UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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March 9, 1987

MEMORANDUM FOR: C. J. Heltemes, Jr., Director Office of Analysis and Evaluation of Operational Data

FROM: A. Bert Davis, Acting Regional Administrator, Region III

SUBJECT: ABNORMAL OCCURRENCE REPORT TO CONGRESS FOR FOURTH QUARTER CY 1986

Enclosed in response to your memorandum dated January 30, 1987, are write-ups on the following proposed abnormal occurrences:

1. Cleveland Clinic
2. Toledo Hospital
3. St. Luke's Memorial Hospital [redacted]

In addition, we recommend that [redacted] be classified as an abnormal occurrence. A write-up is enclosed. Because of the extent of the contamination this event is considered to meet the criteria as a major reduction in the degree of protection of the public health and safety. Further, the event and the [redacted] for the control of licensed activities.

You had identified the Show-Cause Order to Highland Waterford Medical Services as a potential abnormal occurrence. Upon review, we suggest that it does not meet the criteria because of the lack of direct safety significance and the relative small size of the licensee's program. We have prepared an Enclosure 3 write-up on this matter.

We have not submitted an updated report on Davis-Besse, in accordance with discussions with Jack Crooks of your staff. We understand this item will be closed out in the Third Quarter Report. For Allied Chemical Corporation, there is nothing additional to report beyond the closeout information submitted in our October 27, 1986, memo on the Third Quarter Report.

If you have any questions, please contact Jan Strasma of my staff (FTS 388-5674).

A Bert Davis

A. Bert Davis
Acting Regional Administrator

Enclosures: As stated

See Attached Distribution

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Distribution

cc w/enclosures:
H. R. Denton, NRR
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J. M. Taylor, IE
W. C. Parler, General Counsel
J. J. Fouchard, PA
G. W. Kerr, SP
Regional Administrators

Therapeutic Misadministration at Cleveland Clinic, (Cleveland, Ohio)

Date and Place -- On October 6-8, 1986, a patient at the Cleveland Clinic Foundation, Cleveland, Ohio, received a series of therapeutic radiation exposures which resulted in a radiation exposure that was about 67 percent greater than the prescribed dosage.

Nature and Probable Consequences -- A 58-year-old female patient received two radiation treatments a day for three consecutive days, October 6-8, 1986, for treatment of bone marrow disease. These treatments -- because of an error in calculating treatment time -- resulted in the patient receiving a radiation dose of approximately 2,000 rads head-to-waist, as opposed to the intended 1,200 rads.

The patient was discharged from the hospital on October 10, 1986, but was readmitted on October 20, 1986, for symptoms believed to result from the radiation exposure (unable to swallow, fever, and chills). She was discharged after treatment, but later admitted on November 10, 1986, with skin burns. The patient died on November 18, 1986.

A panel of NRC medical consultants reviewed the case and concluded that the radiation treatments had "minimal effect, if any, upon the fatal outcome of her disease." The skin burns were not attributable to the radiation treatment, but rather to a variety of drugs -- chemotherapy -- given to the patient prior to and in addition to her radiation treatments.

Cause or Causes -- The misadministration was caused by an error in the calculations performed to determine the exposure time to deliver the desired radiation dosage. The physicist who performed the calculations used the distance from the cobalt-60 radiation source to the patient, instead of the distance from the exterior of the radiation therapy device to the patient. The physicist entered the measurement into a programmable calculator that already accounted for the internal distance from the radiation source to the exterior of the device. Therefore, the internal distance was added twice with the result that a longer treatment time was scheduled. (The further the source is from the patient, the longer the treatment time required.)

In 1982 Cleveland Clinic adopted new procedures as a result of a therapeutic misadministration at that time. These new procedures included a system of dual verification of all dose calculations prior to the first day of treatment. In this case, however, the procedure was not followed and there was no recheck of the physicist's calculations.

The error was discovered on November 11, 1986, when a dosimetrist reviewed the patient's treatment records and checked the calculations.

The licensee reported the misadministration to NRC Region III (Chicago) on November 17, 1986.

Actions Taken to Prevent Recurrence

Licensee -- The licensee has adopted revisions to its procedures providing that all dose calculations will be independently performed by two qualified individuals and that, prior to the first treatment, the technologist will verify that the duplicate calculations have been performed. In addition, the treatment data will be reviewed weekly by the chief technologist. A quality assurance audit by the licensee's Radioisotope Committee is to be performed quarterly for a year and then annually thereafter.

NRC -- On November 20, 1986, NRC Region III issued a Confirmatory Action Letter documenting the licensee's agreement to institute the improvements in its procedures listed above.

A special NRC inspection was conducted beginning November 20, 1986. The inspection identified two violations of NRC requirements -- failure to report the therapeutic misadministration within 24 hours and failure to obtain approval of the licensee's Radioisotope Committee for physicians to use NRC-licensed materials. (This second violation is not directly related to the misadministration.) Enforcement action on these violations is pending.

The NRC retained a special medical panel to review the case, consisting of two physicians and a physicist. The panel concluded that the patient's deteriorating condition, ending in her death, was not the result of the misadministration.

Diagnostic Misadministration at St. Luke's Hospital (Racine, Wisconsin)

Date and Place -- On October 21, 1986, a patient at St. Luke's Hospital, Racine, Wisconsin, received a whole body iodine-131 diagnostic scan while the intended procedure was to be a thyroid scan.

Nature and Probable Consequences -- On October 6, 1986, a patient received a diagnostic thyroid scan using iodine-123, an accelerator-produced radioisotope (accelerator-produced radioisotopes are not subject to NRC regulation, but are under state jurisdiction). The attending physician then gave oral instructions for an iodine-131 scan because the previous scan was not definitive. The nuclear medicine technologist erroneously arranged for a whole body scan instead of a thyroid scan as intended by the physician. The whole body scan involved 1.53 millicuries of iodine-131, which is approximately 30 times the normal 50 microcurie dosage for a thyroid scan.

After the scan was performed on October 21, 1986, the attending physician discovered the error. The whole body scan, however, did provide the physician with the diagnostic information desired.

The radiation exposure, while in excess of that intended, did not result in any immediate medical effects, according to the licensee. The typical dosage for a therapeutic procedure -- 4 to 6 millicuries -- would cause a significant reduction of thyroid activity. Thyroid damage can be compensated for through the use of medication.

Cause or Causes -- The misadministration was caused by a misinterpretation of the attending physician's oral instruction to the medical technologist. The physician requested an "iodine-131 scan," which the technologist incorrectly assumed to be whole body scan. Typically, the licensee uses iodine-123 for thyroid scans and iodine-131 for either thyroid scans or whole body scans.

Actions Taken To Prevent Recurrence

Licensee -- The licensee has revised its procedures for prescribing radioiodine for medical procedures and provided training on the revised procedures. All prescriptions are now to be in written form and will be reviewed by a nuclear medicine physician and verified by the technologist prior to administration of the radiopharmaceutical to the patient.

NRC -- NRC Region III (Chicago) issued a Confirmatory Action Letter on January 9, 1987, documenting the licensee's agreement to change its procedures. The changes will be incorporated into the facility's NRC license.

The NRC conducted a special inspection on December 15, 1986, to review the circumstances of the misadministration. The inspection did not identify any violations of NRC requirements, but determined that improvements were needed in the patient prescription process to preclude similar misadministrations in the future.

The NRC also retained a medical consultant to evaluate the misadministration and its possible medical effects. The consultant's report is pending.

Diagnostic Medical Misadministration -- Toledo (Ohio) Hospital

Date and Place -- On November 18, 1986, a patient at Toledo Hospital, Toledo, Ohio, received a misadministration of a radiopharmaceutical when the wrong radioactive material was administered.

Nature and Probable Consequences -- The physician of a 62-year old female patient planned a bone scan for the patient as an outpatient at the Diagnostic Center at Toledo Hospital. The bone scan normally involves a 20 millicurie dose of technetium-99m MDP. The Hospital's procedures provide that the referring physician's office notify the Diagnostic Center by telephone of the scheduled procedure. The procedure is then scheduled, and the hospital's nuclear medicine department notified to order the radiopharmaceutical.

In this instance, the physician's office notified the Diagnostic Center but kept no record of the telephone conversation. The intended procedure was a bone scan, but the Center's receptionist recorded a "total body scan, rule out metastases, carcinoma." This was interpreted by the nuclear medicine department as an order for a thyroid metastatic disease scan, which is also known as a "total body scan." Toledo Hospital normally uses a 20 millicurie dose of iodine-131 for such a procedure, which is usually performed on patients who have had their thyroid removed. (The organ principally affected by an iodine dose is the thyroid.) The nuclear medicine department confirmed with the Center's receptionist that the thyroid metastatic disease scan was the prescribed procedure. The receptionist, however, did not verify the procedure with the referring physician's office.

On November 18, 1986, the patient was administered the iodine-131. She returned to the Diagnostic Center the following day and said she was scheduled for a bone scan. There was no bone scan scheduled, and the error was consequently discovered.

The patient had previously been diagnosed as having mild hypothyroidism (underactive thyroid) and was taking medication to make up for the decreased thyroid function. The iodine-131 dosage was estimated to cause a 6,760 rad dose to the thyroid, while other organs received a relatively small dose. (A rad is a standard measure of radiation.) This dosage to the thyroid is less than would normally be expected because of the reduced thyroid function. The expected dosage would be three to seven times what this patient is estimated to have received.

The thyroid dose is expected to significantly decrease the patient's thyroid function, necessitating an increase in the medication (thyroxin) the patient was already receiving. The prescribed thyroxin dosage was increased to three times the original prescribed dose.

Both the hospital and her physician plan to continue to monitor the patient.

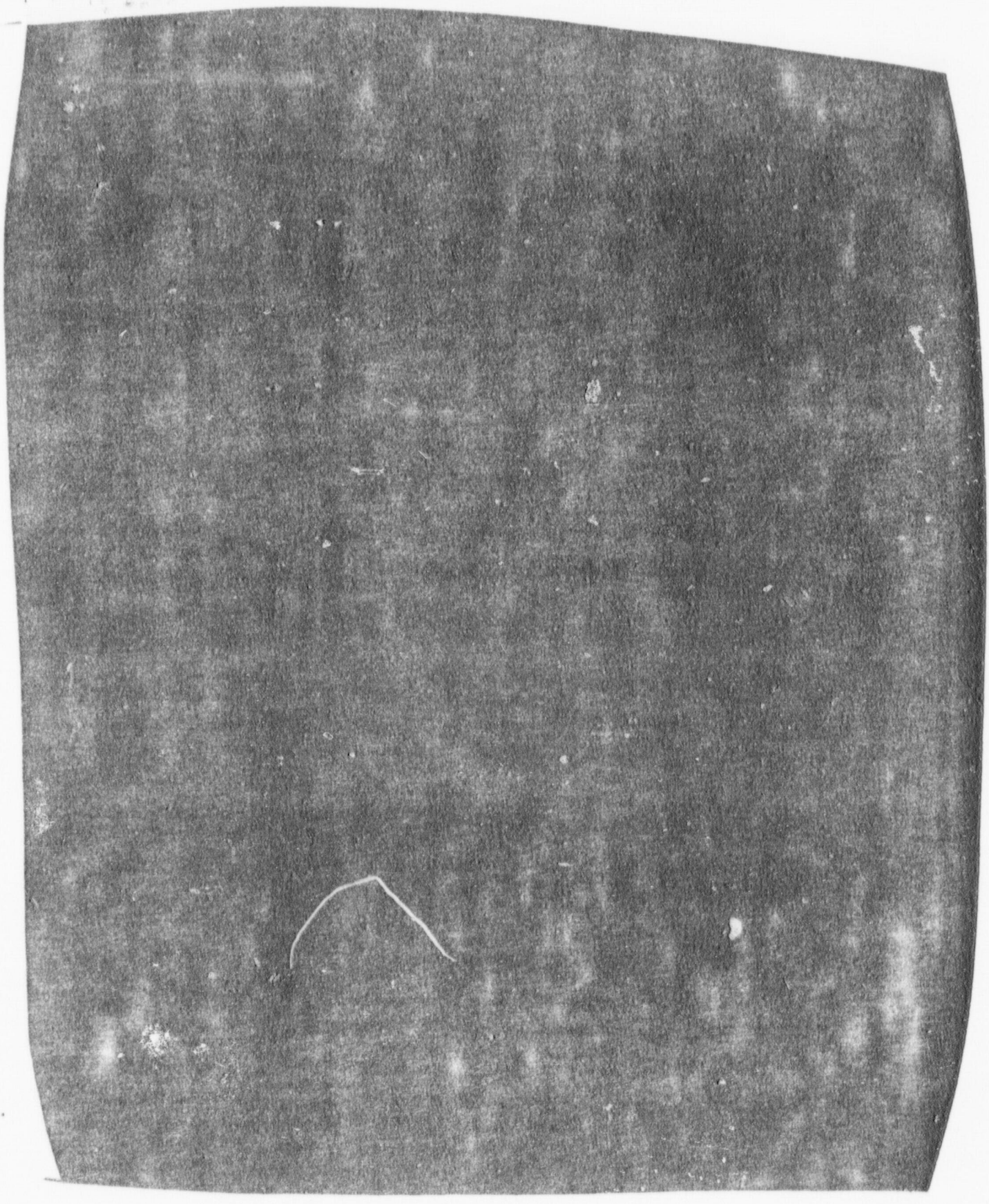
Cause or Causes -- The apparent cause of the misadministration was a failure to accurately communicate the prescribed procedure to the hospital's Diagnostic Center. The precise method of failure could not be determined since the patient's physician did not have a record of the telephone conversation in which the procedure was scheduled.

Actions Taken to Prevent Recurrence

Licensee -- The Hospital has instituted a change in its procedures for scheduling outpatient diagnostic doses. All prescriptions for nuclear medicine procedures are to be in written form and reviewed by a nuclear medicine physician and verified by a technologist prior to the administration of the radiopharmaceutical to the patient.

NRC -- NRC Region III (Chicago) conducted a special inspection at Toledo Hospital on November 25, 1986, to review the circumstances of the misadministration. No violations of NRC requirements were found during the inspection. Region III issued a Confirmatory Action Letter to the Hospital on November 21, 1986, documenting the Hospital's agreement to change its procedures for scheduling procedures involving radiopharmaceuticals. The agency also retained a medical consultant to review the possible health effects of the misadministration.

This incident is considered closed for the purposes of this report.



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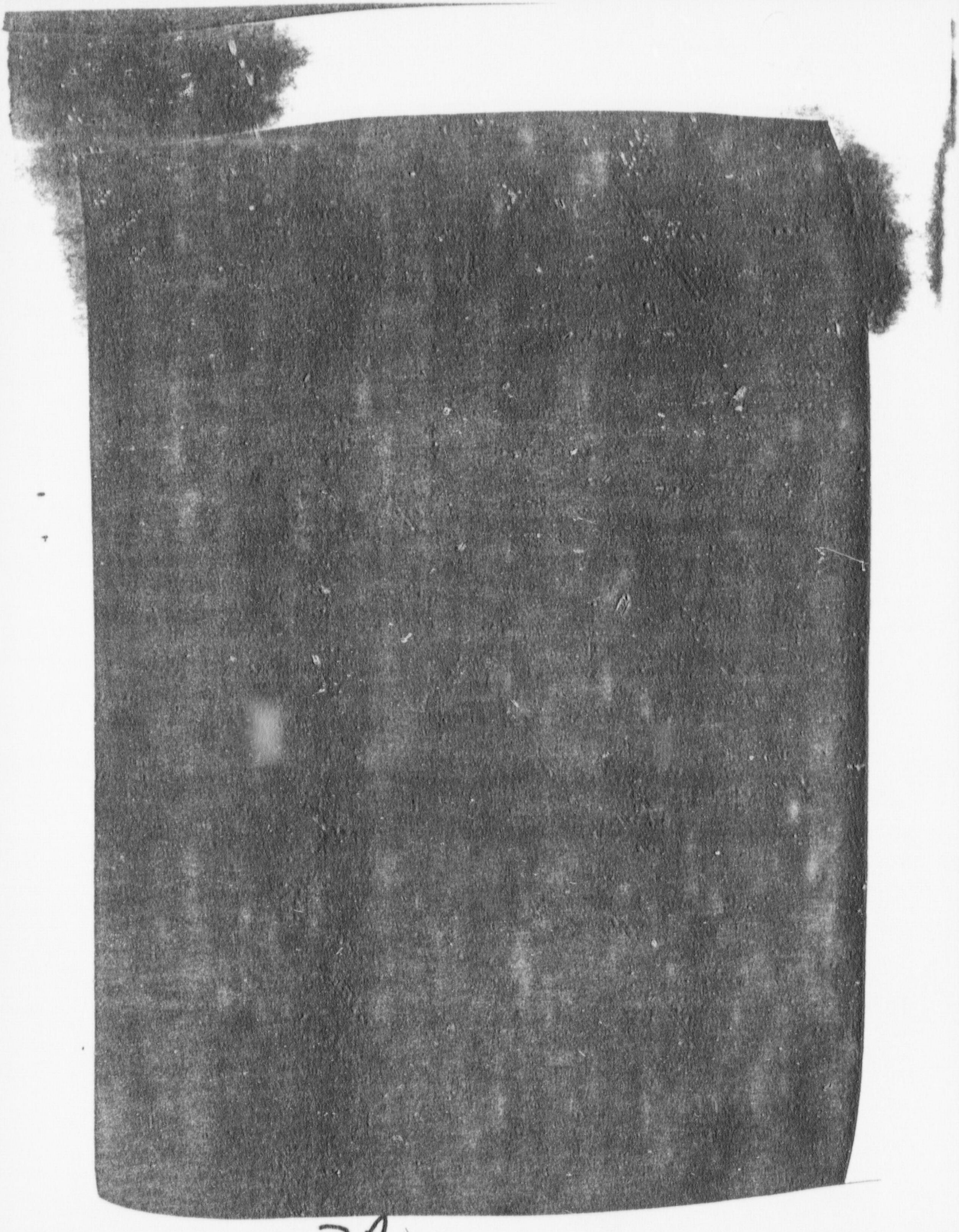

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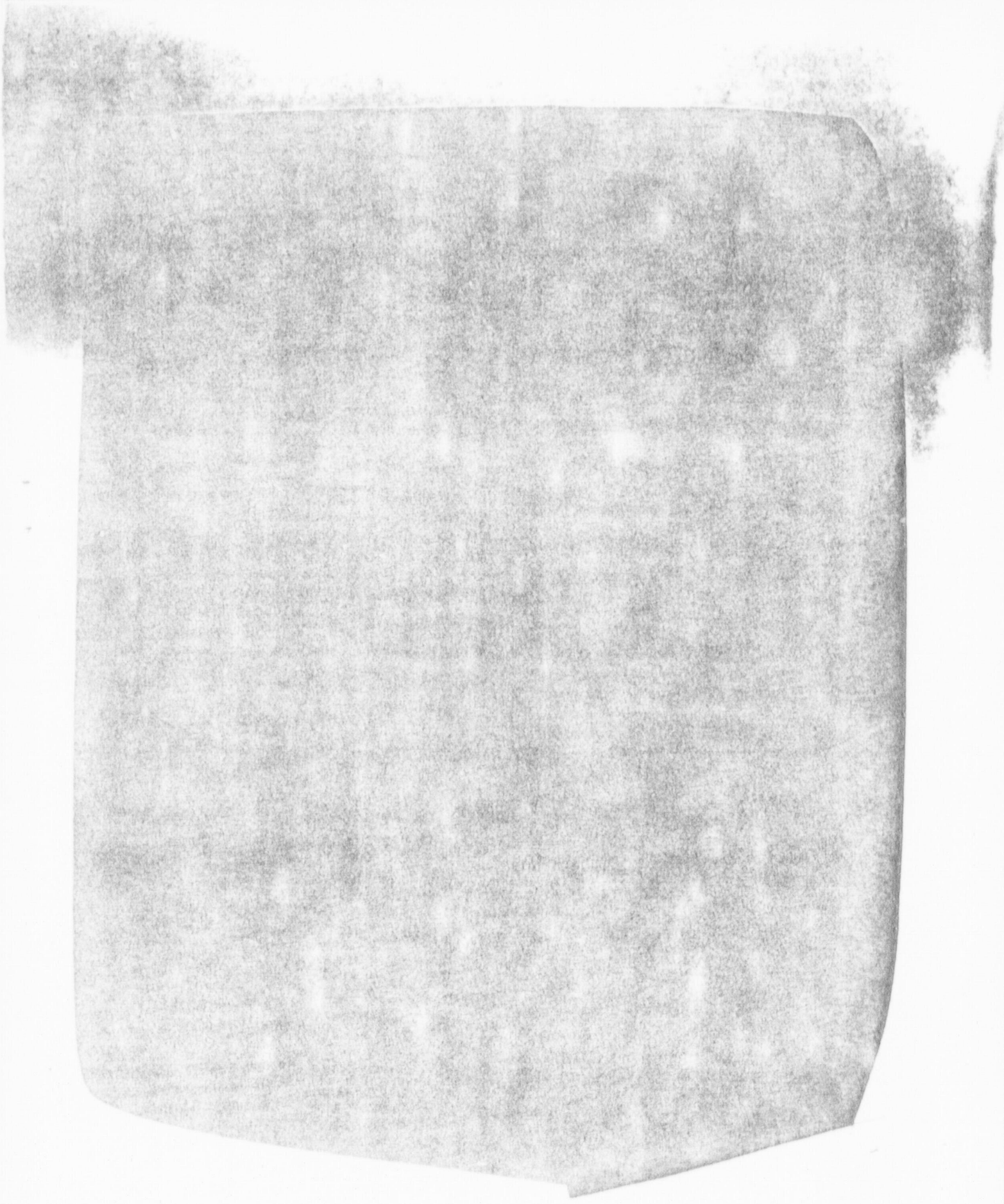

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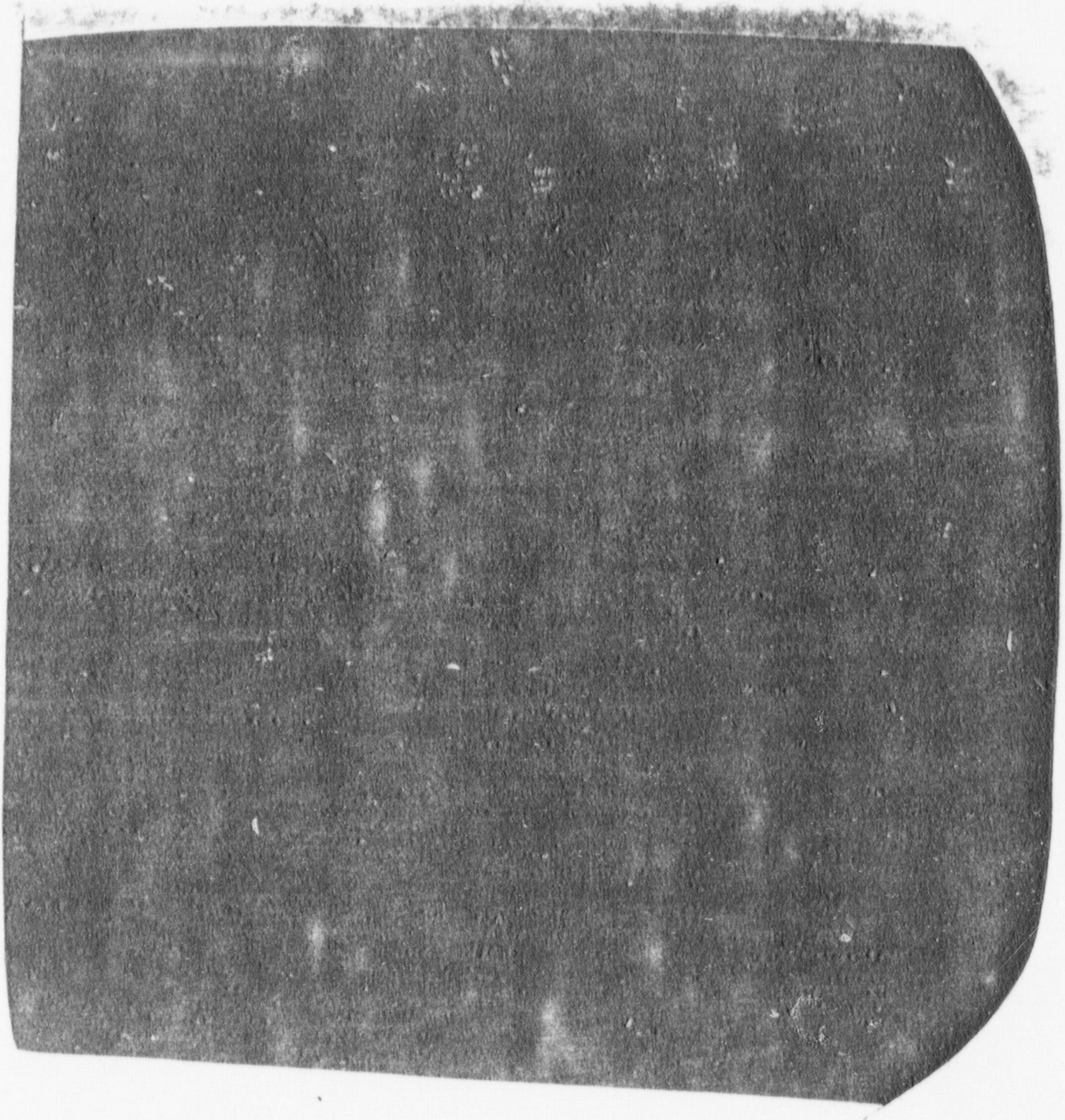

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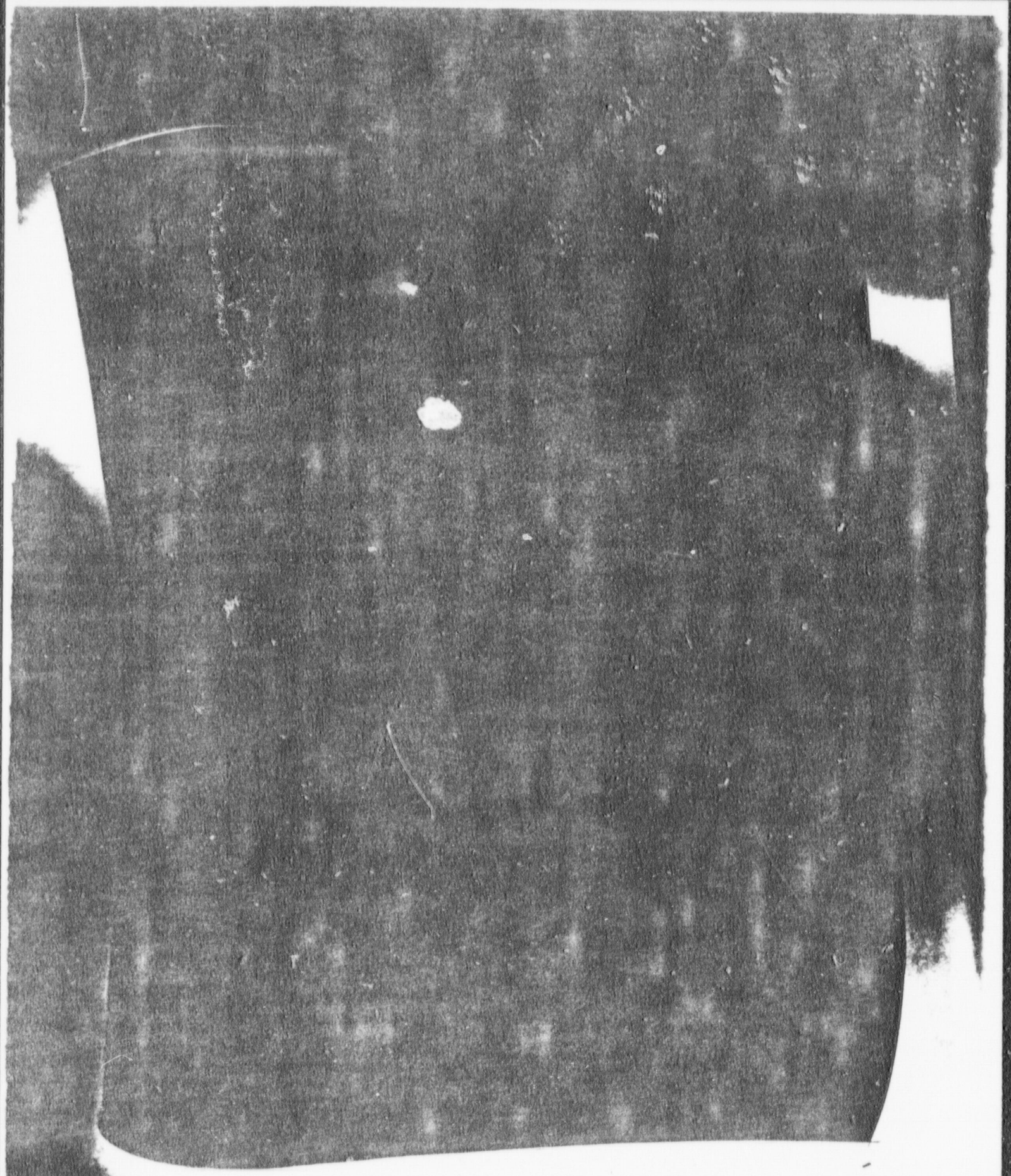

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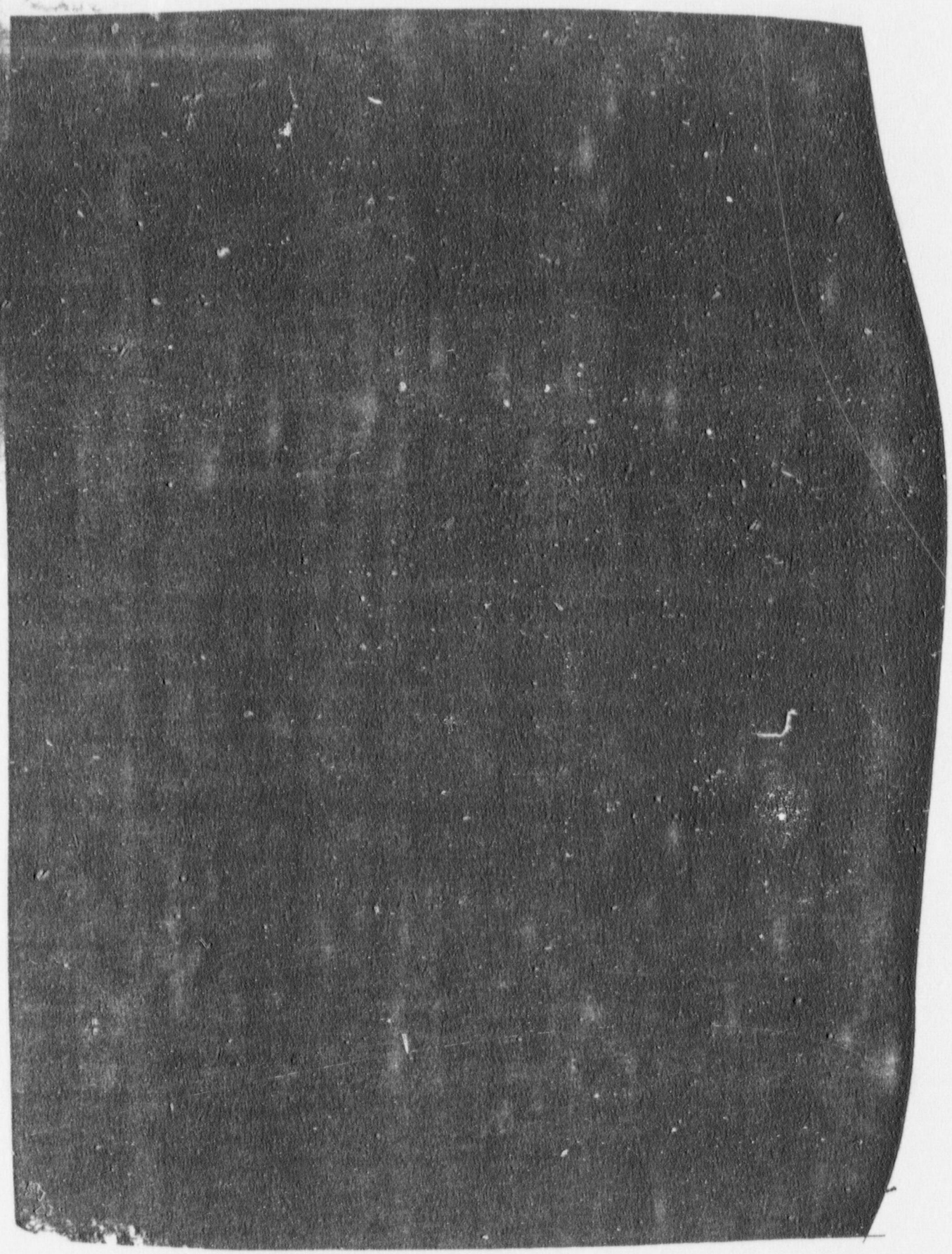

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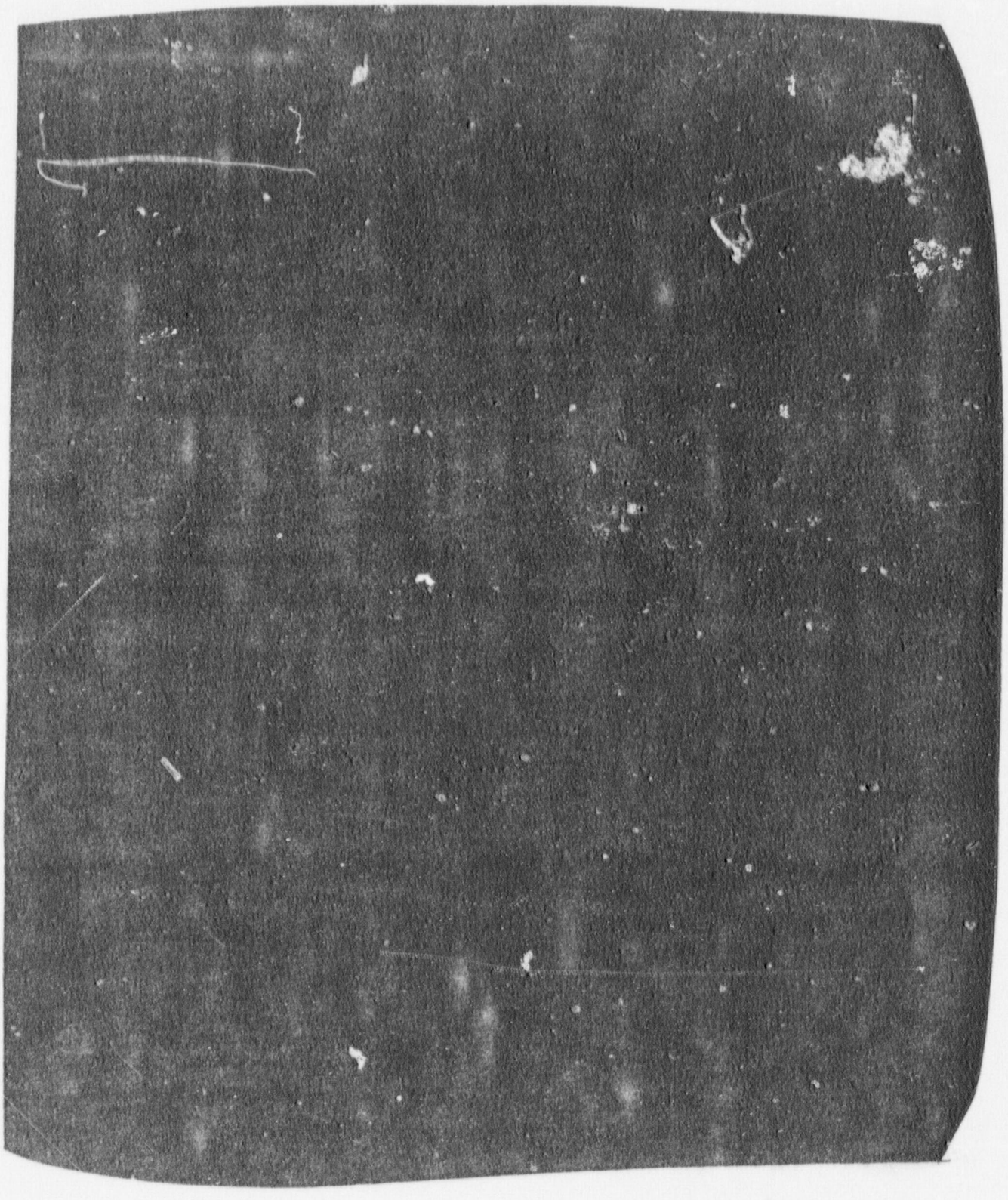
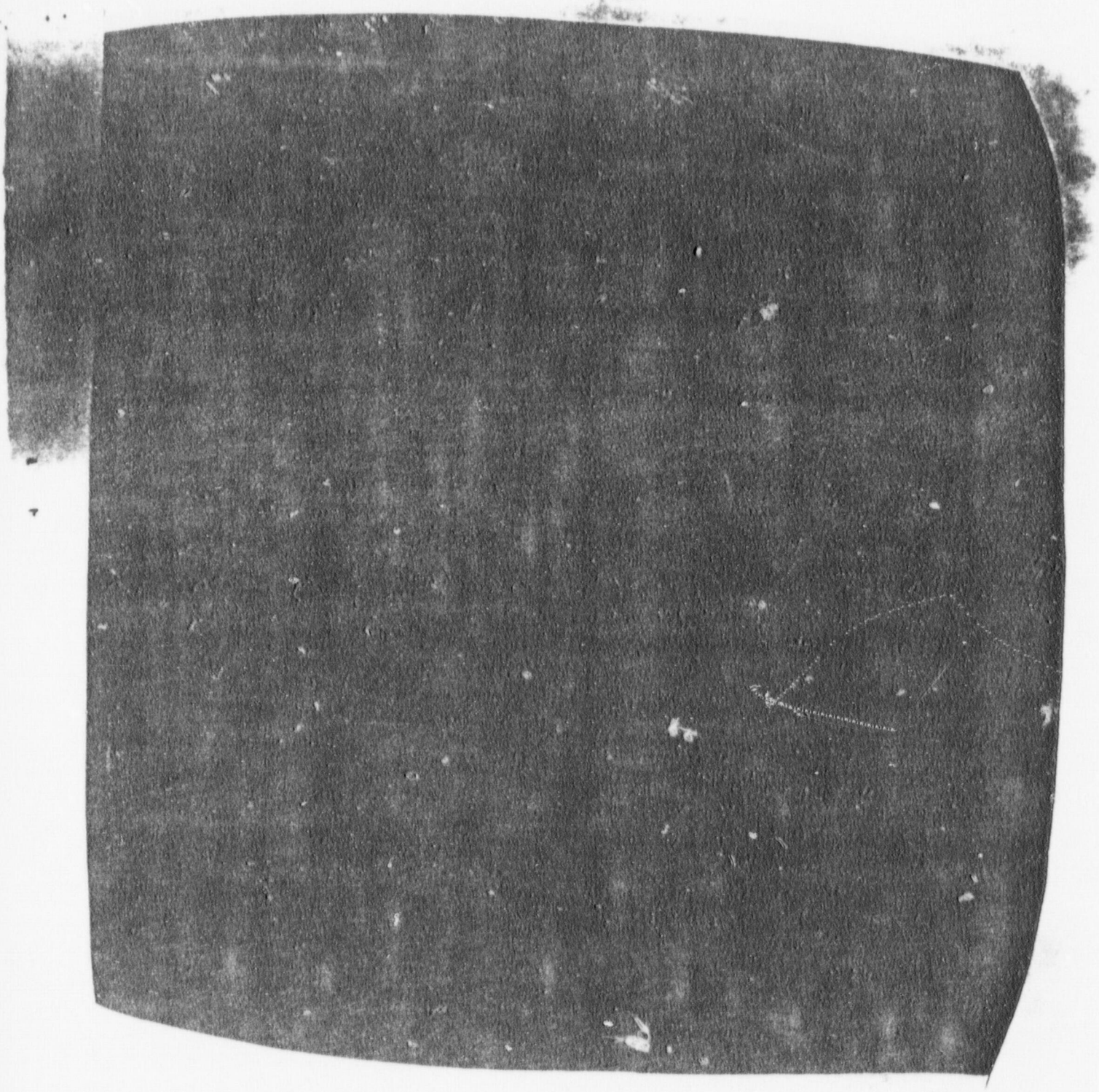
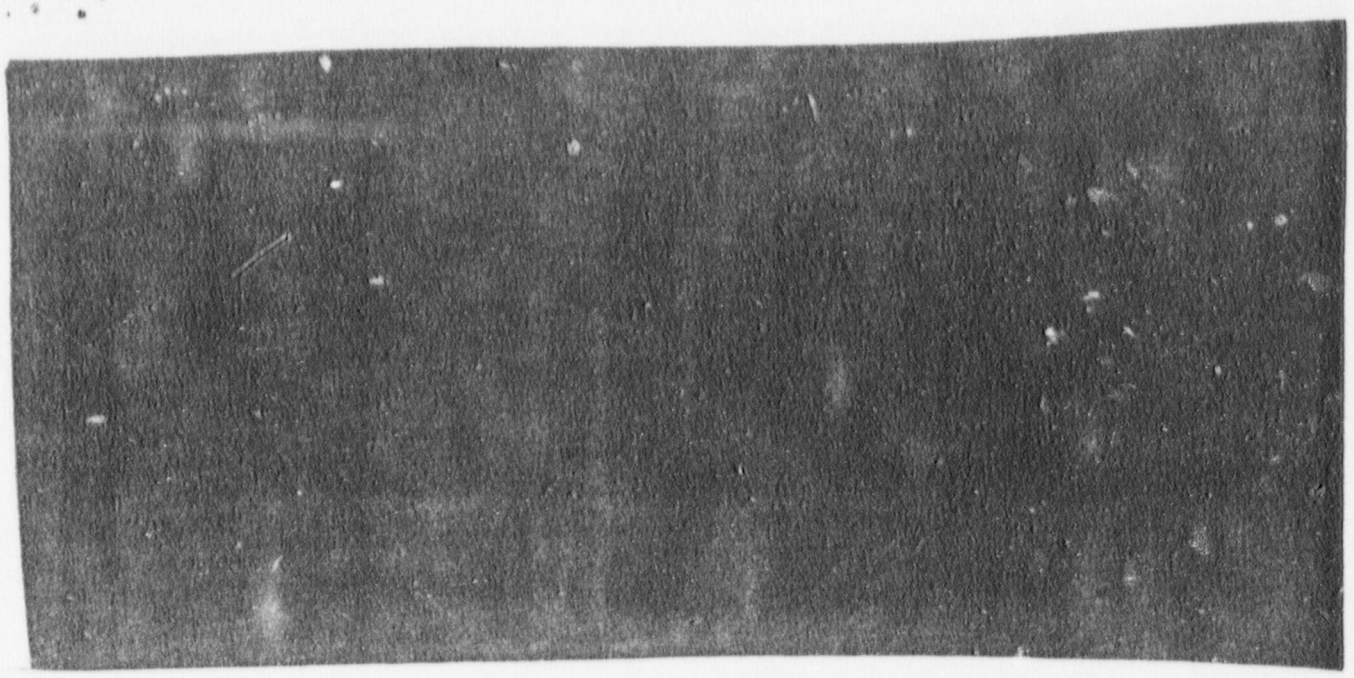






Enclosure 3 Item - Dr. Kedarnath Joshi

On December 23, 1986, the Director of the Office of Inspection and Enforcement ordered Dr. Kedarnath B. Joshi to show-cause why his NRC license should not be revoked. The Highland Waterford Medical Services (HWMS) in Pontiac, Michigan also was issued an Order to show-cause why its NRC license should not be modified to prohibit Dr. Joshi from engaging in any NRC licensed activity at its facility.

Dr. Joshi, of Livonia, Michigan, is licensed by the NRC to use radiopharmaceuticals for diagnostic studies at his private clinics. HWMS was not one of his clinics.

An NRC inspection between June 12 and July 1, 1986, determined that Dr. Joshi administered radiopharmaceuticals to patients at the HWMS facility from May 21 through June 11, 1986, although his license did not authorize use at that location.

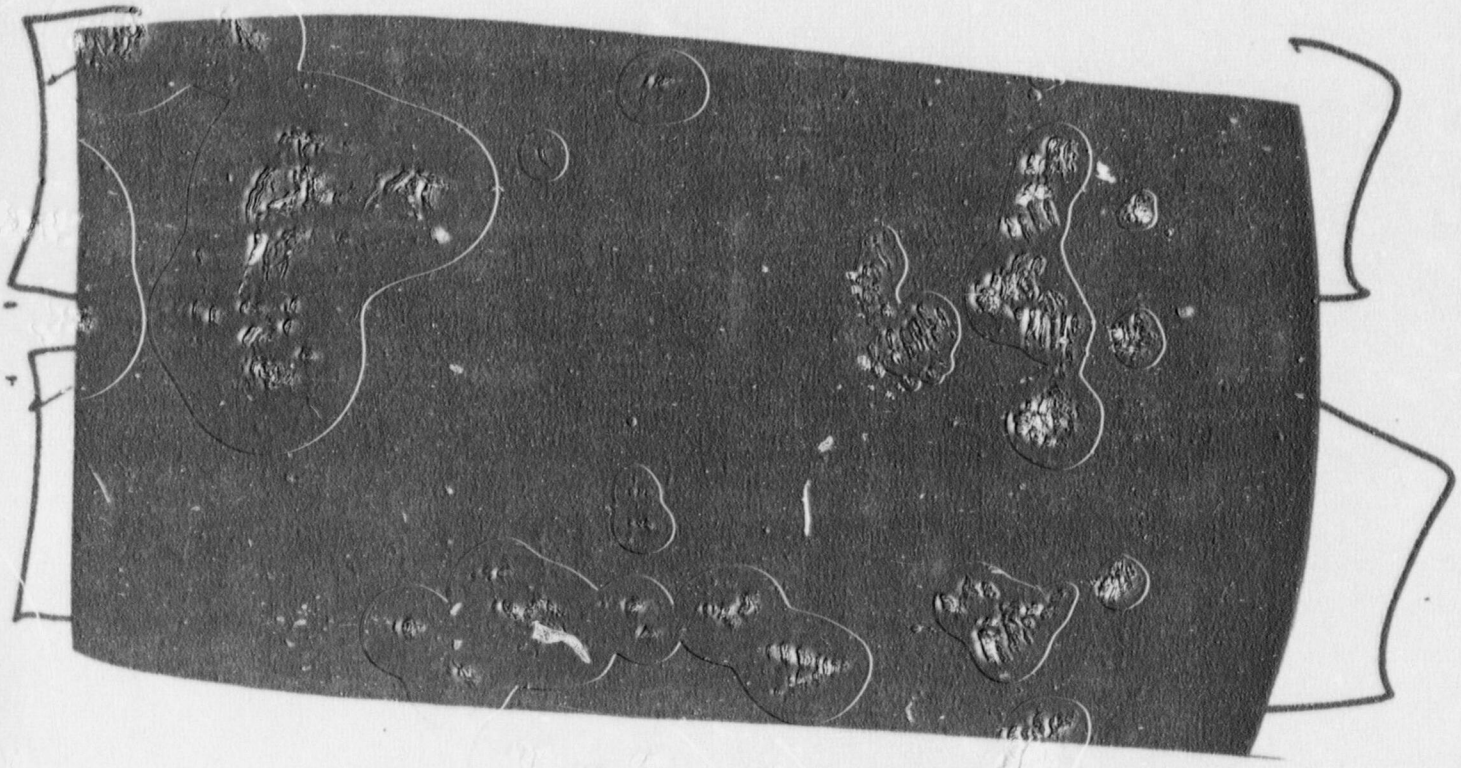
In addition, even though a technologist and two consultants informed Dr. Joshi he would need an amendment to his license to use radiopharmaceuticals at HWMS, and even though the radiopharmaceutical supplier refused to deliver material to HWMS for Dr. Joshi, the NRC staff determined he "willfully and egregiously circumvented the conditions" of his license by requesting the supplier to deliver material to a vacant building in Pontiac, Michigan where he formerly conducted radioisotope procedures. (The supplier did not know the building was vacant.) Dr. Joshi then administered the radiopharmaceuticals to patients on June 9, 10, and 11, 1986.

On January 14, 1987, Dr. Joshi responded in writing to the NRC show-cause Order and requested a hearing. The Highland Waterford Medical Services did not respond to the show-cause Order, and has terminated Dr. Joshi's services.

The enforcement action resulting from Dr. Joshi's activities did not have any direct safety significance. He was authorized to perform the medical procedures using licensed materials, but the authorization was restricted to his private practice clinics. The Show Cause Order was issued because he willfully violated his license by performing diagnostic procedures at Highland Waterford Medical Services.

This matter was considered as a possible Abnormal Occurrence Report meeting the criteria for a serious deficiency in management or procedural controls. It was judged not to meet the criteria because of the small size of the medical program and the absence of any direct safety significance.

Letter to Ray L. DiIulio, President, St. Luke's Hospital, from W. L. Axelson, Chief, Nuclear Materials Safety and Safeguards Branch, NRC Region III, forwarding Inspection Report No. 86-01, Docket No. 030-03425, January 15, 1987.



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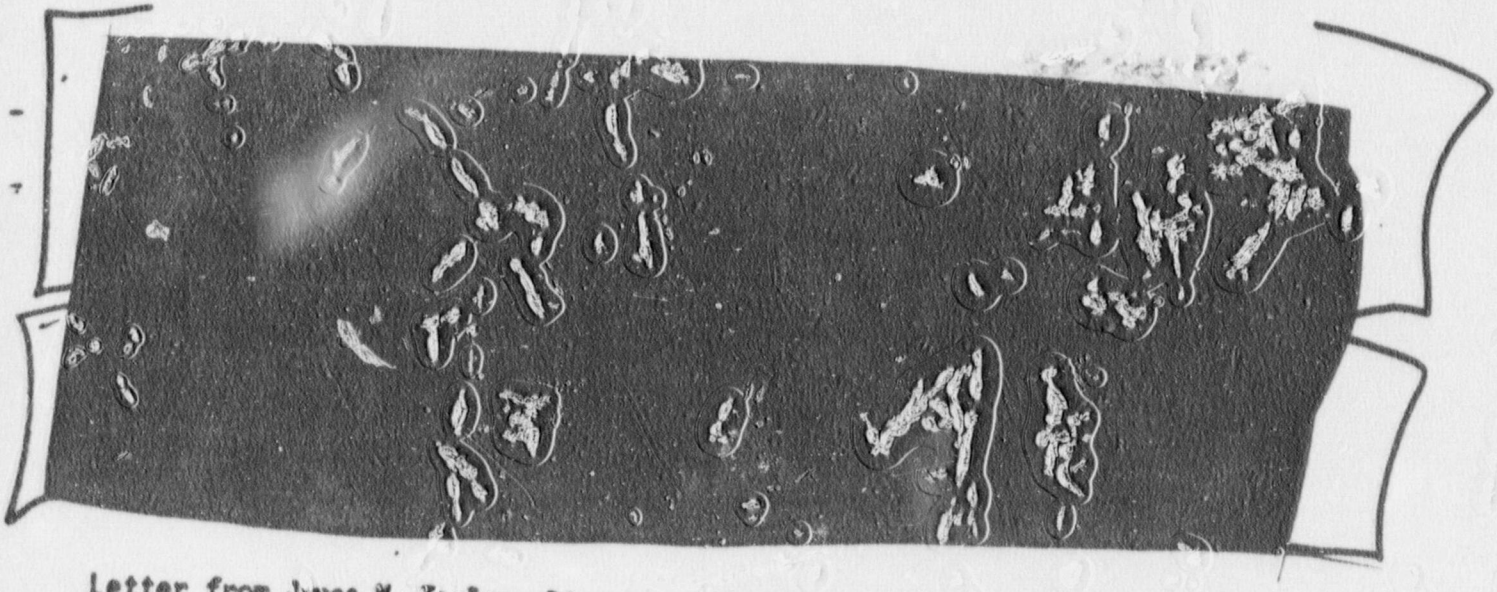
List of References -- Fourth Quarter Abnormal Occurrence Report

Letter from Jack A. Hind, Director, Division of Radiation Safety and Safeguards, NRC Region III, to William S. Kiser, Chairman, Board of Governors, Cleveland Clinic Foundations, forwarding Inspection Report No. 86-01, Docket No. 30-00394, February 12, 1987.



Letter from James M. Taylor, Director, Office of Inspection and Enforcement, NRC, to Kedarnath B. Joshi, M.D., forwarding Order to Show Cause, Docket Nos. 030-13313 and 030-29339, December 23, 1986.

Letter from James M. Taylor, Director, Office of Inspection and Enforcement, NRC, to Highland Waterford Medical Services, forwarding Order to Show Cause, Docket No. 030-29339, December 23, 1986.

Letter to William Jeffries, Radiation Safety Officer, Toledo Hospital, from W. L. Axelson, Chief, Nuclear Materials Safety and Safeguards Branch, NRC Region III, forwarding Inspection Report No. 030-02685, January 9, 1987.