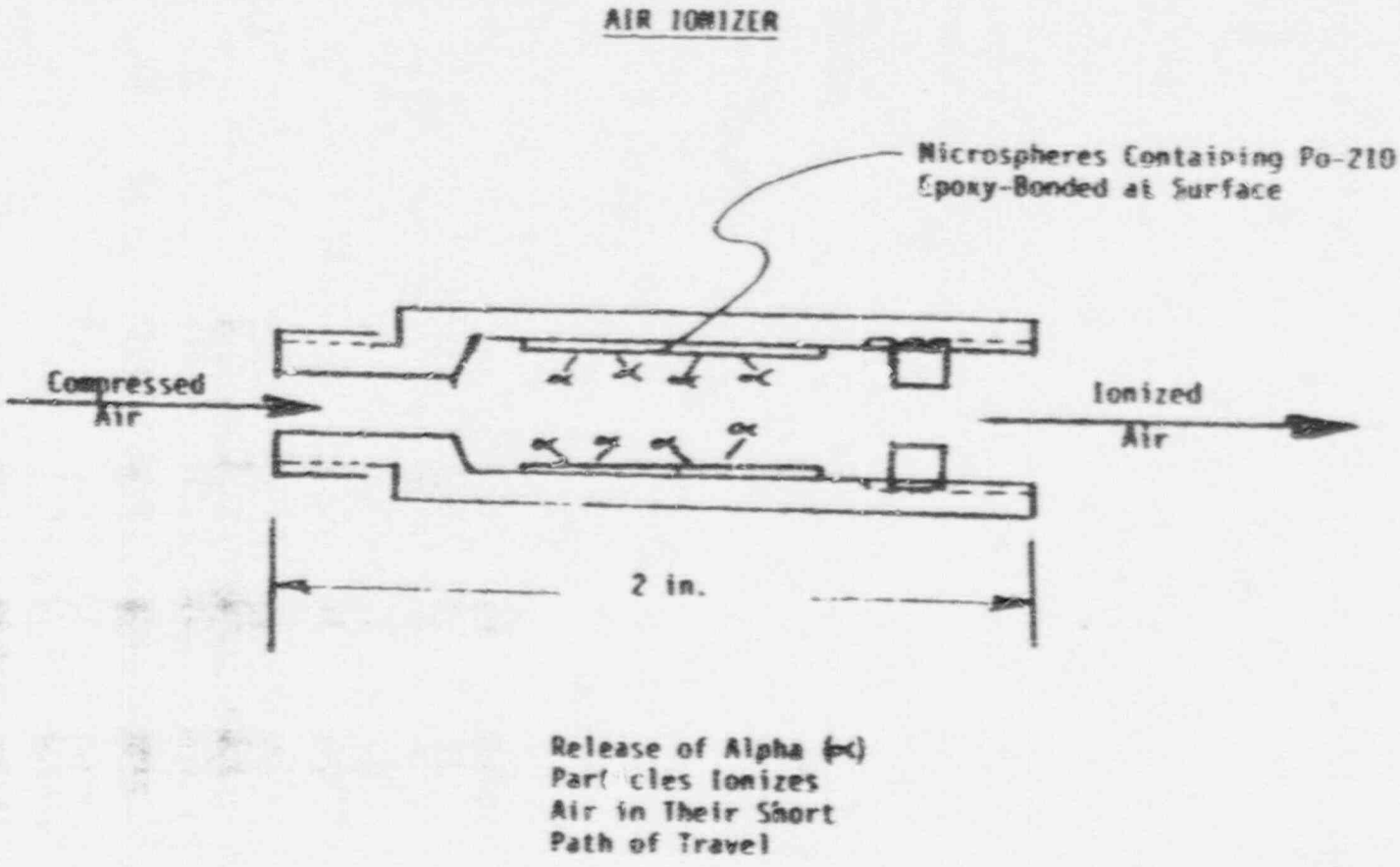


Figure 1 Sketch of a typical series 900 3M static eliminator.

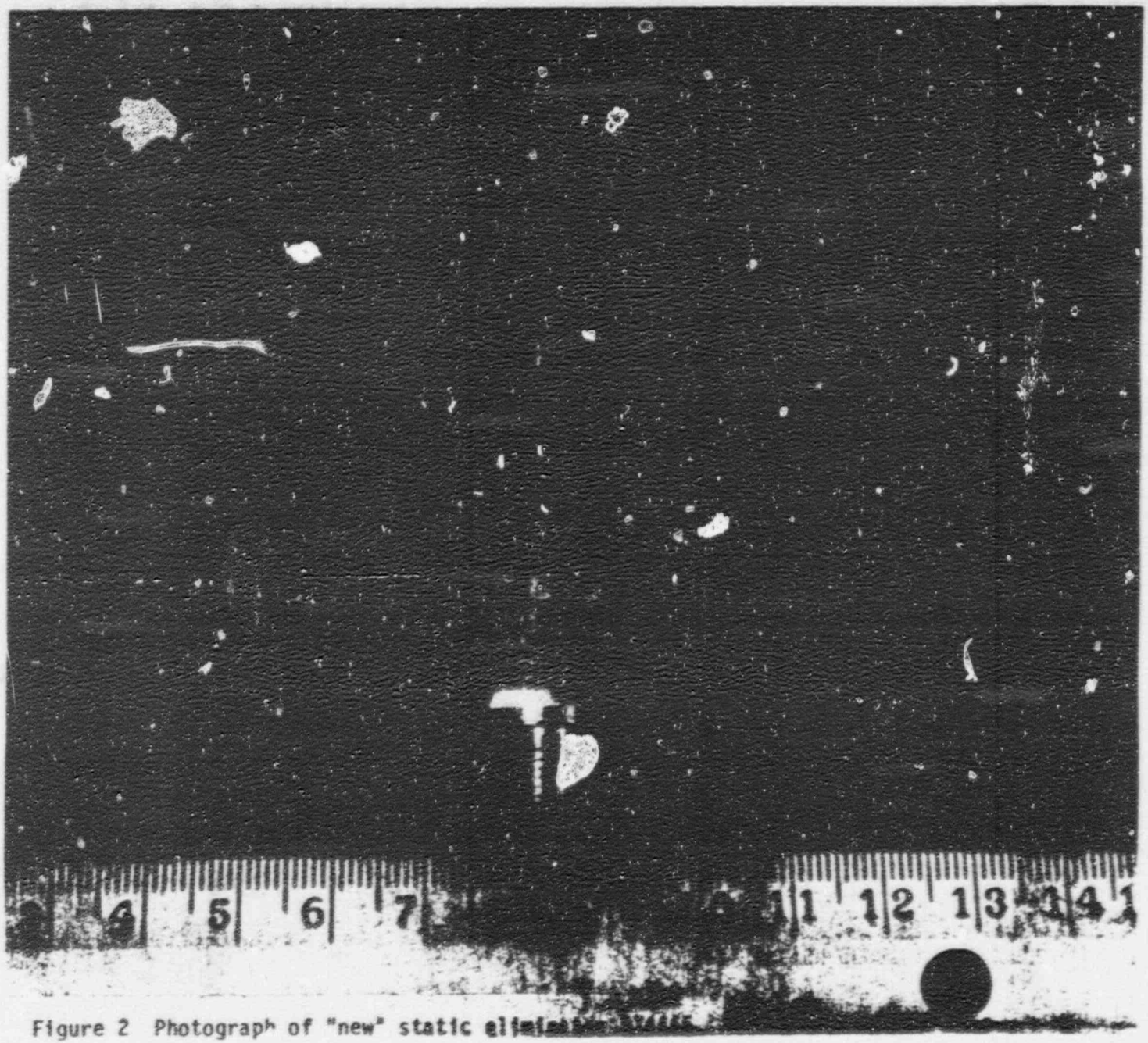


Figure 2 Photograph of "new" static elimi[illegible]

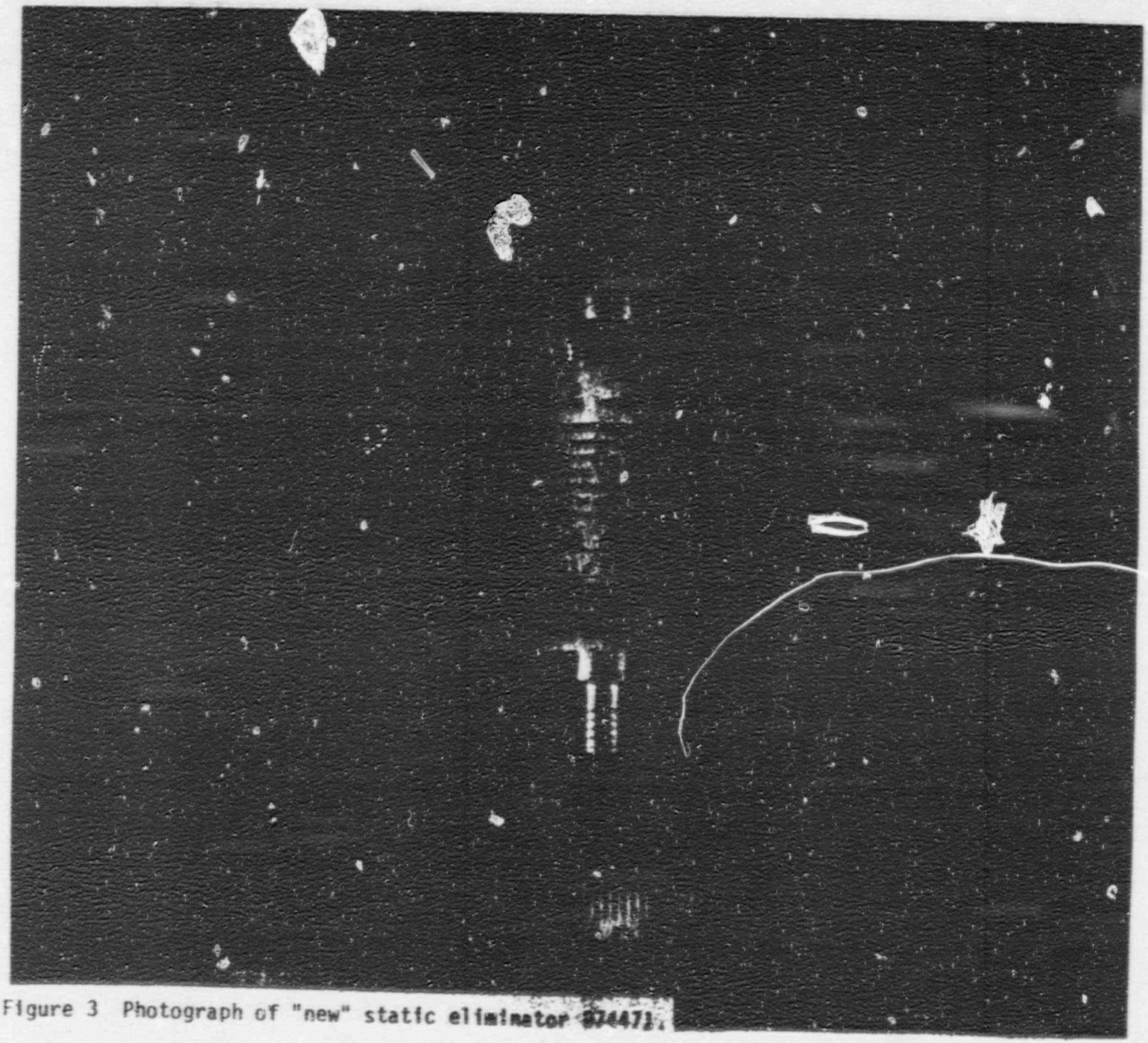


Figure 3 Photograph of "new" static eliminator 874471.

Figure 4 Photograph of static eliminator D64601 from the manual filling station. The case on this device appeared to be made from brass.

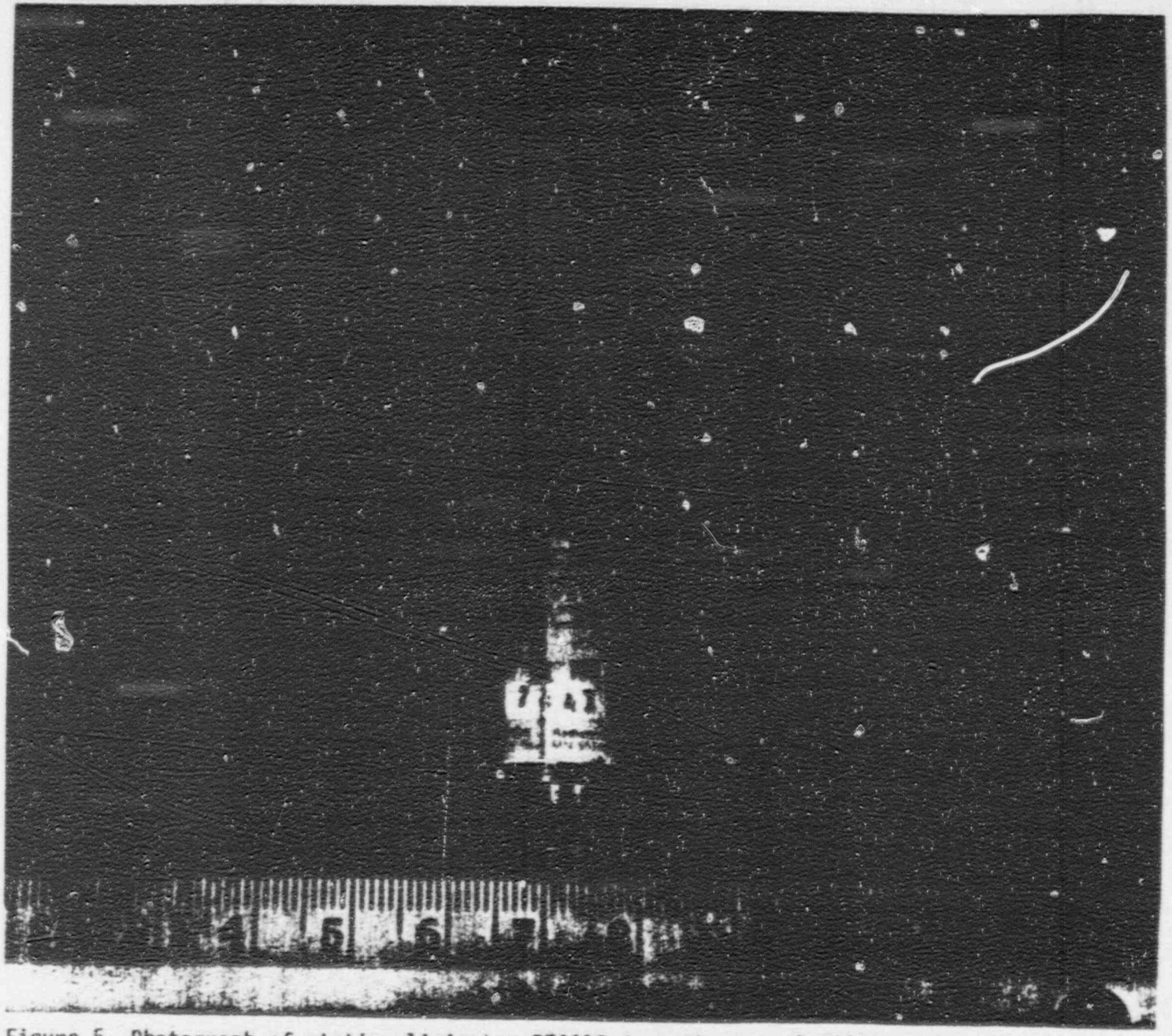


Figure 5 Photograph of static eliminator D74410 from the manual filling station.

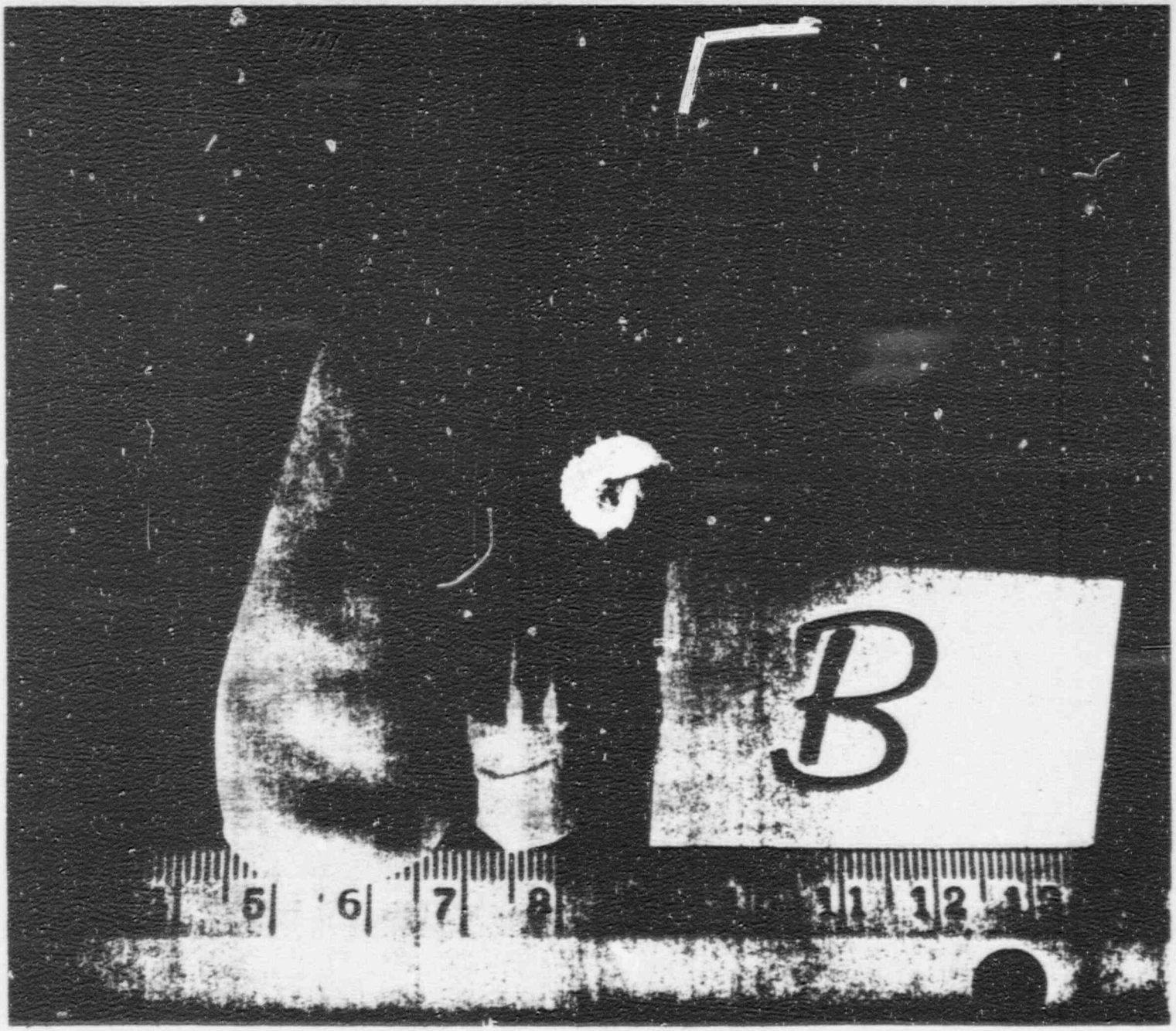


Figure 6 Photograph of device identified as "B" , from the bottle washing facility. Note the scratches/gouges on the casing.

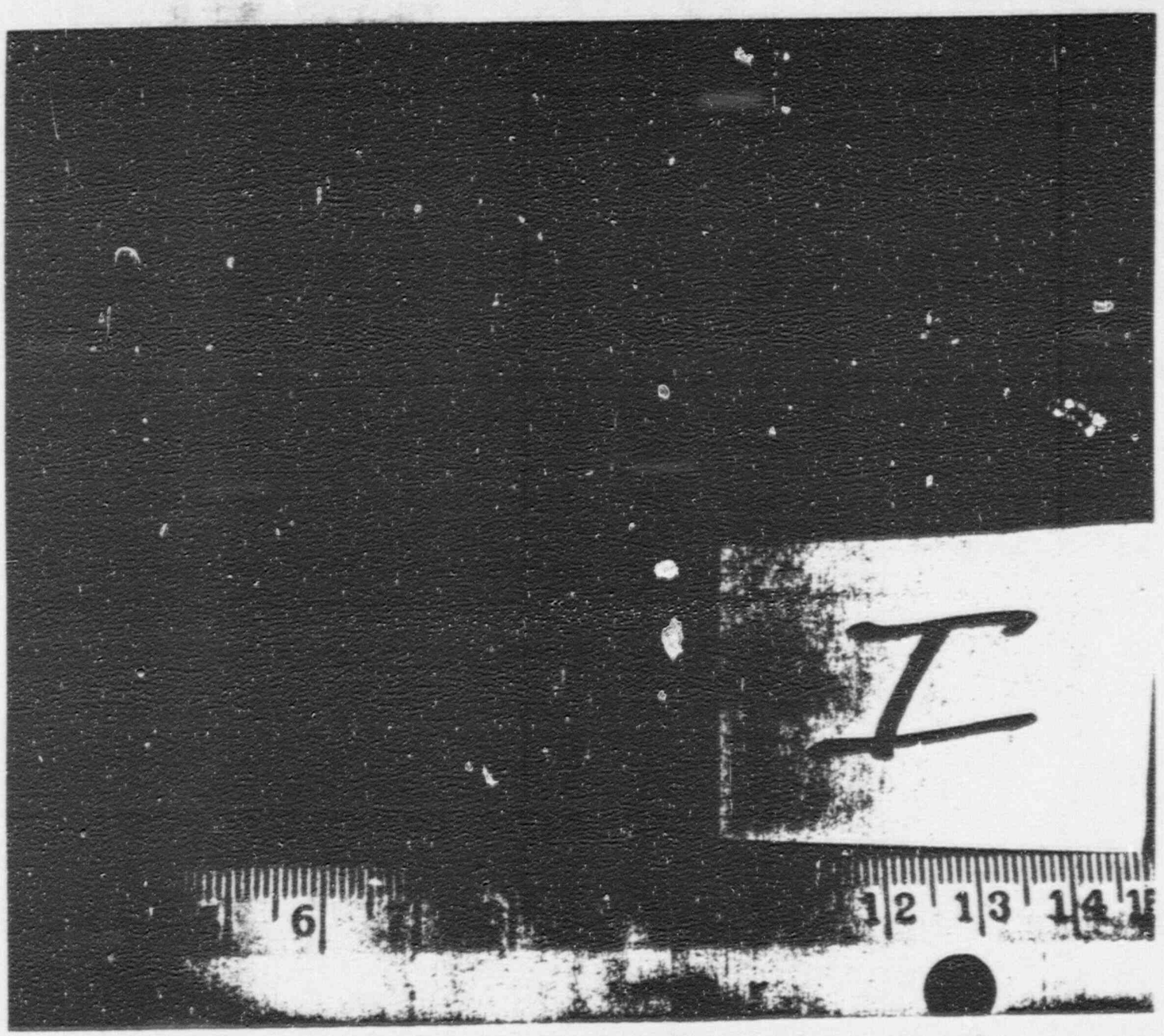
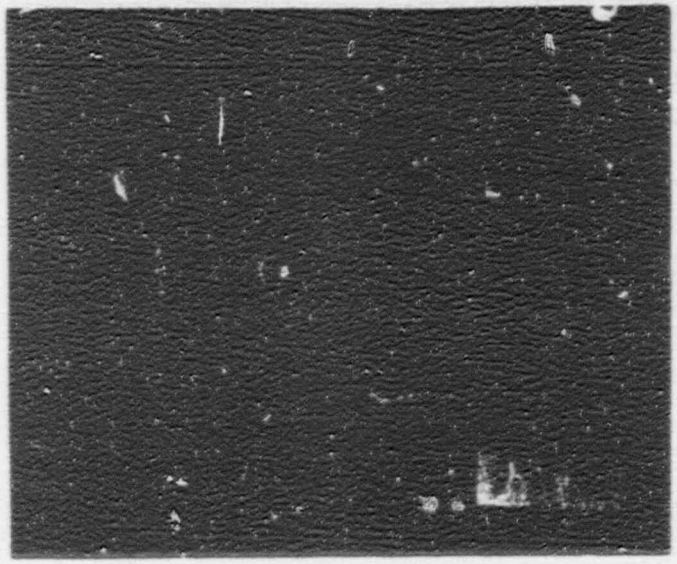
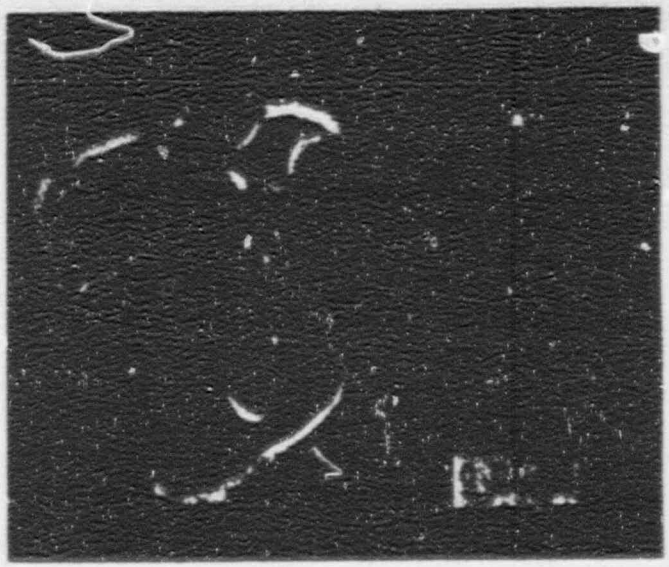


Figure 7 Photograph of static eliminator "I" . Note the scratches on the surface.



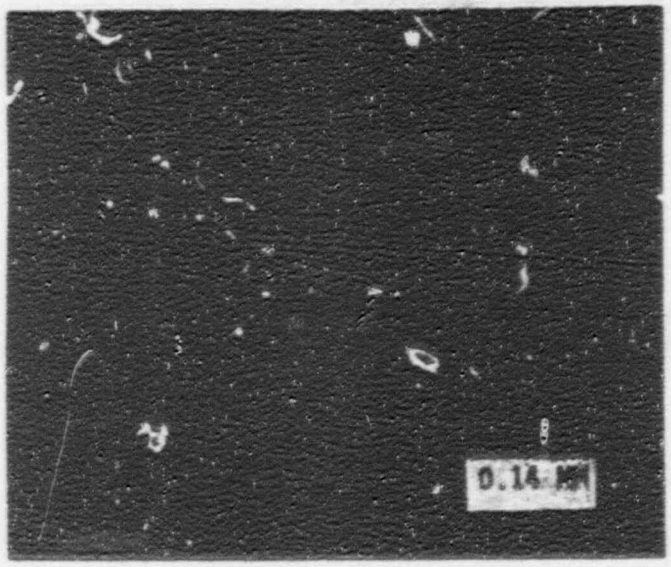
130X

Figure 8 Low magnification SEM photo of the amber epoxy.



900X

Figure 9 Higher magnification SEM photo showing no areas of cracking in the epoxy.

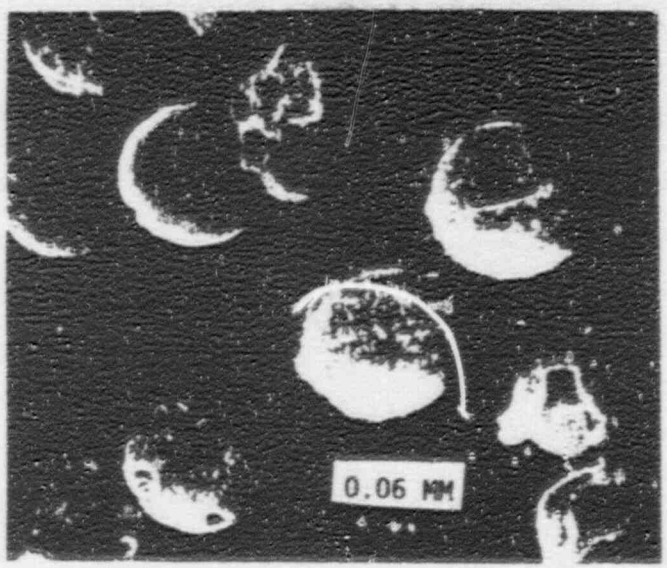


130X

Figure 10 SEM photo of black epoxy.

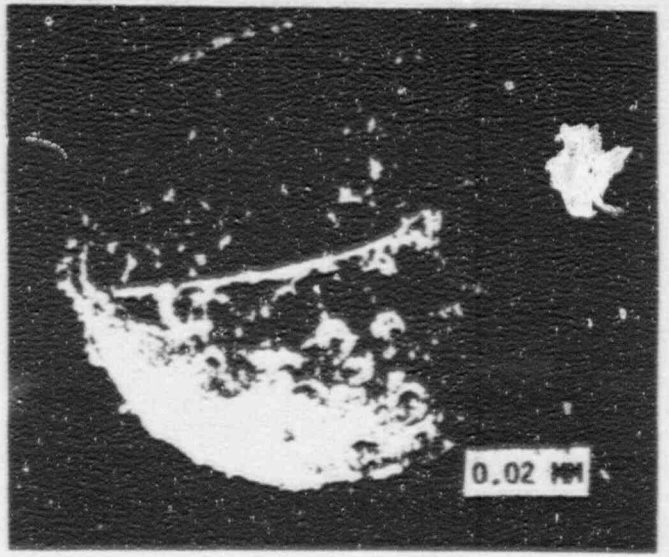
900X

Figure 11 No cracks were visible in the black epoxy at higher magnification.



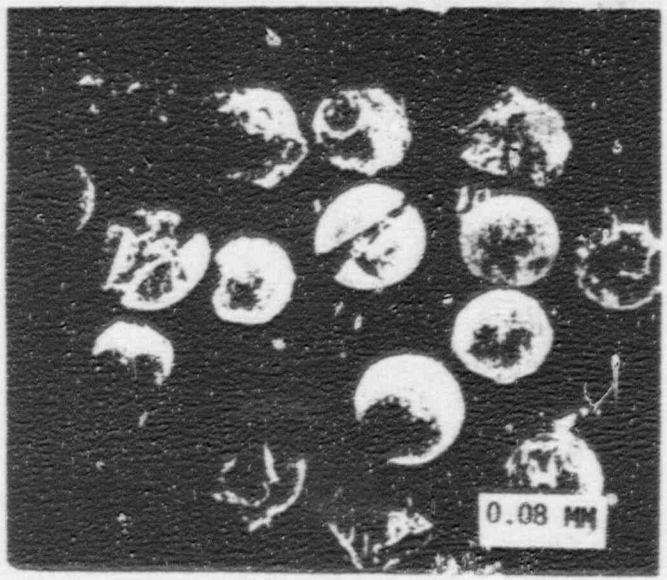
450X

Figure 12 SEM photo of "new" non-radioactive microspheres.



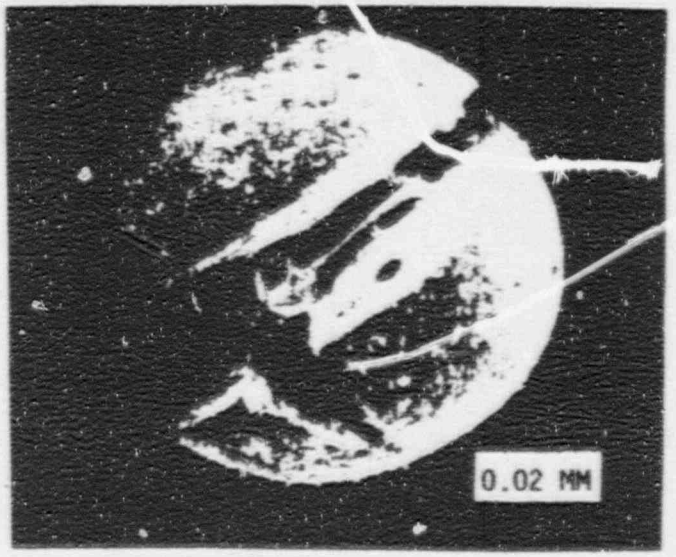
1350X

Figure 13 Higher magnification photo showing cracked microsphere.



315X

Figure 14 A second field also showed cracked microspheres.



1350X

Figure 15 Higher magnification SEM photo depicting cracking of the microsphere.

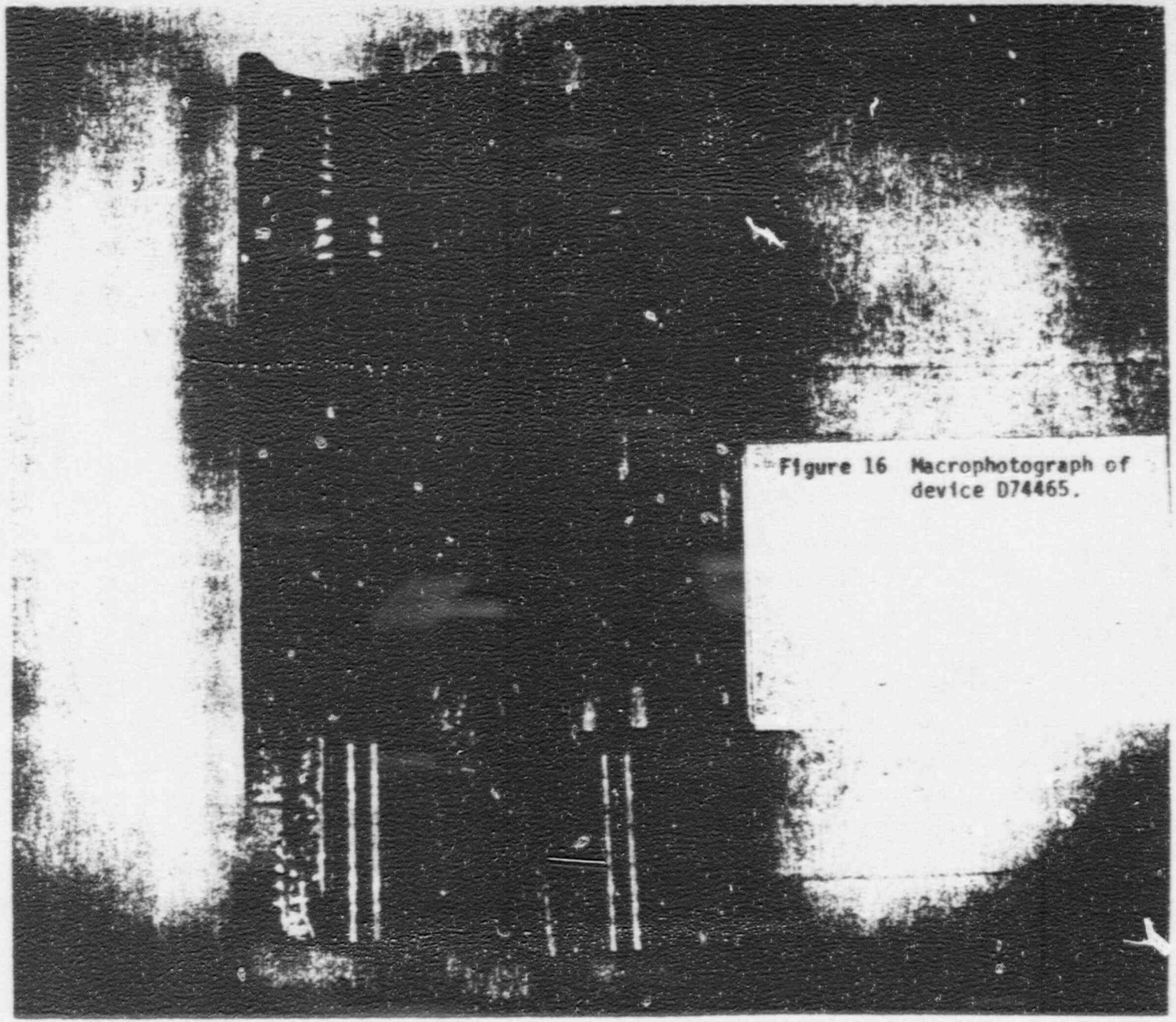
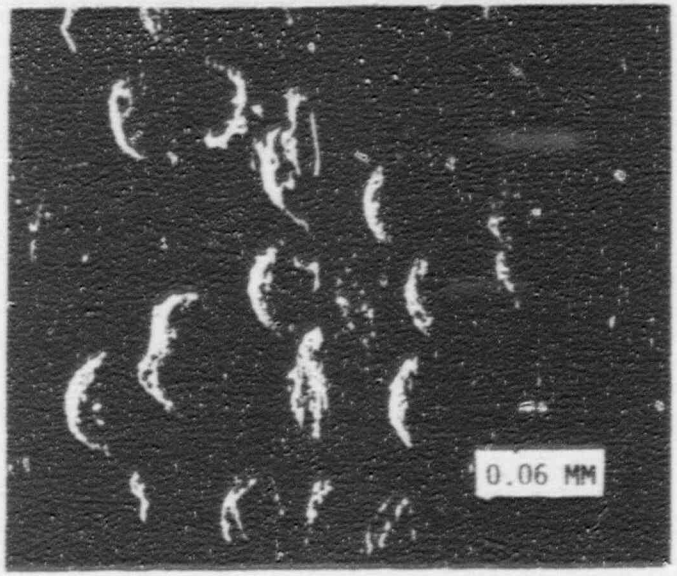
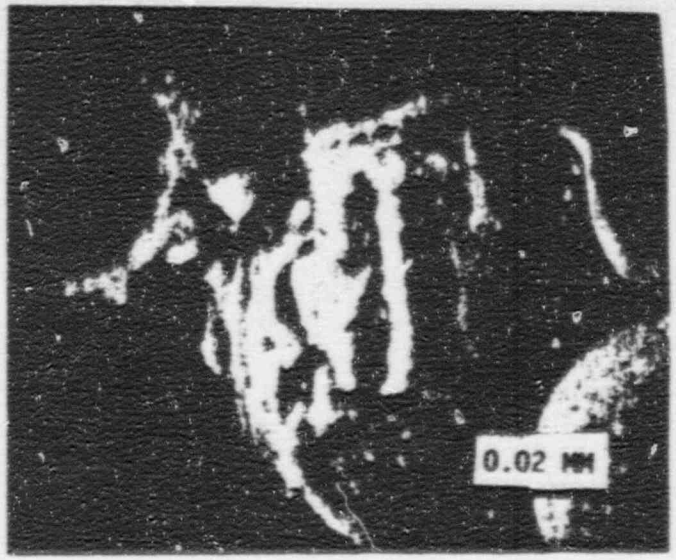


Figure 16 Macrophotograph of device D74465.



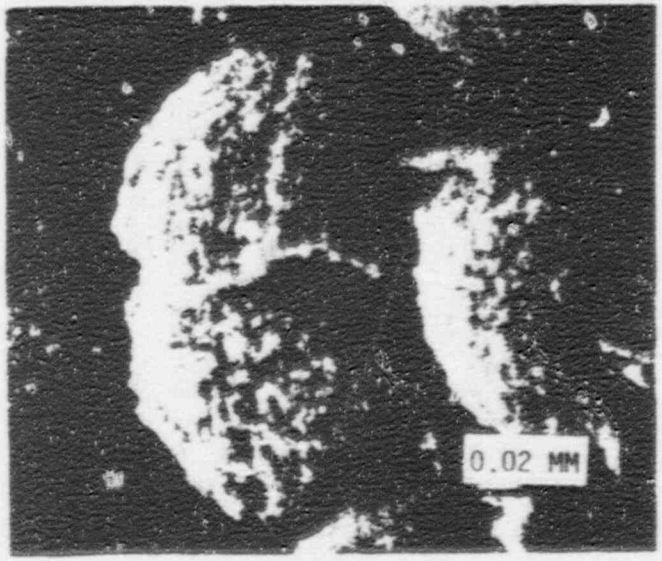
400X

Figure 17 Low magnification SEM photo of a typical area on static eliminator D74465.



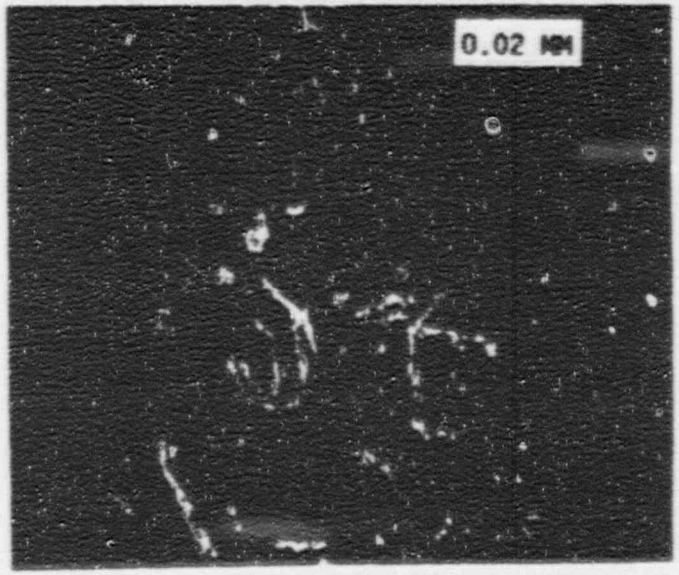
1200X

Figure 18 Higher magnification fractograph of a damaged microsphere.



1200X

Figure 19 A second microsphere appeared to be cracked.



1100X

Figure 20 Another area of D74465 showing apparently damaged microspheres and possible decohesion around sphere - arrows.

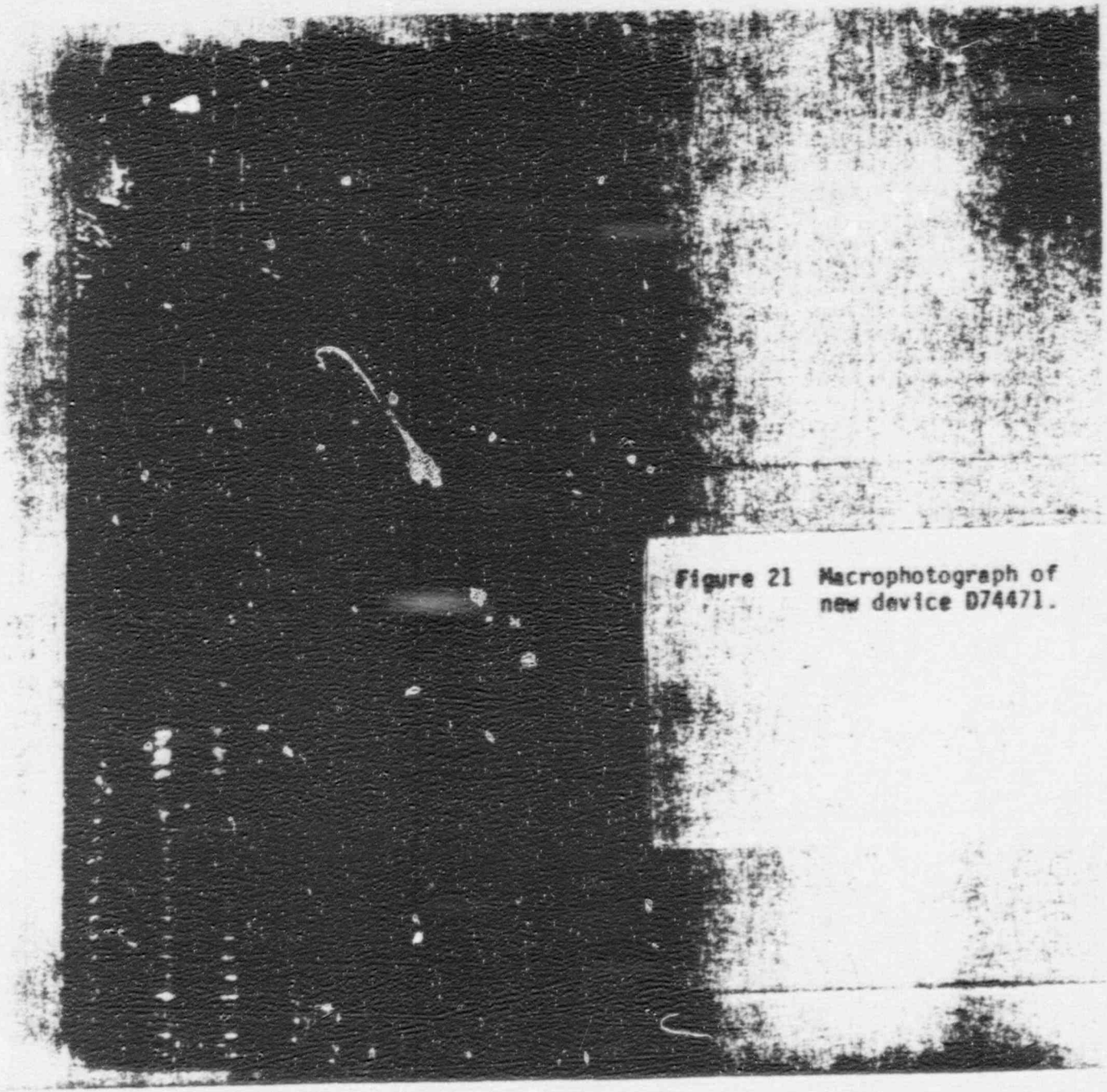
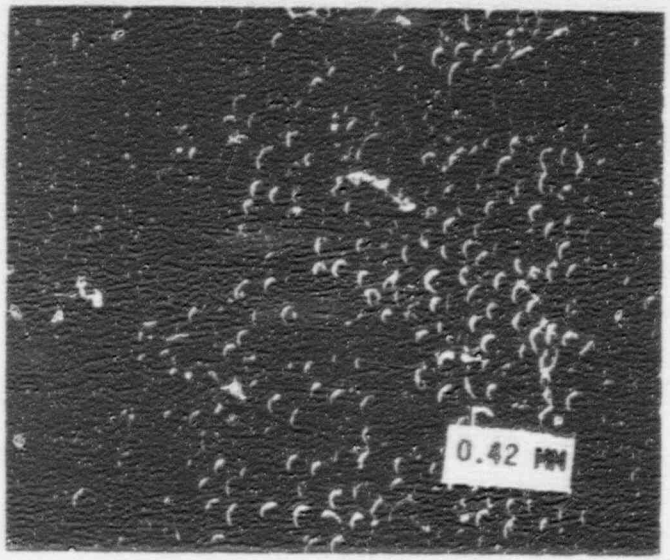
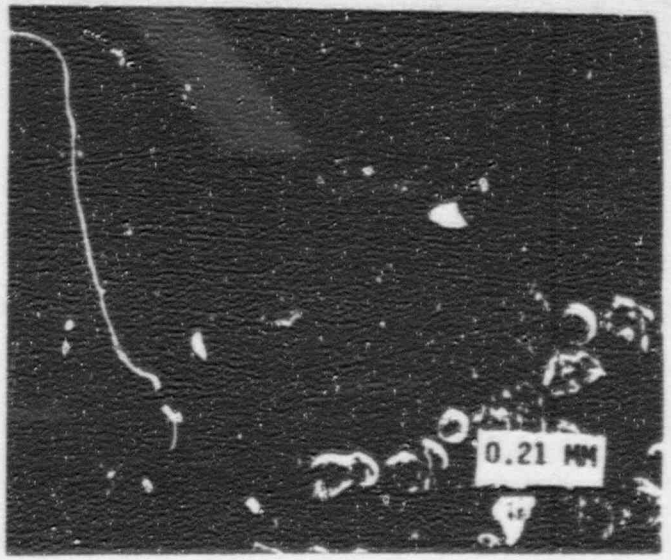


Figure 21 Macrophotograph of new device D74471.



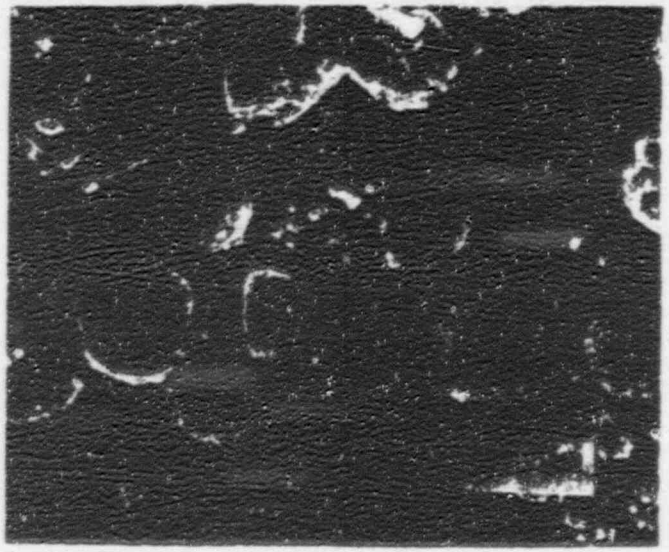
60X

Figure 22 Low magnification fractograph of static eliminator D74471.



120X

Figure 23 Cracking of the epoxy was observed on this static eliminator.



350X

Figure 24 Some decohesion and microsphere damage (arrows) was noted on this specimen.

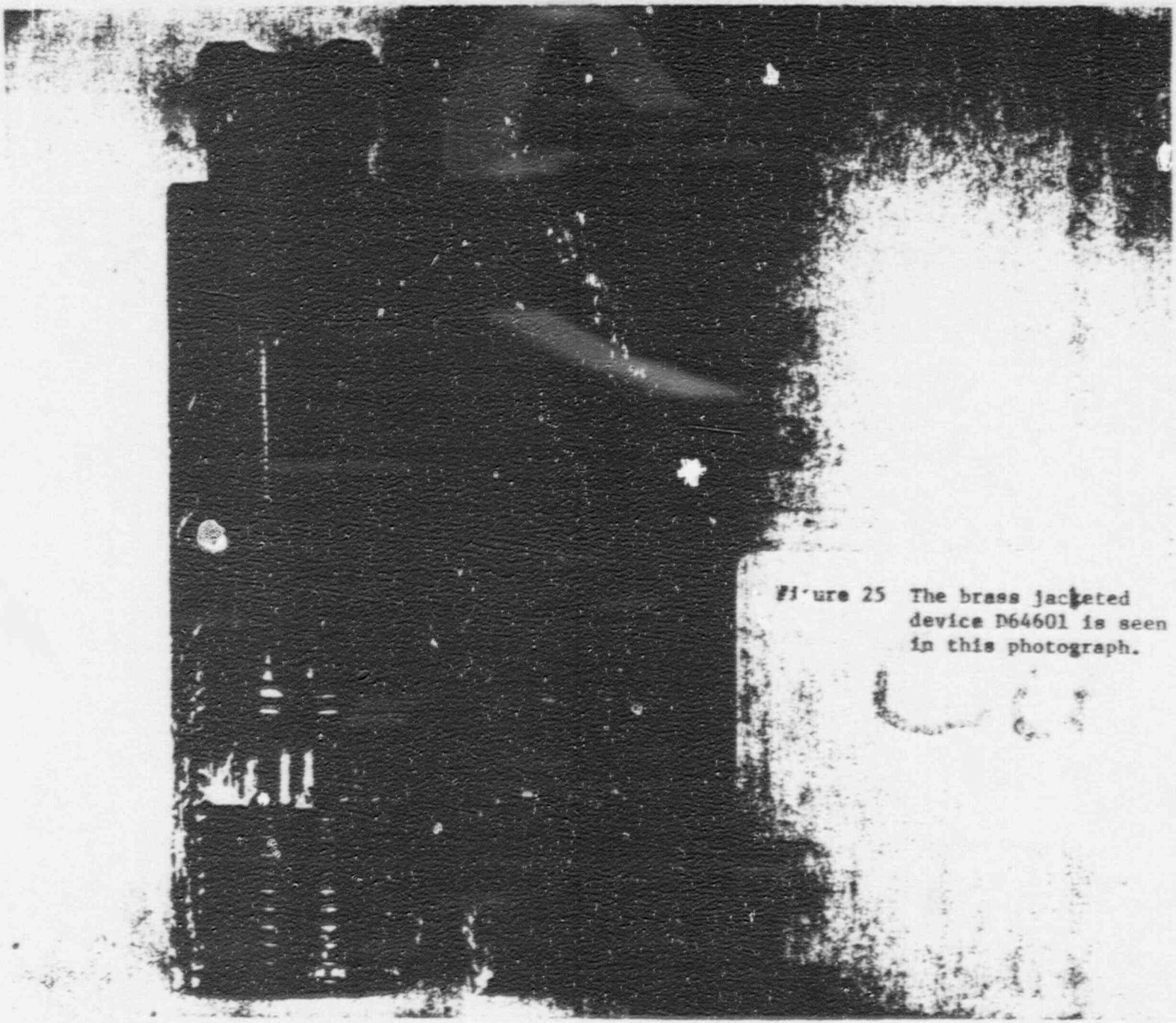


Figure 25 The brass jacketed device D64601 is seen in this photograph.

260X

Figure 26 SEM photo of epoxy (typical) on static eliminator D64601.

400X

Figure 27 Fractograph showing decohesion of microspheres (arrows) and damaged microspheres.

400X

Figure 28 A second area showed cracking epoxy in area of the microspheres (D64601).

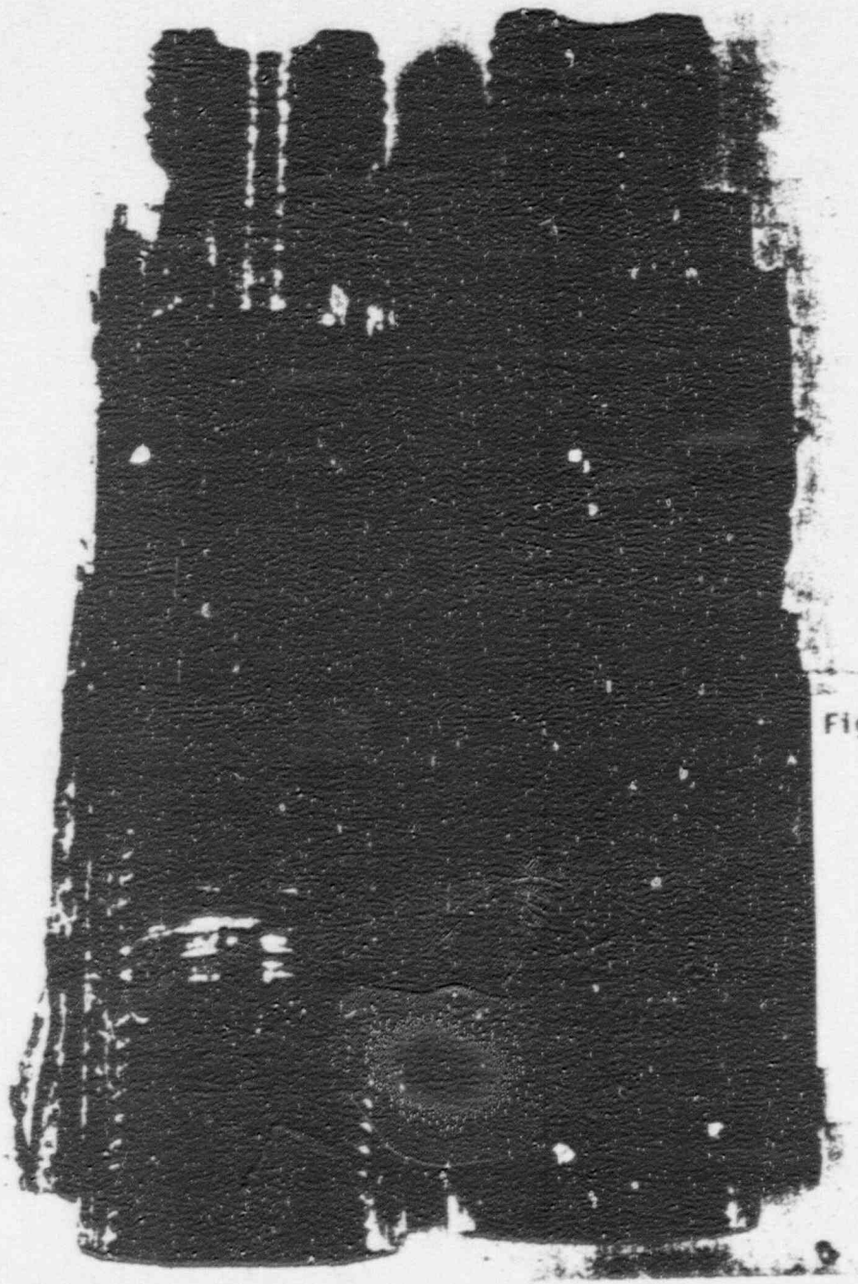
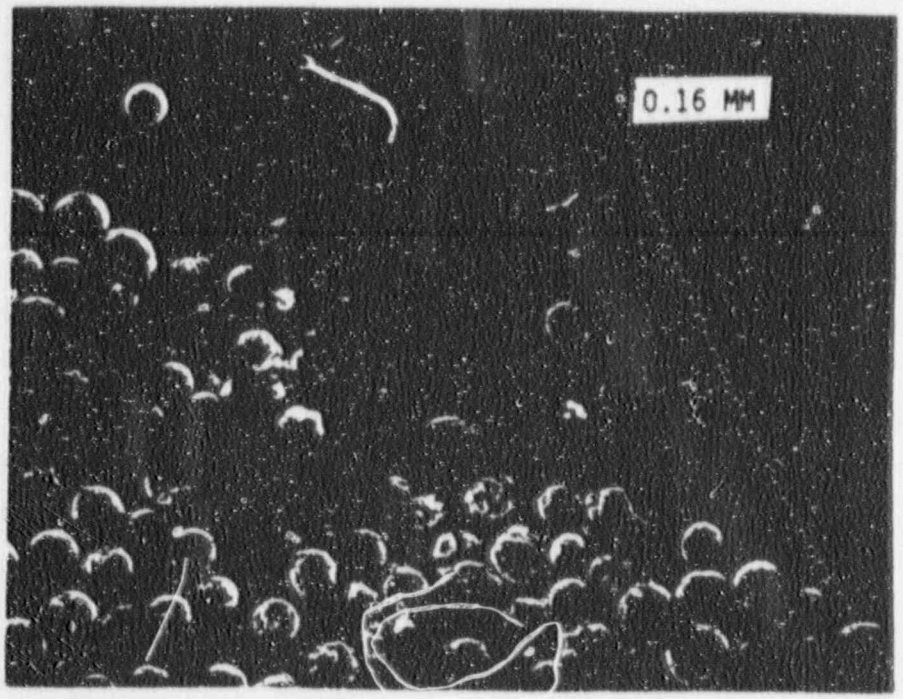
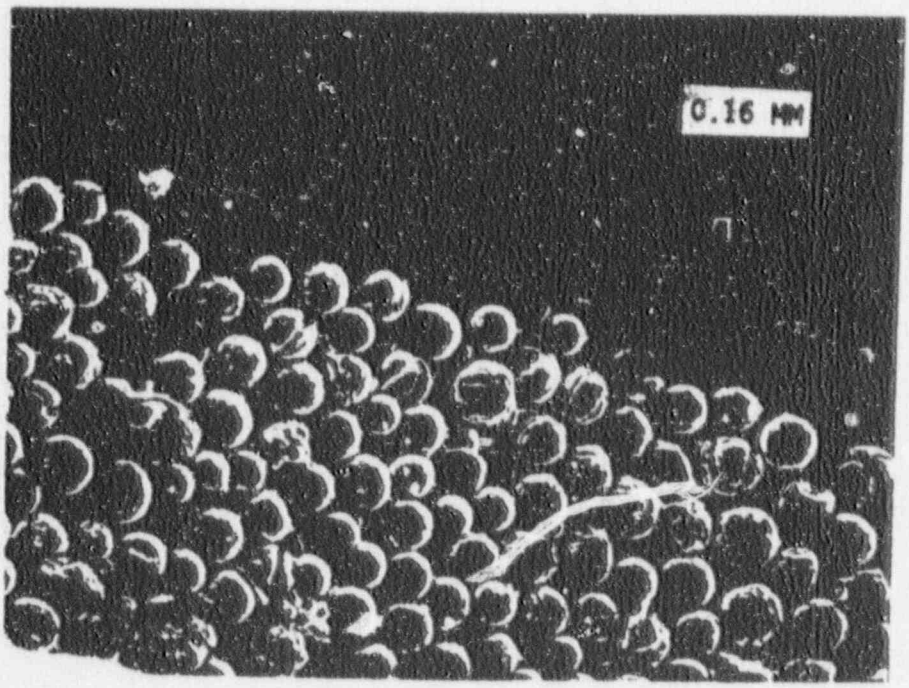


Figure 29 Device D74410 from the manual filling station is seen here. The arrows show an area of missing epoxy.



160X

Figure 30 Significant cracking of the epoxy is shown on D74410.



160X

Figure 31 A second area of D74410 showing the typical condition of epoxy and microsphere damage.

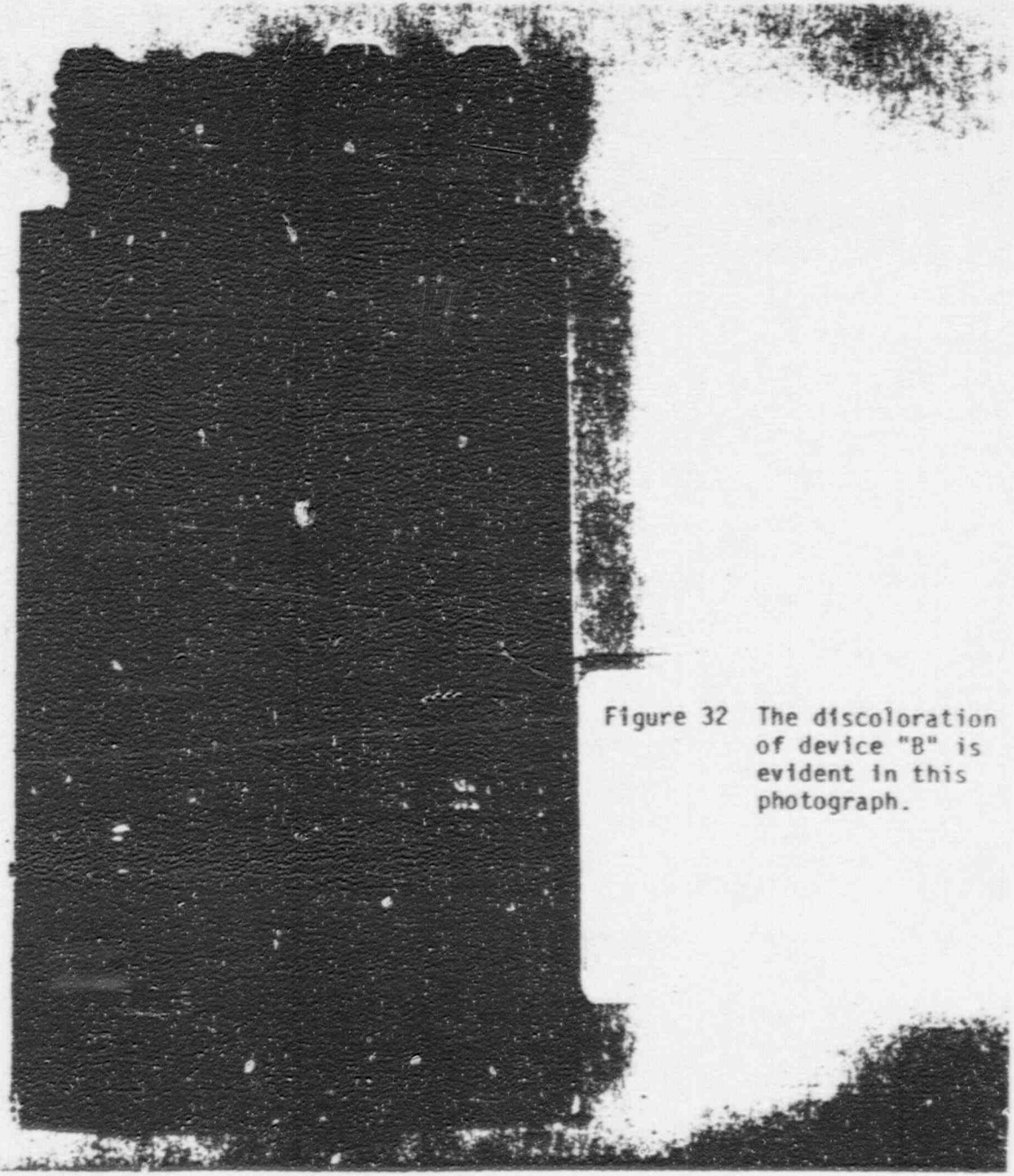
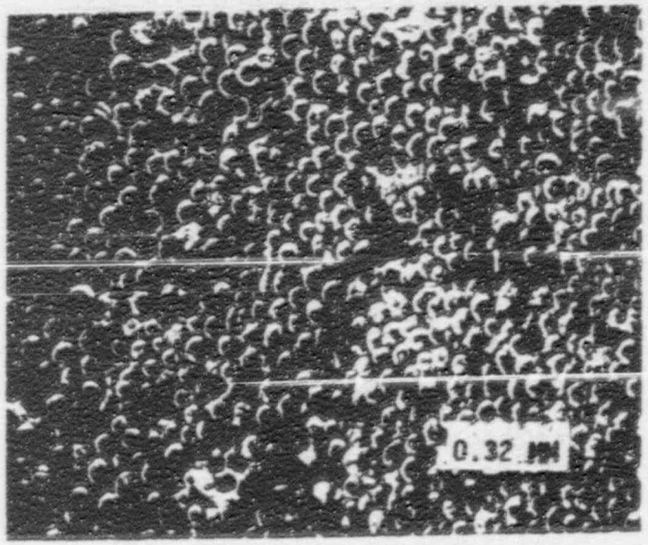
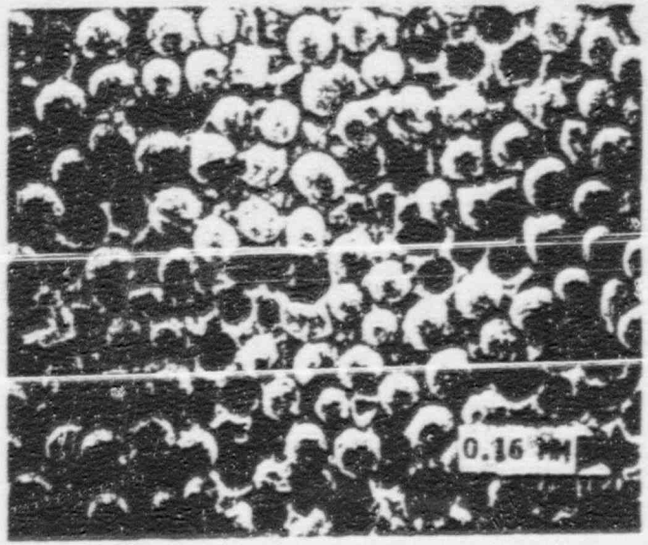


Figure 32 The discoloration of device "B" is evident in this photograph.



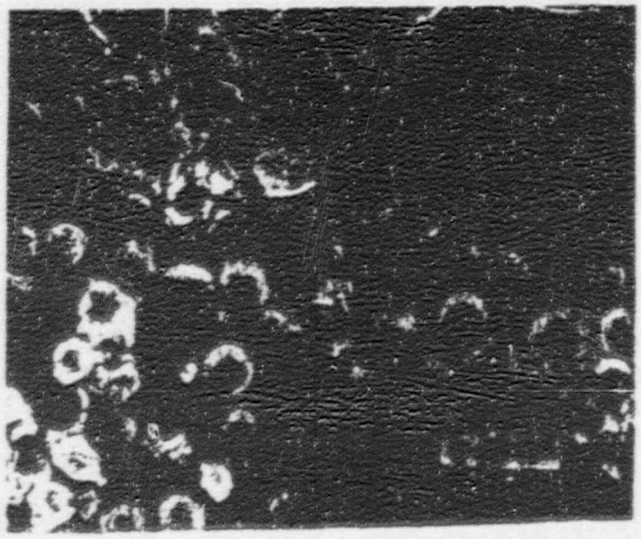
30X

Figure 33 Low magnification SEM photograph showing missing microspheres (dark dots).



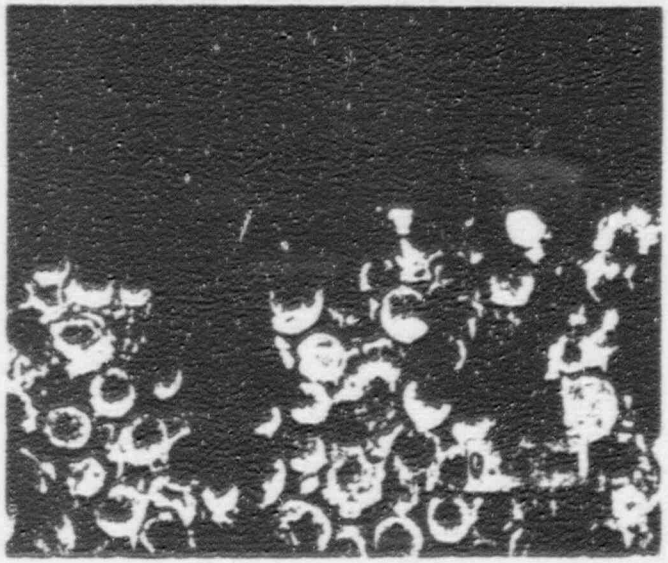
160X

Figure 34 This higher magnification fractograph showing the areas of missing microspheres.



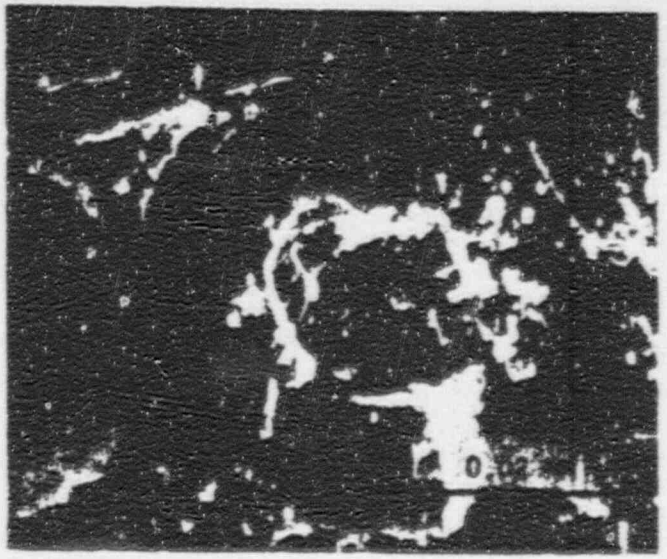
160X

Figure 35 Cracked microspheres and a definite "reptile skin" cracking of the epoxy is seen in this fractograph.



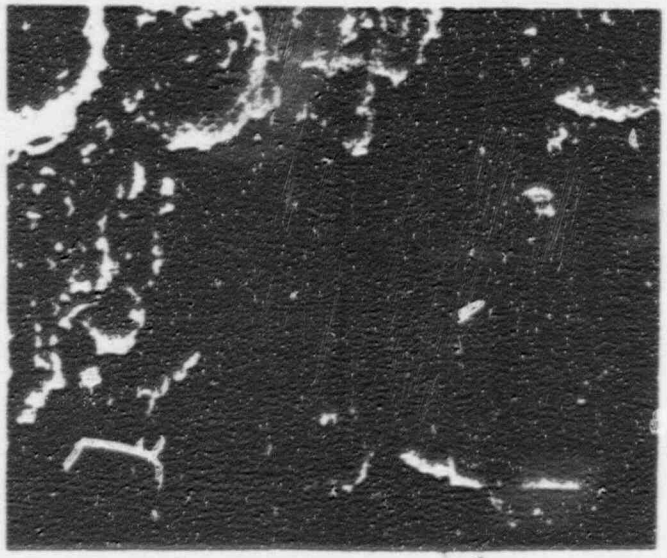
160X

Figure 36 Low magnification SEM photo (sample B) of another area showing damage to both epoxy and microspheres.



1200X

Figure 37 Higher magnification SEM photo of damaged microsphere (Figure 36-arrows).



800X

Figure 38 SEM photo of an area where a microsphere is missing - no apparent swelling of epoxy.

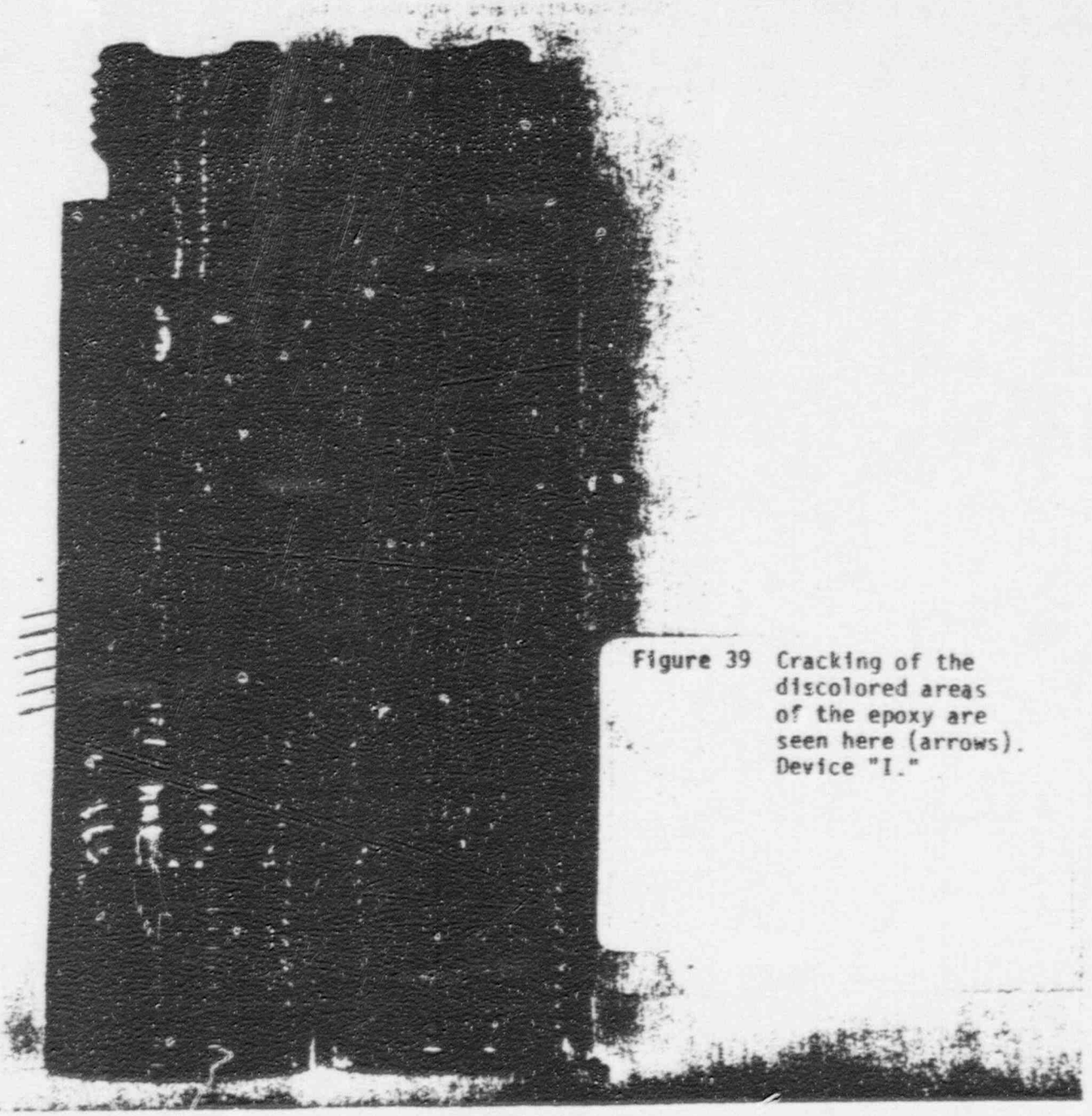
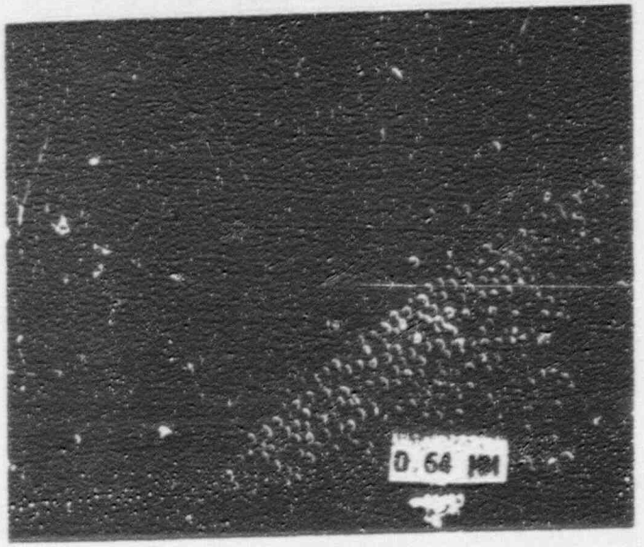


Figure 39 Cracking of the discolored areas of the epoxy are seen here (arrows). Device "I."

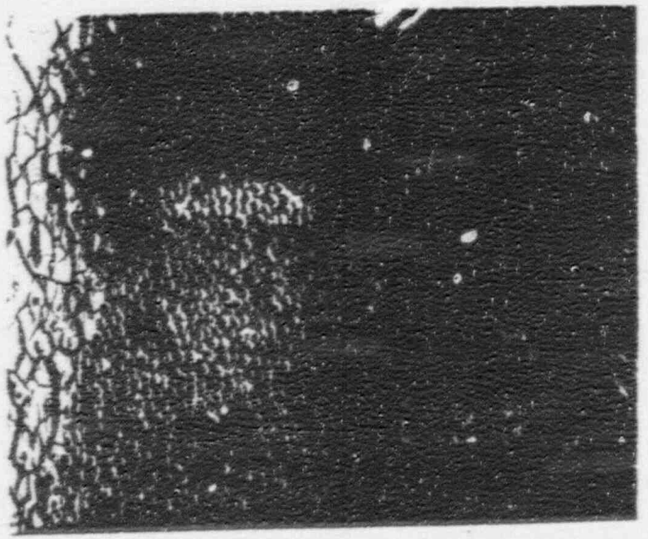


40X

Figure 40 SEM photo of "reptile skin" effect on specimen I.

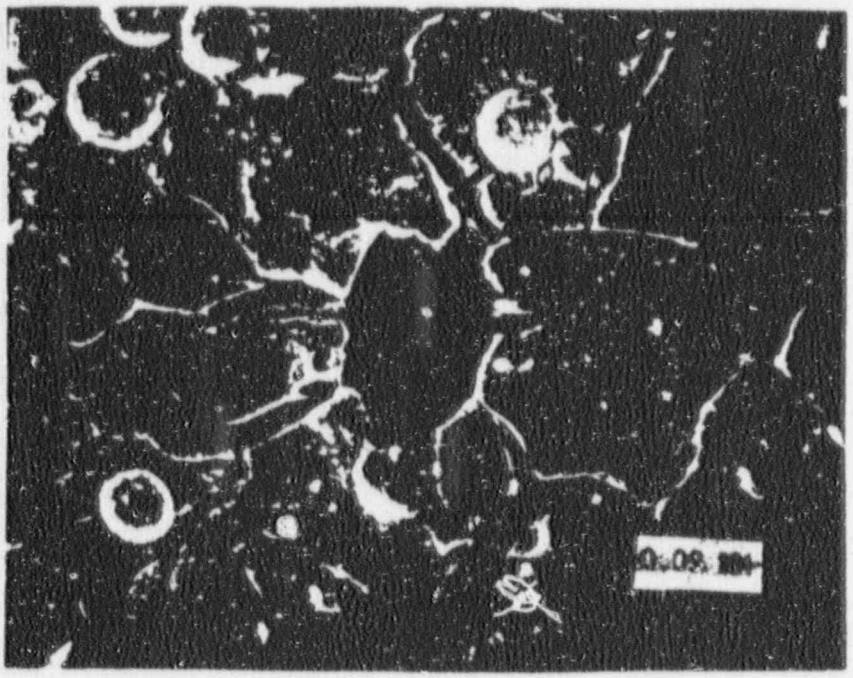
80X

Figure 41 Microspheres noted outside the area of interest (arrow) and craters visible in epoxy.



40X

Figure 42 This fractograph shows that the epoxy under the microspheres is apparently cracking also.



280X

Figure 43 Higher magnification fractograph of a typical crater. Note decohesion around remaining microspheres.

280X

Figure 44 Microsphere damage and epoxy damage are seen in this SEM photo of specimen "I."

NRC FORM 335 (2-87) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

SEE INSTRUCTIONS ON THE REVERSE

1. REPORT NUMBER (Assigned by TIDC, add Vol. No., if any)
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2. TITLE AND SUBTITLE
Failure Investigation of 3M Series 900 Static Eliminators

3. LEAVE BLANK

4. DATE REPORT COMPLETED
MONTH: April YEAR: 1988

5. AUTHOR(S)
C. Czajkowski

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MONTH: July YEAR: 1988

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U.S. Nuclear Regulatory Commission
Washington, DC 20555

Region I
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475 Allendale Road
King of Prussia, PA 19406

11a. TYPE OF REPORT
Technical

b. PERIOD COVERED (Inclusive dates)

13. ABSTRACT (200 words or less)

Numerous instances of facility contamination by polonium-210 microspheres have been reported. These contamination events appear to be caused by leakage or ejection of the radioactive material from static elimination devices manufactured by the Minnesota Mining and Manufacturing Company (3M). The Ashland Chemical Company (Easton, Pennsylvania) was the first facility determined to be contaminated and was subsequently subjected to a comprehensive review by the U. S. Nuclear Regulatory Commission (USNRC). Therefore, devices from this facility were chosen for examination.

A failure investigation has been performed on six static eliminators. The investigation consisted of visual inspection, sectioning and scanning electron microscopy of six devices. It is concluded that non-uniform and imperfect microspheres appear to have been manufactured and installed in devices. Handling incident to use may induce loosening of the microspheres and the epoxy binder used in device manufacture may not be suitable for the varied service conditions.

14. DOCUMENT ANALYSIS - a. KEYWORDS/DESCRIPTORS
static eliminators
polonium-210
microspheres
epoxy
scanning electron microscopy failure

b. IDENTIFIERS/OPEN ENDED TERMS

15. AVAILABILITY STATEMENT
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17. NUMBER OF PAGES

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Release

SUMMARY OF RETURNED DEVICES AND
TEST RESULTS OF 3M PO-210 DEVICES

(Data as of October 7, 1988)

Total number of devices returned	49,108.
Portion of total number of devices returned from all customers	88.88%
Returned devices leaking <0.005 uCi	1.15%
Returned devices leaking >0.005 uCi	1.89%
Portion of devices used in food, beverage, cosmetic and pharmaceutical (FBCP) applications that has been returned	97.44%
Returned FBCP devices leaking <0.005 uCi	1.87%
Returned FBCP devices leaking >0.005 uCi	4.69%

Enclosure 7

Release

SUMMARY OF THE U.S. NUCLEAR REGULATORY COMMISSION'S (NRC'S) 1988
INSPECTIONS OF MINNESOTA MINING AND MANUFACTURING COMPANY (3M)

Inspection 1

Date of inspection: January 25, 1988-April 29, 1988

Conducted by: RIII materials staff

Licenses inspected: 22-00057-06, 22-00057-32G

Locations: 3M facilities in St. Paul, MN; New Brighton, MN; Austin, TX

Report: Issued July 1, 1988

Results: Five apparent violations

(1) Failure to adequately evaluate device environment before lease

(2) Failure to notify generally licensed customers about damaged and/or leaking devices

(3) Failure to report damaged and/or leaking devices to NRC

(4) Failure to notify NRC of device design modifications

(5) Failure to perform adequate leak tests on returned devices

Status of enforcement action: Awaiting completion of Office of Investigations (OI) investigation

Inspection 2

Dates of inspection: April 27-29, 1988

Conducted by: RIII materials staff

Licenses inspected: 22-00057-32G
(Limited to review of 3M's actions in response to NRC Orders issued January 25, February 5, February 12, and February 18, 1988)

Location: 3M facility at New Brighton, MN

Report: Issued June 16, 1988

Results: No violations

Status of enforcement action: Closed

ENCLOSURE 8

Inspection 3

Dates of inspection: June 14, 1988-July 28, 1988

Conducted by: RIII and NMSS materials staff

Licenses inspected: 22-00057-06, 22-00057-34G, 22-00057-59MD
(Focused on manufacturing, testing and distribution of industrial and medical sources)

Locations: 3M facilities at New Brighton, St. Paul, and Woodbury, MN

Report: Issued August 19, 1988

Results: Two apparent violations

(1) Failure to properly label Static Meter containing tritium

(2) Failure to notify NRC of revised manufacturing procedure for iodine-125 seeds

Also identified 12 "concerns" which, if uncorrected, could lead to health and safety problems

Status of enforcement action: 3M's response dated September 16, 1988 under review

Inspection 4

Dates of inspection: August 1-11, 1988

Conducted by: RIII materials, emergency preparedness, and radiological protection staff; radiological site assessment representative (Oak Ridge Associated Universities (ORAU)); fire protection engineer (Professional Loss Control Inc., subcontractor to ORAU); Minnesota Department of Health, Occupational Health Section; Minnesota Department of Labor and Industry, Occupational Safety and Health Division; U. S. Environmental Protection Agency

Licenses inspected: 22-00057-06, 22-00057-07
(Team assessment that reviewed radiation protection programs of both licenses and, for the 06 (manufacturing) license, also reviewed emergency preparedness, fire protection and industrial safety and chemical hazards related to 3M's radiologic program)

Locations inspected: 3M facilities in New Brighton and St. Paul, MN

Report: Issued September 21, 1988, but not yet released to public pending 3M's review for proprietary information

Results: Four apparent violations

(1) Improper storage of radioactive material in unrestricted area

(2) Failure to maintain up-to-date list of authorized signatures needed for approval of orders of radioactive material

(3) 3M employee was observed drinking soda while working in area where unsealed radioactive materials were located

(4) Failure to maintain records of laboratory area surveys

Also identified a series of concerns and recommendations (e.g., radiation, industrial, chemical, fire safety) as indicators of performance which, if unchecked, could lead to health and safety problems

Status of enforcement action: Awaiting 3M's response to September 21, 1988 Notice of Violation