UNITED STATES NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

IE Investigation Report No. 76-01

Subject: Riverside Methodist Hospital
License No. 34-01055-03

Erroneous cobalt-60 teletherapy output data used over an extended period of time to determine patient treatment times resulted in patients receiving total doses significantly greater than those prescribed.

Period of Investigation: April 20-22 and May 12 and 13, 1976

Investigators:

for → G. A. Phillip — 6/23/76 (Date)

for → W. H. Schultz — 6/23/76 (Date)

J. E. Foster — 6/23/76 (Date)

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Reviewed By:

G. T. Lonergan, Chief — 6/23/76 (Date)
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REASON FOR INVESTIGATION

On April 19, 1976, Region III was advised by the Food and Drug Administration in Columbus, Ohio that the local news media there had reported that 255 patients treated at the licensee's facility had received overexposures of radiation. Region III initiated an investigation on April 20, 1976.

SCOPE OF INVESTIGATION

This investigation was conducted to obtain information concerning the circumstances surrounding the exposures received by patients receiving teletherapy treatments and to determine the medical significance of the exposures. The investigation consisted of a selective examination of procedures and records, observations, independent measurements, and interviews with personnel. While the investigation into the cause has been completed, the effects of exposures on patients will involve extended follow-up. IE:III retained the services of a medical consultant on April 19, 1976, to examine the clinical aspects of this case. An inspection of the activities conducted under Byproduct Material License No. 34-01055-03, which authorized the use of cobalt-60 teletherapy unit issued to the Riverside Methodist Hospital, was conducted concurrently with this investigation. A separate report of this inspection (76-02) is attached to this investigation report as Exhibit A.

CONCLUSIONS

1. The overexposure of patients resulted from errors made by a radiation physicist in determining the output of the teletherapy unit.

2. Unexpected reactions were experienced by a number of patients and were observed by therapists during the period prior to discovery of the erroneous output data. These reactions were initially attributed by the therapists to individual differences in patient tolerance and treatment plans.

3. No malfunction of the cobalt-60 teletherapy unit was involved in this matter.

4. Correct source output data were determined by the licensee and used in planning patient treatments as of January 30, 1976. The correct calibration of the teletherapy machine was independently verified by Region III on April 21, 1976.

5. Notification of patient referring physicians and the patients or patients' families has been made by the licensee.

6. Plans for medical follow-up of patients are being developed by the licensee.

7. The principal cause of the occurrence was the preparation by Individual "F" of a series of incorrect calibration (source output) curves, which were used as the basis for calculating exposure times for patients receiving radiation therapy treatments. The errors in the calibration curves can be characterized as follows:

   a. Individual "F" drew the initial source output curve as a straight line on linear graph paper. The output curve can be a straight line only on semilog graph paper.

   b. Individual "F" drew subsequent graphs, using only one point and the slope of the previous graph. A second point on the new graph was not determined by measurement.

   c. Individual "F" inadvertently changed the slope of the graph by changing the scale of the abscissa.

   d. Subsequent graphs contained discontinuities which resulted when the ordinate of the graph was displaced.

   e. The specific details of the errors in the graphs are described in the report submitted to RMH by their consultant, Individual "G."

SUMMARY OF FACTS

During the period March 1, 1975 to January 30, 1976, patients who had been administered cobalt-60 teletherapy treatments at Riverside Methodist Hospital (RMH), Columbus, Ohio, received a radiation dose of 10% or more above that planned. On January 30, 1976, the treating physicians were informed by the radiation physicist that the teletherapy unit output data, which had been used to determine the exposure time necessary to deliver the planned radiation dose

to patients, were erroneous. This resulted in longer exposure periods and therefore, higher doses than intended. From January 30, 1976 until May 6, 1976, the radiation physicist had contended that the erroneous output data had resulted from the progressive deterioration of a radiation measuring probe used periodically to calibrate the unit's output. The discrepancy between the actual and intended dose therefore became greater with the passage of time. On May 6, however, the radiation physicist admitted to RMH management that he had not used the probe but had used output values from incorrect output curves which he had prepared.

Although all patients treated during this period of time received more than the planned radiation dose during each treatment, the total dose received by some patients did not exceed the planned total dose because the series of treatments was not completed for some reason. It was ascertained that 275 living patients, as of January 30, 1976, had received greater than 10% in excess of the total planned dose. It should be recognized that in establishing a therapy program for a given malady the total radiation dose decided upon to be administered may vary from institution to institution or from therapist to therapist. Also, it should be noted that some patients are considered terminal before a series of treatments is begun and that the treatments are only palliative. Additionally, 118 patients who were deceased as of January 30, 1976 received a total radiation dose of at least 10% more than intended. Twenty other patients were treated during the period March 1, 1975 to January 30, 1976 who did not exceed the 10% above planned dose because their scheduled treatments were not complete.

Following discovery of the calibration error on January 30, 1976, the teletherapy unit's output was immediately calibrated correctly and adjustments were made in the treatment schedule of current patients to avoid exceeding their planned total dose. A radiologist and a radiation physicist were retained by RMH as consultants to review the matter, evaluate the magnitude of the problem and to determine the patient population affected and the significance of their exposures. Following receipt of reports from the two consultants, RMH initiated action to notify the referring physicians and their patients. RMH is formulating plans for long-term follow-up of overexposed individuals.

Eugene L. Saenger, M.D. was retained by Region III as an NRC Medical consultant on this case.

The State of Ohio Department of Public Health was informed telephonically on April 19, 1976 by Region III that an investigation was being initiated at RMH. No representatives of that agency participated in the investigation.

This occurrence received extensive publicity by all news media.

The following items of noncompliance were identified during an inspection of this licensed activity conducted concurrently with the investigation.

1. License Condition No. 12 states that licensed material shall be used by or under the supervision of Individual "D".

   Contrary to the above, licensed material was used under the supervision of an individual not authorized by this license condition (Not related to the incident. See Paragraph 6, Exhibit A).

   This is an Infraction.

2. License Condition No. 14.A states, in part, that teletherapy sources shall be tested for leakage at intervals not to exceed six months.

   Contrary to the above, no leak test was performed between July 13, 1973, and August 3, 1974, a period exceeding six months (Not related to the incident. See Paragraph 6, Exhibit A).

   This is an infraction.

3. 10 CFR 20.203(c)(1) "Caution signs" states that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "Caution High Radiation Area".

   Contrary to the above, the door to the teletherapy room, a high radiation area, was not posted with a sign bearing the words "Caution High Radiation Area" (Not related to the incident. See Paragraph 17, Exhibit A).

   This is an Infraction.

   This item of noncompliance was corrected by the licensee during the inspection.

4. License Condition No. 17.C states that electrical interlocks on the entrance door to the teletherapy room shall be tested for proper operation at least once every six months, and that records of test results shall be maintained for inspection by the Commission.

Contrary to the above, no records were maintained showing results of tests of electrical interlocks on the entrance door to the teletherapy room (Not related to the incident. See Paragraph 11, Exhibit A).

This is a Deficiency.

5. 10 CFR 19.11 "Posting of Notices to Workers" states, in part, that each licensee shall post specified documents or a notice which describes the document and states where it may be examined.

Contrary to the above, the required documents were not posted, nor was a notice posted which described the documents and stated where they may be examined (Not related to the incident. See Paragraph 16, Exhibit A).

This is a Deficiency.

6. 10 CFR 20.203(e)(1) "Caution signs" states that each area or room in which licensed material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in an amount exceeding 10 times the quantity of such material specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "Caution Radioactive Material."

Contrary to the above, the door to the teletherapy room was not posted with a sign bearing the words "Caution Radioactive Material" (Not related to the incident. See Paragraph 17, Exhibit A).

This item of noncompliance was corrected by the licensee during the inspection.

The above noted items of noncompliance were not contributory to the occurrence under investigation.

DETAILS

Introduction

On April 19, 1976, Region III received a telephone call from the Columbus, Ohio Office of the Food and Drug Administration advising of a local Columbus news media report that the licensee had released information concerning the overexposure of approximately 255 patients who had undergone cobalt-60 teletherapy treatments during the period March 1975 through January 1976.

During subsequent telephone conversations on April 19 with administrative representatives of RMH, Region III received confirmation of this information and was advised that the patients received an average of 19% more than prescribed, with the maximum being 40%. It was indicated during these conversations that a progressively deteriorating instrument probe had given low readings when used periodically to measure the teletherapy unit's output. The disparity between the actual and measured output became greater with passage of time. RMH further advised that a radiation physicist and a radiologist had been retained as consultants by the licensee. The radiation physicist had performed a calibration of the teletherapy unit and had reviewed the entire matter. RMH further indicated that the teletherapy unit was functioning properly. Region III advised RMH that an investigation was being initiated and that Dr. Eugene L. Saenger had been retained as an NRC Medical Consultant for this case.

Background

Under NRC Byproduct Material License No. 34-01055-03 Riverside Methodist Hospital, Columbus, Ohio is authorized to possess and use a maximum of [illegible] curies (2 sources) of not more than 10,000 curies each) of cobalt-60 as teletherapy sealed sources, Picker Corporation Model [illegible]802A or Neutron Product Model NPI-20-6500. One maximum 10,000 curie source is used in a Picker Corporation Model 6296 C-9 teletherapy unit. This license was last amended in its entirety on December 17, 1975.

The unit was installed at RMH in August 1[illegible]72 and the cobalt-60 source, Serial No. PX-933, had a strength of 6885 curies. The initial survey of the facility after installation was made by Individual "L" on August 14, 1972. The initial output of the

unit, as measured by Individual "L," was 169 R/min at 80 cm (Source to Detector Distance). A survey of the teletherapy unit by Individual "F" on March 31, 1976 showed an output of 112.5 R/min at 80 cm (Source to Detector Distance).

Interview With Individual "A" on April 20, 1976

Following initial discussions with Individual "A" and two attorneys, Individuals "B" and "C" from the hospital's law firm upon arrival at RMH on April 20, 1976, Individual "A" was interviewed. Individual "A" advised that on January 30, 1976, measurements were made of the output of the cobalt-60 teletherapy unit. Through these measurements it was discovered that earlier output values used to determine the exposure time necessary to administer planned radiation doses to patients were lower than the unit's actual output. This had resulted in patients receiving higher doses than intended. He indicated that action had been taken immediately to adjust the exposure time of patients currently being treated so that they received no more than the intended total radiation dose.

According to Individual "A," the next several days were spent assessing the situation and making adjustments in the treatment schedule for patients who were currently undergoing a series of treatments. Through an examination of data it was concluded that the radiation measuring probe which had been used to calibrate the teletherapy unit had undergone a gradual deterioration. The discrepancy between the actual and measured output, was initially small but became greater and greater. He indicated that in late 1975 the probe was sent to Victoreen Instrument Company in Cleveland, Ohio to be checked and that it was returned to the hospital in mid-January 1976. It was not used to measure the teletherapy unit's output until January 30, 1976. At that time it was found that the measurements made on January 30, 1976 with the recently calibrated Baldwin-Farmer probe were obviously inaccurate. A second probe, which had been obtained recently as an adjunct to a linear accelerator being installed at the hospital, was then used to measure the unit's output. This confirmed that the first probe was reading low.

Through calculations using the actual output determined on January 30, 1976, it was possible to determine how far back in time erroneous data had been used in establishing exposure times for patient treatments. It had been determined that in March 1975 a single treatment administered to a patient was 10% more than intended. This discrepancy became gradually larger as subsequent calibrations

were made with the deteriorating probe and exposure times were adjusted accordingly. He indicated that 40% over the planned total dose was the maximum received by any patient during the period March 1, 1975 to January 30, 1976.

Individual "A" stated that the two physician therapists, Individuals "D" and "E," were puzzled by the increasing number of patients who manifested unexpected reactions during their series of treatments. He indicated that in Individual "D's" case it appeared that he was too close to the situation so that the gradual change did not cause him to suspect something was wrong. Regarding Individual "E," Individual "A" said he had joined the hospital staff in September 1975 and therefore initially had little past experience with the hospital facility and the patients being treated to use as a basis for comparison. Individual "A" said, however, that the symptoms the two physicians saw in patients caused them to conclude that there was a problem at about the same time the defective condition of the probe was discovered. (It should be noted that the probe was later found not to be defective).

On February 18, 1976 the Executive Committee of the Board of Trustees met to consider the problem. The Committee recommended that outside consultants be retained to review all available data to determine the scope of the problem; i.e., how many patients were involved and the amount of overexposure the patients had received. It was also the Committee's recommendation that full disclosure should be made when the consultant's reviews were completed. It was planned that disclosure should be made first to the referring physicians, second to the patients, and finally to the public.

Following these recommendations. Individual "H," a radiologist, was retained as a consultant and visited RMH on March 2, 1976 to undertake a clinical review of patient records. Individual "G," a radiation physicist, was also retained as a consultant. On March 5 and 6, Individual "G" accompanied by Individual "J," another radiation physicist, visited RMH to review calibration data, to make an independent calibration of the teletherapy unit, and to calculate the actual dose that had been received by patients.

On March 24, Individual "G's" report was received by RMH. Following a review of the report, the contents were discussed during a conference call between RMH personnel, Individual "G" and Individual "H," who also furnished the hospital with a report of his review. Preparations were then made by RMH to notify the referring physicians

and patients. It was decided by RMH that a form letter for each patient would be sent to the patient's referring physician advising him of the recalculated dose. (Individual "A" stated that Radiation Therapy routinely sends a notification to the referring physician advising him of the radiation dose received by his patient during the course of treatment.) The form letter also gave the referring physician the option of informing the patient himself or of having the hospital do so. A copy of the form letter used for this purpose was obtained and is attached to this report as Exhibit B.

Individual "A" said that during the week of April 12, 1976, 250 letters were sent to referring physicians. The hospital staff was also informed of the problem during that week. The hospital's Board of Trustees was informed of the plan to inform the public. A press release was being prepared for this purpose with the intention of releasing it on April 20, 1976. Meanwhile, plans were being made to contact patients whom the referring physicians requested the hospital to notify. Individual "A" said that RMH wanted the patients to be informed before the story was carried by the news media. However, on Saturday, April 17, 1976 the story was "leaked" to the press by an unidentified individual and reporters began making inquiries of the hospital. It therefore became necessary for the hospital to hold a news conference on April 18, 1976 to release the information. A second news conference was held on April 19, 1976 to provide additional information to the press.

Individual "A" stated that the hospital had intended to inform NRC, although they were not obligated to do so by law, before the matter was released to the public. This, however, was overlooked when it became necessary to make a press release prematurely.

Individual "A" advised that the hospital intended to institute a longterm follow-up program regarding the patients involved. He indicated that the hospital considers it unfortunate that the matter became public before all patients could be personally notified.

Interview With Individual "N" On April 21, 1976

Individual "N" stated that she had completed a formal training program at Presbyterian-St. Luke's Hospital in Chicago and was employed by the licensee in September, 1975 as a Certified Radiation Therapy Technologist. Since that time she has worked in the Radiation Therapy Department at RMH and has operated the teletherapy unit on a full time basis. She stated that during her term of employment she has noted no malfunctions or problems with the teletherapy unit or related components.

Individual "N" stated that the Radiation Therapy Department has two physician therapists, Individuals "D" and "E". She stated that both therapists work independently and rotate the assignments on a weekly basis. For example, for a period of a week Individual "D" will see all new patients who will be given therapy treatments and during the same week Individual "E" will see on a follow-up basis all patients who have already started the treatment program. Individual "N" stated that each therapist works independently in providing information to the physicist for use in calculating doses. The following week the duties of Individuals "D" and "E" will be reversed.

Interview With Individual "O" On April 21, 1976

Individual "O" stated that she is a Certified Therapy Technologist and that she was employed by the licensee during the period December 1972 through August 1973, when she left. She was rehired in June, 1975. She has routinely operated the teletherapy unit and has noted no malfunctions or problems with the teletherapy unit or related components.

Individual "O" described the duties of the two Radiation Therapy Department physician therapists, Individuals "D" and "E". She stated that both therapists work independently and rotate responsibilities weekly. One therapist will see all new patients who will be given therapy treatments, and the other therapist will follow the treatment program for these patients who are already involved in the treatment program. She also stated that each therapist works independently in providing information to the physicist, which the physicist uses in calculating the doses to patients.

Interviews With Individual "F" On April 21, and 22, 1976

Individual "F" stated that he was employed by the licensee on November 5, 1973 as a radiation physicist in the Department of Radiology. He stated that he has various duties, including the following which relate to radiation therapy: (1) answering questions of department personnel regarding operation and maintenance of equipment, (2) performing leak tests on the cobalt-60 sealed teletherapy source, (3) checking the interlock switch on the door to the teletherapy room for proper operation, (4) calibration of the teletherapy unit, and (5) calculating patient doses, using information obtained from the radiation therapist and from the calibration data relating to the output of the teletherapy unit.

Individual "F" produced records which showed that he had calibrated the teletherapy unit at intervals ranging from several weeks to three months. These calibrations were made during the period May 10, 1974 through April 21, 1976. The calibration records supplied by Individual "F" for review showed that the output of the teletherapy unit was as follows:

Date	Output at 80 cm (Extenders In)	Output at 80 cm (Extenders Out)
May 10, 1974	137.1 R/min	1[illegible]0.8 R/min
July 25, 1974	130.2 R/min	133.2 R/min
September 5, 1974	126.7 R/min	129.6 R/min
October 13, 1974	116.7 R/min	119.5 R/min
January 1[illegible], 1975	111.03 R/min	113.8 R/min
February 10, 1975	108.9 R/min	112.2 R/min
June 9, 1975	98.4 R/min	102.4 R/min
July 24, 1975	95.6 R/min	97.9 R/min
September 8, 1975	89.2 R/min	92.4 R/min
October 18, 1975	86.6 R/min	88.3 R/min
November 7, 1975	84.3 R/min	86.5 R/min
March 31, 1976	107.9 R/min	112.5 R/min

Copies of the calibration data sheets prepared by Individual "F" for the period May 10, 1974 through November 7, 1975, were obtained and are attached to this investigation report as Exhibit C.

Individual "F" stated during the interview on April 21, 1976 that the calibrations were made with a Keithley Instruments Model 616 digital electrometer (Serial No. 25112) and a Baldwin-Farmer Model 2505/3 0.6 cc thimble chamber probe. Sometime during September, 1974 the digital electrometer became inoperative and on September 18, 1974 it was sent to Keithley Instruments for repair. The unit was repaired on October 2, 1974. Individual "F" said he continued making calibrations with the equipment until November of 1975. At that time the probe appeared to give inconsistent readings and was sent to Victoreen Instrument Company on November 25, 1975, for calibration. The probe was calibrated by Victoreen and returned to the licensee on January 9, 1976. Individual "F" attempted to calibrate the teletherapy unit after the probe had been calibrated by Victoreen but obtained extremely low output readings. He then made other attempts to calibrate the teletherapy unit using a new Baldwin-Farmer Model 2505/3 0.6 cc thimble chamber probe and a PTW 0.2 cc thimble chamber probe. Both the new Baldwin-Farmer and the PTW probes showed similar results and were used to calibrate the teletherapy unit.

As a result of the malfunction of the original Baldwin-Farmer thimble chamber probe it was determined by Individual "F," on or about January 30, 1976, that the teletherapy unit was not properly calibrated and that patients had been given radiation doses in excess of those prescribed.

Individual "F" informed the radiation therapists of the problem. They initiated an investigation to determine which patients had been exposed in excess of prescribed doses and also the magnitude of the overexposures.

Individual "F" stated that the defective Baldwin-Farmer Model 2505/3 probe deteriorated slowly and that it was not apparent from one calibration to the next that the probe was malfunctioning. Individual "F" stated that he did not compare output readings of the teletherapy unit with either a physical decay curve or with any previous output measurements he had made with the probe. Therefore, he did not realize that the decrease in source output was greater than should occur, allowing only for physical decay of the source. He stated that each time a calibration was made he assumed that the output calibration for the source was accurate and that it was not necessary to compare the readings with previous readings.

Individual "F" indicated that he no longer had in his possession the output curves he and his predecessor had prepared. He suggested that they could be obtained from Individual "A."

Individual "F" stated that at no time during the period September 18, 1974 (when the Keithley Electrometer became inoperative) through January 30, 1976 (when the calibration error was discovered) did he attempt to borrow or rent backup instrumentation to verify measurements made with RMH instruments. He also stated that he made no attempt to seek assistance from other radiation physicists in the Columbus, Ohio area.

Personal Monitoring

Personnel who operate the teletherapy unit are provided with thermoluminescent dosimeters (TLD), which are read each month by Individual "F.". During the investigation the personnel monitoring records were reviewed. It was noted that all licensee personnel who operate the teletherapy unit received less than 25% of the 1250 millirem per quarter limit specified in 10 CFR 20.101(a).

Independent Measurements

On April 21, 1976, Warren McConnagle, Ph.D., Region III physicist, performed a radiation survey and confirmation calibration of the cobalt-60 teletherapy unit. The result of his measurement of the unit's output agreed well with the value being used by RMH. A copy of McConnagle's April 22, 1976 memorandum report is attached to this report as Exhibit D.

NRC Medical Consultant Visit to RMH on April 21, 1976

On April 21, 1976 Dr. Eugene L. Saenger's, NRC Medical Consultant, made an initial visit to RMH. Dr. Saenger's report on this visit, dated May 26, 1976, is attached to this report as Exhibit E.

Interview With Indivi al "D" on April 21, 1976

On April 21, 1976, Individual "D," the Director of Radiation Therapy, was interviewed. Individual "D" stated that he was at a loss to explain why the problem was not recognized sooner. In retrospect, he now realized that the number of patients who experienced unexpected reactions to the radiation therapy treatments gradually increased. He said individuals differ in their tolerance to radiation exposure and the amount of exposure they receive before reactions occur. As patients experienced these reactions, he attributed them to individual differences. It did not occur to him that something was causing an increasing number of patients to manifest unexpected reactions until about the time the Baldwin-Farmer probe was found to be defective.

Individual "D" indicated that the period of concern was established by calculating back from January 30, 1976, using reliable data, to the point at which the erroneous data would have resulted in an overdose during a single treatment of 10% or less. He indicated that the 10% cutoff was decided upon, since it was generally accepted among radiologists that any dose less than 10% over the planned dose is not significant.

Individual "D" said that 275 patients still living were treated during this period. He indicated that approximately 25 of those patients did not receive radiation doses in excess of the planned total dose because for some reason they did not complete the series of treatments.

Individual "D" said that in many cases radiation therapy is only palliative and that many patients receiving treatments are terminal cases. In addition to the number of living patients mentioned above, a list of deceased patients had been compiled. Individual "D" had said he did not know the number of patients in this category but that it was approximately 200. He indicated that this information could be obtained from Individual "A."

Interview With Individual "E" on April 21, 1976

On April 21, 1976, Individual "E", a Radiation Therapist, was interviewed. He stated that he had joined the RMH staff in September, 1975 in radiation therapy. He indicated that during the next several months he noted more significant patient reactions to therapy treatment than he had been accustomed to seeing at other medical facilities. He realized that the number of such cases gradually increased and because of this he inquired of Individual "F," the Radiation Physicist, as to whether any checks of the teletherapy unit were being made. He indicated that this question was raised only a day or two before Individual "F" discovered the probe was malfunctioning during efforts to calibrate the teletherapy unit on January 30, 1976.

Individual "E" indicated that his first concern was to determine at what point in the schedule of treatments they were with patients currently undergoing a series of treatments and to make appropriate adjustments to be sure they did not exceed the planned total dose. After that was done and assurance was gained that the actual output had been determined, the task became one of determining what doses past patients had received. He indicated that they were currently involved in a large number of contacts with referring physicians and patients who had been treated during the period March 1, 1975 to January 30, 1976, as well as attempting to continue a routine treatment schedule.

During this interview Individual "E" indicated that, although he had initiated efforts to have his name added to the license as an authorized user, the license had not been amended by NRC designating him an authorized user of the teletherapy unit. Individual "E" said he had encountered difficulty obtaining and providing the documentation concerning his training and experience which is required by NRC.

Interview With Individual "I" on April 22, 1976

On April 22, 1976, Individual "I" stated that he is the Director of the Department of Radiology, which consists of three sections, Nuclear Medicine, Diagnostic Radiology, and Radiation Therapy. He indicated that he is not involved in the day-to-day radiation therapy activities.. He stated that if the radiation physicist encountered any problems involved in his work in radiation therapy he would be expected to discuss it with Individuals "D" or "E", rather than himself. If problems were encountered by Individuals "D" and "E", the physicians involved in those activities, he would expect them to bring the problems to his attention. Individual "I" stated that he was not aware of any problems in the radiation therapy activity until the end of January 1976, when the erroneous output calibration problem was identified.

Individual "I" indicated that the activities of the radiation physicist, Individual "F", are not limited to radiation therapy. He also performs professional services for the rest of the Department of Radiology. Individual "I" said that during the last year, Individual "F" had considerable involvement in the acquistion and installation of a linear accelerator. Because of this work, in addition to his regular duties, Individual "F" had been working long hours during the last several months. Individual "I" said that the addition of another physicist or at least a technician to assist Individual "F" had been under consideration by the hospital.

Individual "I" stated, that while he had participated in meetings dealing with the current problem in radiation therapy, he had not been involved in the detailed activities related to it.

Contact With Individual "K" on April 22, 1976

On April 22, 1976, Individual "K" was interviewed concerning the dates the Baldwin-Farmer probe was shipped and received back at RMH.

Individual "K" provided copies of the shipping and receiving documents which pertain to the probe shipment. The documents indicate that the probe was shipped to the Victoreen Instrument Company on November 25, 1975, and was received back at the hospital on January 9, 1976.

Individual "K" indicated that the probe may have remained in the Shipping/Receiving Department for several days before being picked up by the physicist.

Discussions With Licensee Management on April 22, 1976

On April 22, 1976, discussions were held with Individuals "A", "D", "I", and "P". The results of the inspection of the licensed teletherapy activites were reviewed including the items of noncompliance noted. A separate report, No. 76-02 of that inspection has been prepared. (Exhibit A).

Licensee Management was informed that Individual "E" was not named on the teletherapy license as an authorized user. Licensee management stated that in the future Individual "E" would work only under the supervision of Individual "D", the authorized user, until he became designated as an authorized user by amendment to the license.

The NRC investigators indicated to licensee management that several items containing pertinent information had not been made available during the investigation. It was agreed that these items would be furnished to Region III upon receipt of a letter from Region III requesting them. Subsequently, a letter dated April 28, 1976, confirming this request was sent to RMH. A copy of this letter is attached to this report as Exhibit F.

Contact With FDA on April 26, 27, and 29, 1976

On April 26, 1976 IE:III received a telephone call from Individual "M," a representative of the Food and Drug Administration, Columbus, Ohio office who advised that he planned to initiate an investigation at RMH that day. On April 27, 1976 IE:III was contacted by Individual "Q" of the FDA's Bureau of Medical Devices and Diagnostic Products, Silver Spring, Maryland. Individual "Q" stated that the basis for the FDA investigation was that agency's jurisdication over the use of medical devices and that a malfunctioning probe, an instrument meeting the FDA definition of a medical device, was apparently involved in the incident. Individual "Q" expressed an interest in his agency's acquiring the probe for examination. On April 29, 1976 IE:III contacted Individual "M" to advise him that the NRC had no objection to the FDA's acquiring the probe and requested that IE:III be furnished the results of any examinations made of it.

Contact With FDA on April 30, 1976

On April 30, 1976, Individual "M" telephonically contacted IE:III to pass on information regarding FDA's investigation into the functioning of the Baldwin-Farmer radiation probe.

Individual "M" advised that he had contacted the former Victoreen Instrument Company employee who had actually performed the calibration of the probe. Discussion between Individual "M" and this individual led to the discovery of an error in the calibration factor assigned to the probe during its calibration by Victoreen. A typographical error apparently transposed two numbers on the calibration sheet, changing the actual calibration factor of 4.817×10^{9} coulombs to 4.187×10^{9} coulombs, an error of approximately 15%.

It was indicated that essentially the same information had been obtained from an individual currently employed by Victoreen.

Visit to Victoreen Instrument Company on May 6, 1976

On May 6, 1976, two IE:III representatives visited the Victoreen Instrument Company, Cleveland, Ohio to obtain information relative to the calibration of the Baldwin-Farmer radiation probe. Two Victoreen officials contacted during this visit advised that Victoreen does not calibrate non-functional equipment. Further information regarding calibration, condition, or shipping of the probe was not provided.

The position of the company was that Victoreen had a "client relationship" with RMH, and would not release any further information concerning the probe without authorization from the hospital.

Telephone Conversation With Individual "A" on May 6, 1976

Individual "A" informed IE:III representatives in a telephone conversation on May 6, 1976, that there had been additional developments which he desired to make known to IE:III. He reported the following:

1. RMH had determined without a doubt that the probe was not at fault in the improper calibration of the teletherapy unit.

2. Much of the story as to the cause of improper calibration, which placed the blame on "the progressive deterioration of an instrument probe used to measure the machine source output", was contrived by the radiation physicist Individual F.

3. Individual "F" made an error in calculation, which was brought to light on January 30, 1976.

4. The error was brought to light when RMH confronted Individual "F" with the possibility of calculational error. Individual "A" characterized the error in the following manner. Individual "F" used values provided by the source supplier and the recorded measured values provided by Individual "L" to develop a decay curve and made extrapolations which proved to be faulty. Actual machine source output measurements had not been made by Individual "F", except on one occasion in May 1974.

5. Individual "A" reported that Individual "F" had been immediately suspended, but indicated that he would possibly be available to supply additional information. Individual "A" also indicated that the additional information regarding the cause of the improper calibration did not change the amount of calculated excess exposure received by individual therapy patients.

Based on the above information, Individual "A" was informed that IE:III representatives would return to RMH to pursue the additional developments.

IE:III representatives resumed their investigation at the Riverside Methodist Hospital on May 12, 1976.

Interview With Individual "A" on May 12, 1976

On May 12, 1976, Individual "A" was interviewed concerning recently developed information which he had brought to the attention of IE:III during the telephone conversation with him on May 6, 1976.

Individual "A" confirmed his earlier telephone statement to the effect that Individual "F" had admitted that actual measurements had not been utilized in the output calibration of the teletherapy device.

When questioned as to how this information came to light, Individual "A" indicated that the consultants retained by the hospital had examined a large amount of data and had performed independent measures relative to the Baldwin-Farmer probe. They found the probe to be damaged and inoperative, but their analysis indicated that the probe had not malfunctioned during the time period in question. Data on decay curves produced by Individual "F" and

recently proffered calibration worksheets which were of questionable validity were also examined, raising further questions concerning Individual "F's" actions. Individual "A" stated that when Individual "F" was shown the technical errors in his data, the analysis which exonerated the Baldwin-Farmer probe and he was questioned on his actions, he admitted that actual output measurements had not been made for the teletherapy device.

Individual "A" indicated that the hospital's attorneys were undecided as to whether Individual "F" should be asked to make a written statement concerning his actions. Individual "A" was advised that a written statement would be requested for Individual "F" as part of IE:III's investigation effort.

When questioned concerning the circumstances which led to the discovery of the teletherapy device miscalibration on January 30, 1976, Individual "A" stated that the therapists, Individual "E" in particular, had begun to notice unexpected reactions to teletherapy treatments and had asked that the device be checked.

Individual "A' indicated that Individual "F's" statements concerning his background and training had been checked by the hospital and found to be correct.

During this interview, Individual "A" was requested to provide copies of a number of documents for use in IE:III's investigation of the incident. Documents requested included: copies of each consultant's report to the hospital, patient lists, dose calculations, letters of notification to patients and doctors, calibration curves, and calibration worksheets which had been recently proffered by Individual "F".

It was indicated that all of the requested material would be provided the following day.

Interview with Individual "F" on May 12, 1976

On May 12, 1976, Individual "F" was reinterviewed concerning his calibration of the cobalt teletherapy device at RMH.

Individual "F" stated that on May 10, 1974 he did a full calibration of the teletherapy device, using the Baldwin-Farmer probe. On May 13, 1974, he compared his calibration data with the original open-air source output reading furnished by the source vendor. Individual "F" stated that by using his calibration reading and a calibration

reading generated by Individual "L" in August, 1972, a source decay "curve" was drawn. This "curve" was drawn as a straight line on linear graph paper and was extrapolated for each source output calibration period. Calibration readings were derived by taking values from this "curve" and translating them into probe readings on a calibration sheet. Actual calibration measurements using a probe were not done.

In June 1974, a different type of linear graph paper was used for making up the extrapolated decay "curve," and the scales used for the graph were changed from five units per month to six units per month. These changes modified the original "curve," as the line's slope was changed by the changes in scale. Since the "curves" were made up for relatively short periods of time and were not compared with previous "curves," the modified slope of the line was not noticed.

On November 25, 1975, the Baldwin-Farmer probe was sent to Victoreen Instrument Corporation for a routine calibration. The probe and a calibration sheet giving a new calibration factor were received at the hospital on January 9, 1976.

Individual "F" stated that upon receipt of the probe he noticed that the graphite cover of the probe was cracked. He also noted that the new calibration factor showed a fifteen percent differential from its previous calibration. Individual "F" stated that he called Victoreen Instrument Corporation to verify the new calibration factor and was told that the calibration factor was correct.

When questioned as to how the miscalibration of the teletherapy device came to light, Individual "F" gave the following chronology: During the latter part of 1975, and the month of January, 1976, Individual "E" began to notice anomalous reactions in patients being treated by teletherapy. Individual "E" became concerned over these reactions and finally asked Individual "F" to calibrate the teletherapy device. The requested calibration of the teletherapy device was done by Individual "F" on January 30, 1976. This calibration was performed with two probes, the Baldwin-Farmer and a PTW, so as to compare the calibration readings of the two probes.

The readings of the probes used in this calibration were dissimilar, with the PTW probe reading much higher than the expected reading from the source output decay "curves" generated by Individual "F". Individual "F" then realized that the output of the teletherapy device was higher than the output values which had been used to calculate patient exposur times.

A calibration of the teletherapy device, using the PTW probe, was done by Individual "F" and patient exposure times were immediately recalculated by the therapists for those patients currently undergoing treatment.

Individual "F" stated that the consultants called in by the hospital had shown him the errors that he made in his source output decay "curves." Individual "F" admitted that he had made a "human error" in the construction of the source output decay "curves."

Individual "F" indicated that he had not viewed the calibration of the teletherapy device as a high priority function and that the device's importance had "diminished" when a new linear accelerator had been purchased. The bulk of Individual "F's" work had then been directed toward the linear accelerator.

At the conclusion of the interview arrangements were made for Individual "F" to prepare a signed statement to the hospital and a signed release for the statement to be furnished to IE:III. Copies of the statement and release are attached as Exhibits G and H, respectively.

Interview with Individual "E" on May 13, 1976

On May 13, 1976, Individual "E" was reinterviewed concerning his part in the discovery of the teletherapy device miscalibration. Individual "E" stated that he had begun to notice (in late 1975) unexpected patient reactions to teletherapy treatments. He stated that he had probably noticed the patient reactions more than the other therapist because he had recently transferred to Riverside Methodist Hospital from another hospital where unexpected reactions to teletherapy treatments were rare. He also stated that he was also more accustomed to consulting with a staff physicist than were the personnel at Riverside Methodist Hospital.

Individual "E" indicated that, due to the unexpected patient reactions to teletherapy treatments, in late January, 1976 he began to question Individual "F" concerning the output calibration of the teletherapy device. Individual "E" asked Individual "F" when he had last "put a meter under" the device. Because a specific answer was not given, Individual "E" became concerned.

On or about January 30, 1976, Individual "E" indicated to Individual "F" that the teletherapy device would have to be tested. Individual "E" stated that in his opinion this request was the action which

led to the testing of the teletherapy device and the subsequent discovery of the device's miscalibration.

Regarding his working relationship with Individual "F," he indicated that the relationship was cordial, although contacts were somewhat infrequent. Individual "E" stated that of the personnel at RMH, he may have had the closest relationship with Individual "F," who kept to himself most of the time.

Interview With Individual "D" on May 13, 1976

On May 13, 1976, Individual "D" was interviewed concerning his part in the discovery of the teletherapy device miscalibration.

Individual "D" stated that he had little to do with the discovery of the miscalibration. He indicated that on January 30, 1976 Individual "E" came to him and told him about the discovery of the miscalibration. Dose rates and treatment programs were immediately adjusted to the new calibration figures, interrupting almost all of the day's treatments.

Discussion with Individual "A" on May 13, 1976

Individual "A" was contacted on May 13, 1976 for the purpose of any final discussion on items uncovered during the visit and for the purpose of obtaining the documents previously requested.

A copy of the rate of error calculated by Individual "D" was obtained and is attached to this report as Exhibit I. The calibration curves for a 5 x 5 cm field at 80 cm prepared by Individual "F" were also obtained and are attached to this report as Exhibit J.

Copies of the reports made to the hospital by the two consultants were not provided as originally promised, it being the hospital's position that these reports contained preliminary information which had been subsequently shown to be incorrect, making the reports subject to revision by the consultants.

Individual "A" indicated that hospital officials had asked Individual "F" if he had purposely damaged the Baldwin-Farmer probe himself. Individual "F" stated that he had not damaged the probe.

A commitment was made by Individual "A" that IE:III would be provided copies of the consultants' reports as soon as the finalized reports were available. These reports were subsequently furnished to IE:III for review and they were subsequently returned to RMH. The report prepared by Individual "H," a 2-page letter dated April 6, 1976 indicates agreement with the contents of the

report prepared by Individual "G" and indicates that there are 250 or more patients who are at some degree of risk of difficulty. Individual "G" indicated that there were probably between sixty and eighty patients at modest risk of difficulty, and ten or fifteen at high risk of complication.

Individual "H" also indicates that the 10% above planned dose cutoff point is a reasonable one.

In his report Individual "G" indicates that on March 5, 1976 the exposure rate of the RMH teletherapy unit was measured by four methods, three of which were independent, and it was determined to be 109.3 R/mim at 80 cm. He indicated that he had concluded that the unit had been operating correctly during the overtreatment period and that the unit's exposure rate on any date during that time could be calculated using the normal cobalt-60 half-life.

Individual "G" also reported that the calculation of the dose received by an individual patient involves the use of several calculative factors to convert the calibrated exposure rate into absorbed dose for the individual situation. He compared his calculative factors with those actually used by RMH and concluded that the RMH factors would have resulted in a lower delivered dose than intended if the RMH calibrated dose rate had been correct. The delivered dose would have been in the range of 93% to 95% of that intended.

Contact with FDA on May 14, 1976

On May 14, 1976, Individual "M" telephonically contacted IE:III to pass on additional information regarding FDA's investigation into the functioning of the Baldwin-Farmer probe.

Individual "M" indicated that FDA presently possessed both the electrometer and the Baldwin-Farmer probe which were used at Riverside Methodist Hospital. It was indicated that the two devices would be sent to the National Bureau of Standards (NBS) for testing and that a report of the test would be given to the hospital. A copy of the NBS report to FDA was subsequently furnished to IE:III, a copy of which is attached to this report as Exhibit K.

Attachments:
Exhibits A through K

UNITED STATES NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

IE Inspection Report No. 03000398/76-02

Licensee: Riverside Methodist Hospital
Columbus, Ohio 43214

Riverside Methodist Hospital
Columbus, Ohio

License No. 34-01055-03
Category: G
Priority: IV

Type of Licensee: Teletherapy

Type of Inspection: Routine, Announced

Dates of Inspection: April 21-22, 1976

Principal Inspector: W. H. Schultz — 6/23/76 (Date)

Accompanying Inspectors: G. A. Phillips — 6/23/76 (Date)

J. E. Foster — 6/23/76 (Date)

Other Accompanying Personnel: None

Reviewed By: G. T. Lonergan, Chief
Materials Radiological
Protection Section — 6/23/76 (Date)

Exhibit A
Page 1 of 5

General Informat

1. This was an announced reinspection which was conducted on April 21 and 22, 1976.

2. The inspection was conducted by W. H. Schultz, J. E. Foster, and G. A. Phillip, IE:III.

3. Information in this report was furnished by the following licensee personnel:

Individual "N", Radiation Therapy Technologist
Individual "O", Radiation Therapy Technologist
Individual "F", Radiation Physicist

Inspection History

4. The last previous reinspection of this byproduct material program was conducted on October 20, 1967. During that inspection two items of noncompliance were noted. Both items of noncompliance were posting deficiencies. The door to the teletherapy room was posted with the conventional radiation caution symbol and the words "Caution Radiation Area." However, it was not posted with the words "Caution Radioactive Materials" and "Caution High Radiation Area." This constituted noncompliance with 10 CFR 20.203(e)(1) and 10 CFR 20.203(c)(1), respectively.

Program

5. The licensee uses a cobalt-60 sealed source contained in a Picker Corporation Model 6296 teletherapy unit for treatment of humans. This source and new teletherapy unit replaced the existing Picker Corporation Model 6096B teletherapy unit, which contained a 1,765-curie cobalt-60 sealed source at the time of the new installation in August 1972. The new source had a strength of 7,040 curies when calibrated by Picker on May 16, 1972. At the time of this inspection (April 21 and 22, 1976) the source strength was approximately 4,200 curies.

Organization

6. The cobalt-60 teletherapy unit is used by the Department of Radiation Therapy, a part of the Department of Radiology. At the time of this inspection, the teletherapy unit was being used under the supervision

of two therapists, Individuals "D" and "E." License Condition No. 12 of Amendment No. 8, dated December 17, 1975, designates only Individual "D" as an authorized user. Although the licensee submitted an application, dated October 14, 1975, which requested that Individual "E" be added to the license as an authorized user, this request has not been incorporated into the license thus far. Therefore, the licensee is in noncompliance with License Condition No. 12, in that an individual not specified in this Condition was permitted to supervise the use of the cobalt-60 teletherapy unit.

7. The teletherapy unit is operated by three Radiation Therapy Technologists. These three individuals work under the supervision of Individuals "D" and "E."

8. The Radiation Safety Officer is Individual F, who is also the licensee's radiation physicist. His responsibilities include making various surveys of equipment and ensuring the proper operation of this equipment. He also is involved in the training of the technicians who operate the teletherapy unit.

Administrative Control

9. The personnel responsible for the administrative control of this program are as follows:

Individual "R", Administrator
Individual "A", Senior Associate Administrator
Individual "D", Radiologist

Facilities

10. The Picker Corporation Model 6296 teletherapy unit is located in a shielded concrete room in the Radiation Therapy Department on the first floor of the hospital. The room is provided with a viewing window which permits continuous viewing of patients during treatment. A facility diagram which shows wall thicknesses is included in this inspection report as Attachment "A."

11. The entrance door to the teletherapy room is provided with an interlock switch, which closes the shutter of the teletherapy unit if the door to the treatment room is opened when the source is exposed. Licensee personnel stated that the performance of this switch is routinely checked for proper operation at least every six months. However, no record of this check is maintained. This constitutes noncompliance with License Condition No. 17.C, which states that records of test results shall be maintained for inspection by the Commission.

Equipment

12. The licensee periodically calibrates the cobalt-60 teletherapy unit to ensure that all components of the system are functioning properly. The calibrations are made at intervals ranging from several weeks to three months. The licensee uses a Keithley Instruments Model 616 digital electrometer and a Baldwin-Farmer Model 2505/3 thimble chamber probe to measure the output of the teletherapy unit.

Personal Monitoring

13. All personnel in the radiation therapy department are provided with TLD badges. These badges are read on a monthly basis by the licensee and records are maintained which show exposures received by individuals in the department. During the inspection, the records were reviewed for the years 1974, 1975, and 1976. All exposures were well within limits specified in 10 CFR 20.101(a). In January 1976 the frequency of reading the TLD badges was changed from monthly to every three months.

Radiation Surveys and Evaluations

14. Leak tests are made on the cobalt-60 sealed source by the licensee. The initial leak test on the present cobalt-60 sealed source (Ser. No. PX-933) was made by Picker Corporation on May 15, 1972. All subsequent leak tests were made by the licensee. A review of the records showed the latest leak test was made on January 30, 1976 and showed the presence of less than 0.05 microcuries of contamination. However, the records also showed that no leak test was performed between July 13, 1973 and August 3, 1974, a period in excess of 6 months. This constitutes noncompliance with License Condition No. 14.A, which requires that teletherapy sources shall be tested for leakage at intervals not to exceed six months.

Posting and Labeling

15. Form NRC-3 "Notice to Employees" was posted on the wall adjacent to the teletherapy machine control.

16. Neither the documents specified in 10 CFR 19.11(a) nor the notice specified in 10 CFR 19.11(b) was posted to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies. This constitutes noncompliance with 10 CFR 19.11(a). However, the licensee did post the appropriate notice during the inspection and no further corrective action is required.

17. The entrance door to the teletherapy room was posted with conventional radiation caution symbol and the words "Caution Radiation

Area." However, the door was not posted with the words "Caution Radioactive Material" and "Caution High Radiation Area." This constitutes noncompliance with 10 CFR 20.203(c)(1) and 10 CFR 20.203(c)(1). During the inspection the licensee posted the door to the teletherapy room with the required signs and no further corrective action is required.

Records

18. The licensee maintains records showing the receipt of the cobalt-60 sealed source, the results of the radiation surveys of the unit and the adjacent areas, the results of leak tests, the calibration data for the teletherapy unit, and the results of personal monitoring. A representative sample of these records was reviewed during the inspection. No deficiencies were noted.

Independent Measurements

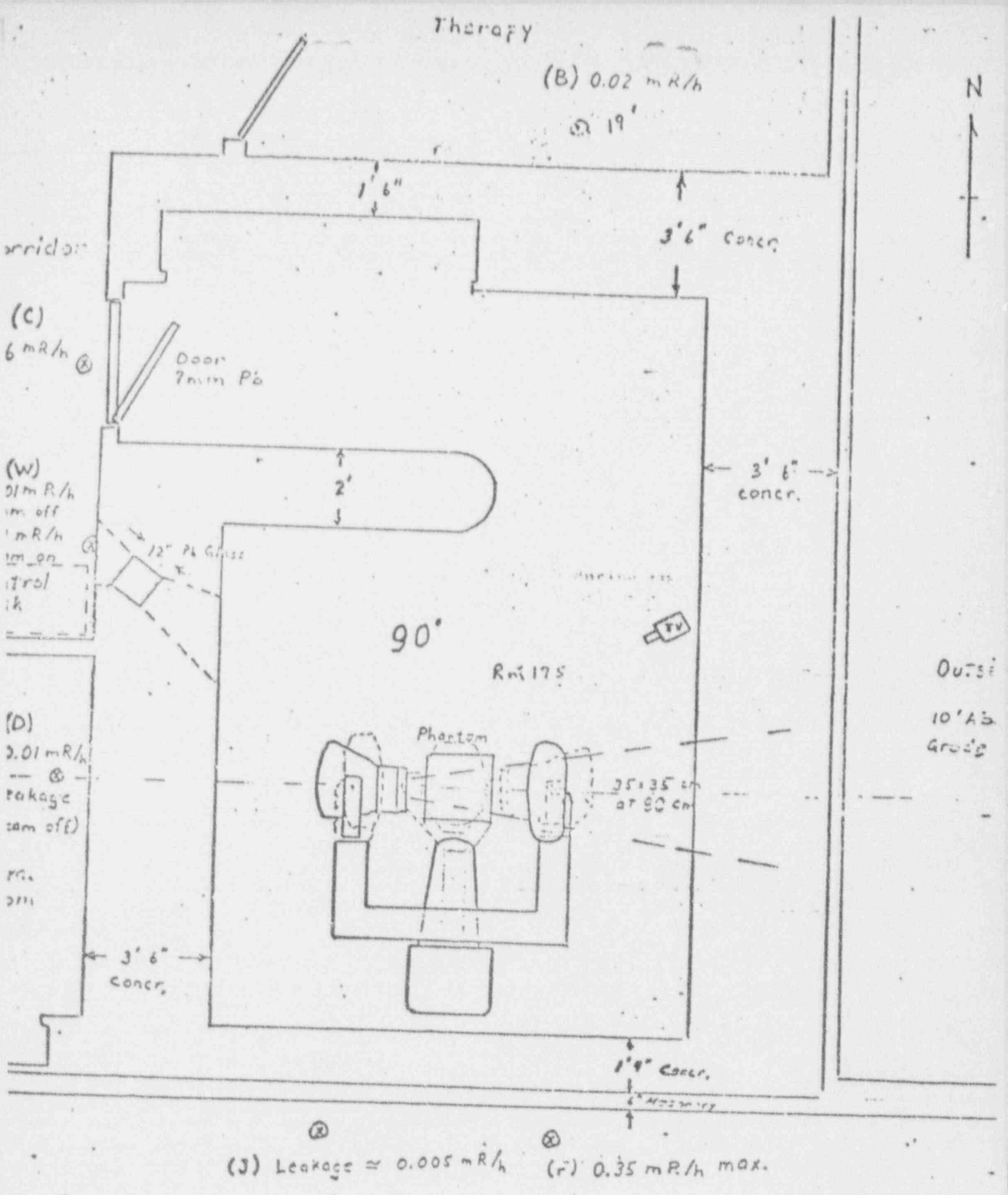
19. During the inspection the NRC representative checked the operation of the door interlock switch. The function was normal.

20. License Conditions

All license conditions were reviewed during the inspection. The only deficiencies were as noted in paragraphs 6, 11 and 14.

Management Discussion

21. At the conclusion of the inspection the findings were reviewed with Individuals "A" and "D." The findings were also reviewed separately with Individual "F" before the management meeting. Licensee personnel stated that all items of noncompliance that had not already been corrected during the inspection would be corrected immediately, that in the future appropriate steps would be taken to ensure that required tests were performed timely, and that only personnel designated on the license as an authorized user would supervise the use of the teletherapy unit. Licensee management stated that until such time as the name of Individual "E" was added to the license as an authorized user he would work under the direct supervision of Individual "D."

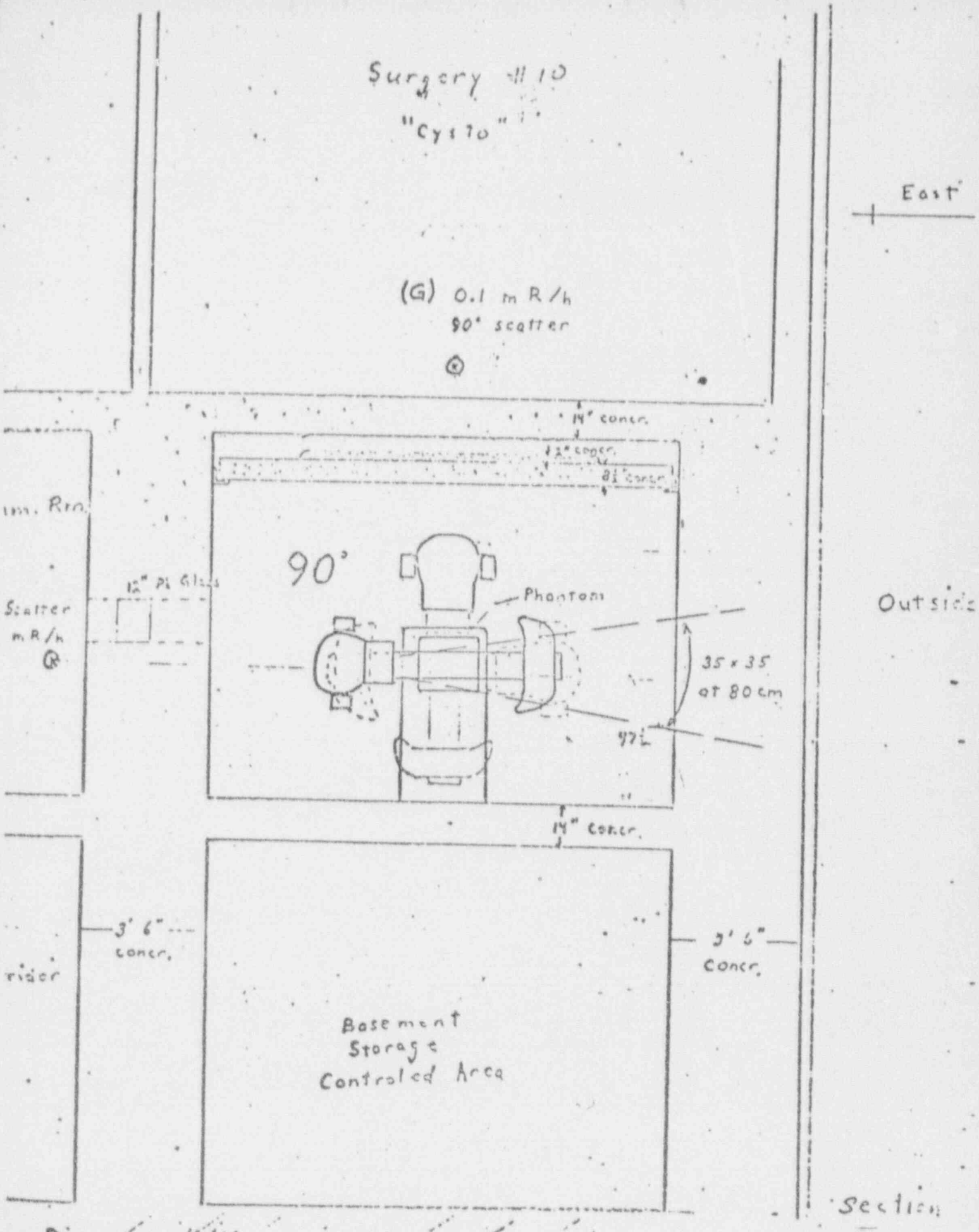


Corridor

Diagram 4(a)

1 m/wk

Plan


Surgery #10
"Cysto"
East
(G) 0.1 m R/h
90° scatter
14" concr.
12" concr.
8½" concr.
Im. Rm.
90°
Phantom
Scatter
m R/h
@
Outside
35 x 35
at 80 cm
97½
14" concr.
3' 6"
concr.
rider
3' 6"
Concr.
Basement
Storage
Controled Area
Section
Diagram #10

_____

_____

Re: _____

Dear Doctor _____

My post-treatment report to you dated _____ shows that your patient, _____, was exposed to _____ Rads of radiation. A recent recalculation indicates that your patient received _____ Rads of radiation. We suggest that you change your records to show the latter figure.

I would welcome a call from and the opportunity to discuss with you possible adverse medical aspects of the increased radiation received by your patient.

While we would expect that, under ordinary circumstances, you would wish to make this situation known to _____, we recognize that you are in the better position to judge how best to act on this information for the welfare of your patient. It is for this reason that we are not undertaking to notify (*him/her*) from this office. If you would prefer that I discuss this matter with (him/her), I would, of course, be happy to do so.

We are interested in following the developments and would appreciate your letting us know if you decide it is not in your patient's best interest to be informed concerning this matter, along with your reasons for your decision. If (he/she) is no longer under your care we would also like to be informed of this fact.

Sincerely yours,

INDIVIDUAL "D"

EXHIBIT B
1 of 1

CALIBRATION Co-Co
(Picker C-9)

DATE: May 10, 1974

SETTING: 10x10cm^2, 80cm SSD, 1.0 min.

CONDITIONS: T= 25 °C P= 759 mm Hg

T & P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 x 10^8 R/coul.

DATA:	Extenders in Q(10^{-8} coul)	Extenders Out Q(10^{-8} coul)
	2.78	2.81
	2.77	2.83
	2.76	2.82
	2.79	2.83
	<2.77>	<2.82>

OUTPUT:	Extenders In (R/min)	Extenders Out (R/min)
	B: 137.1	139.8

5x5 $\frac{137.1}{1.042} = 131.6$

COMMENTS:

CALIBRATION 60-Co
(Picker C-9)

DATE: July 25, 1974

SETTING: 10x10cm^2, 80cm SSD, 1.0 min.

CONDITIONS: T= 25 °C P= 761 mm Hg

T & P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 x 10^8 R/coul.

DATA:

Extenders in Q(10^{-8} coul)	Extenders Out Q(10^{-8} coul)
2.62	2.69
2.64	2.70
2.63	2.71
2.64	2.69
	2.69
<2.63>	<2.697

OUTPUT:

Extenders In (R/min)	Extenders Out (R/min)
130.2	133.2

COMMENTS:

5x5 : $\frac{130.2}{1.042} = 124.8$ $\frac{133.2}{1.042} = 127.8$

$\frac{\text{GRAPH}}{\text{ACT}} : \frac{125}{124.8}$ (0.2%) $\frac{\text{GRAPH}}{\text{ACT.}} = \frac{127.9}{127.8}$ (0.1?

CALIBRATION ^{60}Co
(Picker C-9)

DATE: Sept. 5, 1974

SETTING: 10x10cm^2, 80cm SSD, 1.0 min.

CONDITIONS: T= 24 °C P= 761 mm Hg

T & P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 x 10^8R/coul.

DATA:

Extenders In Q(10^{-8} coul)	Extenders Out Q(10^{-8} coul)
2.55	2.63
2.56	2.62
2.55	2.61
2.57	2.62
<2.56>	<2.627>

OUTPUT:

Extenders In (R/min)	Extenders Out (R/min)
126.7 R/min	129.6 R/min

6x6 check: 121.6x1.042 = 126.7 (0%)

5x5 check: 124.6x1.042 = 129. (0.2%)

COMMENTS:

CALIBRATION Co-Co
(Picker C-9)

DATE: Oct. 13, 1974

SETTING: $5 \times 5 cm^2$, 80cmSSD, 1.0min.

CONDITIONS: T = 23 °C P = 763 mmHg

TAP = 1.00

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 $\times 10^8$ R/coul

DATA:	Extenders in $Q(10^{-8}$ coul)	Extenders out $Q(10^{-8}$ coul)
	2.36	2.43
	2.35	2.44
	2.36	2.43
	<2.36>	<2.43>

OUTPUT:	Extenders in (R/min)	Extenders out (R/min)
	116.7	119.5

COMMENTS:

equipment pt.

CALIBRATION Co-Co
(Picker C-9)

DATE: JAN. 15, 1975

SETTING: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = 26 °C P = 765 mmHg

T&P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA:

Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
2.24	2.29
2.25	2.30
2.24	2.30.
<2.243>	<2.30>

OUTPUT:

Extenders in (R/min)	Extenders out (R/min)
111.03	113.8

COMMENTS: Agrees well with extrapolated adjust curves

CALIBRATION 60-Co
(Picker C-9)

DATE: Feb. 10, 1975

SETTING: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = 25 °C P = 768 mmHg

T&P = 0.99

CHAMBER: N.E. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA:	Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
	2.24	2.33
	2.25	2.32
	2.24	2.33
	<2.24>	<2.33>

OUTPUT:	Extenders in (R/min)	Extenders out (R/min)
	109.9	112.7

COMMENTS:

CALIBRATION ^{60}Co
(Picker C-9)

DATE: June 9, 1975

BEAM: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = 25° °C P = 763 mmHg

T&P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA: Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
2.18	2.10
2.19	2.09
2.19	2.10
<2.18>	<2.10>

OUTPUT: Extenders in (R/min)	Extenders out (R/min)
102.4	98.4
98.1	102.4

COMMENTS:

CALIBRATION ^{60}Co
(Picker C-9)

DATE: July 24, 1975

SETTING: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = _____ °C P = _____ mmHg

T&P = 0.95

CHAMBER: B.F. 0.6cc with 0.5cm [illegible]d-um cap

CALIBRATION FACTOR: 49.01 [illegible]

DATA: Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
1.98	2.02
1.97	2.03
1.98	2.02
<1.98>	<2.02>

OUTPUT: Extenders in (R/min)	Extenders out (R/min)
95.6	97.9

COMMENTS:

CALIBRATION Co-Co
(Picker C-9)

DATE: Sept 3, 1975

SETTING: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = 24 °C P = 762 mmHg

T&P = 1.01

CHAMBER: N.E. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA:	Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
	1.81	1.99
	1.82	1.88
	1.91	1.98
	<1.91>	<1.987

OUTPUT:	Extenders in (R/min)	Extenders out (R/min)
	89.2	92.4

COMMENTS:

CALIBRATION ^{60}Co
(Picker C-9)

DATE: Oct 18, 1975

SETTING: 5x5cm^2, 80cmSSD, 1.0min.

CONDITIONS: T = 25 °C P = 759 mmHg

T&P = 1.01

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA:	Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
	1.75	1.80
	1.78	1.78
	1.73	1.79
	<1.757	<1.797

OUTPUT:	Extenders in (R/min)	Extenders out (R/min)
	86.6	88.3

COMMENTS:

CALIBRATION 60-Co
(Picker C-9)

DATE: Nov 7, 1975

SETTING: 5x5cm², 80cmSSD, 1.0min.

CONDITIONS: T = 24 °C ✓ P = 763 ✓ mmHg

T&P = 1.0 ✓

CHAMBER: B.F. 0.6cc with 0.5cm build-up cap

CALIBRATION FACTOR: 49.01 10^8R/coul

DATA:

Extenders in Q(10^{-8} coul)	Extenders out Q(10^{-8} coul)
1.70	1.75
1.71	1.74
1.71	1.73
<1.717	(1.74)

OUTPUT:

Extenders in (R/min)	Extenders out (R/min)
84.3	86.5

COMMENTS:

Sent chamber in

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

April 22, 1976

J. A. Hind, Chief, Safeguards Branch

REPORT ON TRIP TO RIVERSIDE HOSPITAL, COLUMBUS, OHIO APRIL 21, 1976

I checked the output of the Cobalt-60 teletherapy unit at Riverside Hospital using the following test condition:

Field Size - 10 cm X 10 cm
Source to Detector Distance - 80 cm
Output (corrected) in air - 109.0 R/min
Value used by Riverside Hospital
March 31, 1976 - 112.5 R/min

I made a radiation survey around the source housing with the beam in the "off" position (the maximum reading at 1 meter from the source housing did not exceed 1 mr/hr.

I measured the output in air at 80 cm, 90 cm, 100 cm with the field size at 10 cm X 10 cm. Using the inverse square law, I verified that the optical distance measuring system on the unit was accurate.

Warren McGonnagle
Physicist

Exhibit D
1 of 1

UNIVERSITY OF CINCINNATI
College of Medicine

May 26, 1976

Region III
U. S. Nuclear Regulatory Commission
799 Roosevelt Road
Gley Ellyn, Illinois

SUBJECT: Cobalt Overexposure at Riverside Hospital, Columbus, Ohio

Gentlemen:

The following report will summarize the medical investigations in regard to the cobalt-60 overexposure eipsode at Riverside Hospital to date. I first heard about this unfortunate episode on April 19th, when requested to serve as medical consultant. The hospital was visited on April 21st in the company of several members of your office. At that time a long interview with INDIVIDUAL "D", was conducted. The many circumstances leading up to recognition of the incident were reviewed. indicated that there were approximately 300 individuals who may have been over-treated to some degree at that time. The Methodist Hospital have retained two consultants INDIVIDUAL "G", an expert in radiation physics, and INDIVIDUAL "H", an expert in radiation therapy. At that time as a result of their several consultations IND. "D" and his associates were assembling a roster of all patients whose estimated overexposure was 10% or greater than the calculated dose which had been planned to be given. At that time they did not have a clear picture of all of the possibly involved patients and the mechanisms which they should pursue in following these patients properly. It was recommended that they set up appropriate rosters, notify all patients either through their physician or directly by letter and that they employ an individual possibly a nurse or other person to carry out a proper system for long term follow-up. At the same time a list was requested of all of the living patients and all of the deceased patients who might have been exposed in the time interval over which these over exposures were suspected.

In addition, on April 21 a press conference was held at which time I pointed out that the hospital has taken the full and proper responsibility concerning this episode once it had been discovered and had been painstaking in its efforts to inform both the patients and the public as to the exact status of the situation as best it is known. It is important to emphasize that the precise status of each patient so irradiated under these conditions will only gradually be determined over a period of the next several months to years. These responses are a function not only of radiation doses but of the biological variability of human beings, the nature of biological aggressiveness and extent of the different neoplasms at the time they were treated and the particular physical conditions of therapy at the time it was given.

Exhibit E
1 of 2

COPY

FF 04-22-0107

Thus each patient will quire a separate and Indivic evaluation.

The hospital has provided rosters of 249 patients alive as of March 1976. There is also a list of 154 patients who have died in the interim.

It will be necessary to investigate each of these cases by a review of each clinical history and progress, examinations of pathological tissues and other laboratory tests which may indicate either progression of cancer, overexposure to radiation or both. As can well be recognized this process will be a long and tedious one and the next step of the medical investigation will be to evaluate the overall dose patterns of these patients to try to endeavor to separate those most likely to be at risk from those who are either obviously or apparently at very little or no risk. Since many of these patients received only pallative therapy (to relieve symptoms and endeavor to shrink tumor but not to attempt a cure) and some received curative attempts, it is readily apparent that not all of these patients are at great risk.

After completion of this initial evaluation phase visits to Riverside Hospital will be planned on a bi-weekly or monthly basis as dictated by circumstances to evaluate the developing situation further. In addition a review will be carried out of the deceased patients to determine the involvement if any of radiation exposure in relation to the demise of the patient.

It is important to emphasize the cooperation of the staff of the Riverside Hospital in what appears to be one of the most distressing episodes in the history of radiation therapy. In dealing with a total of over 400 potentially involved patients, it must be recognized that it takes many months to identify and study each patient clearly and appropriately, if the needs of each patient are to be fully considered. We are just beginning in this direction, and I have full confidence that with our mutual cooperation this goal will be achieved. I would appreciate any comments, suggestions, or recommendations that your staff may have so that this matter may successfully proceed.

Sincerely,

Eugene L. Saenger, M.D.
Consultant

ELS/swh

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

April 28, 1976

Riverside Methodist Hospital
ATTN: INDIVIDUAL "A"

License No. 34-01055-03

3535 Olentangy River Road
Columbus, Ohio 43214

Gentlemen:

This is to confirm the request made by Mr. C. A. Phillip of my staff during the investigation conducted on April 20-22, 1976 of activities authorized by NRC Byproduct Materials License No. 34-01055-03.

Specifically, this request was that copies of the following items be furnished to this office:

1. Form letter notifying referring physicians of patients recalculated dose.

2. Initial calibration curve of the cobalt unit by the previous radiation physicist for a 5x5cm. field at 80 cm.

3. Calibration data prepared by IND. "F", including his calibration curve for a 5x5cm field at 80cm.

4. The calculations of IND. "D" concerning the systematic increase in dose error.

5. INDIVIDUAL "H's" report.

6. INDIVIDUAL "G's" report.

7. The patient roster which was reviewed by Dr. Eugene L. Saenger on April 21, 1976.

8. The roster similar to Item 7 of patients now deceased.

8004220651

Exhibit F
1 of 2

To enable Dr. Saenger in his capacity as NRC Medical consultant, to complete a preliminary evaluation as soon as possible, it is requested that copies of the above listed items also be sent directly to him at the following address:

Dr. Eugene L. Saenger
Radioisotope Laboratory
Cincinnati General Hospital
Cincinnati, Ohio 45267

To assure proper delivery and handling it is suggested that this material be sent by registered mail and marked "To Be Delivered To Addressee Only."

Also at the earliest practical time rosters of the above-mentioned patients should be furnished to Dr. Saenger and this office showing each patient's full name, date of birth, social security number, sex and the identification code number assigned. As indicated to you by Mr. Phillip, patient information will be handled as privileged information and information subsequently obtained will be related only to their assigned identification code number.

While we have an immediate need for the information we are requesting at this time, it should be recognized that a review of this information may indicate further data is required.

It is further our understanding that follow-up by Dr. Saenger through visits and telephone contacts with hospital personnel will extend over a period of several years.

Your cooperation is appreciated.

Sincerely yours,

James G. Keppler
Regional Director

Exhibit F
2 of 2

I, IND. "F", make the following statement freely and voluntarily to INDIVIDUAL "R" and "A". I have been advised by IND. "A" that I do not have to make a statement and that any statement I do make may be used in legal proceedings.

I calibrated the teletherapy device used at Riverside Methodist Hospital by plotting three points, an open-air reading, and two calibration readings, and using these points, plotting a decay curve. This curve was used to determine the exposure rates of the device. Due to an error, or errors, the decay curve was distorted and produced a growing discrepancy between actual and calculated exposure rates. As decay curves were plotted for relatively short periods of time, this error was not readily observable for some time. On request, I did a calibration of the device using two probes so as to confirm my readings and discovered the error.

May 12, 1976
(Date)

INDIVIDUAL "F"
(signed) _____

EXHIBIT C
1 of 1

I, IND. "P", freely and voluntarily agree to the release of my signed statement to Mr. James E. Foster, who has identified himself to me as an Investigation Specialist, Nuclear Regulatory Commission. I understand that I do not have to release the statement, and that it may be used in legal proceedings.

INDIVIDUAL "P"
(signed)

5/12/76
(Date)

EXHIBIT H
1 of 1

Columbus, Ohio

RATE OF ERROR CALCULATED BY INDIVIDUAL "D"
RIVERSIDE METHODIST HOSPITAL
AFTER DISCOVERY OF PROBLEM ON JANUARY 30, 1976

1c	Rad Error	% Factor	Date	Rad Error	% Factc
72	5	1.029	1-75	14.4	1.12
	5.1	1.031	2	15.5	1.14
	5.3	1.032	3	16.6	1.15
	4.4	1.027	4	17.8	1.17
	4.6	1.028	5	18.9	1.18
			6	20.2	1.19
73	4.8	1.030			
	4.0	1.035	7	21.4	1.22
	4.2	1.027	8	24.1	1.26
	4.4	1.028	9	24	1.26
	4.7	1.031	10	26.2	1.30
	4.0	1.026	11	28.4	1.33
			12	30.5	1.38
	4.2	1.028			
	4.6	1.031	1-76	33.6	1.43
	3.9	1.027	2	36.4	1.50
	4.2	1.029	3	39.1	1.56
	4.6	1.032	4	41.9	1.64
	4.1	1.029			
74	4.4	1.031			
	4.8	1.035			
	5.2	1.038			
	4.7	1.035			
	7.3	1.056			
	8.2	1.06			
	9.2	1.07			
	10.1	1.08			
	11.0	1.09			
	12.2	1.10			
	12.4	1.11			

EXHIBIT I

^{60}Co EXPOSURE RATE: (R/min) for 5x5 cm^2 at 80 cm S.S.D.

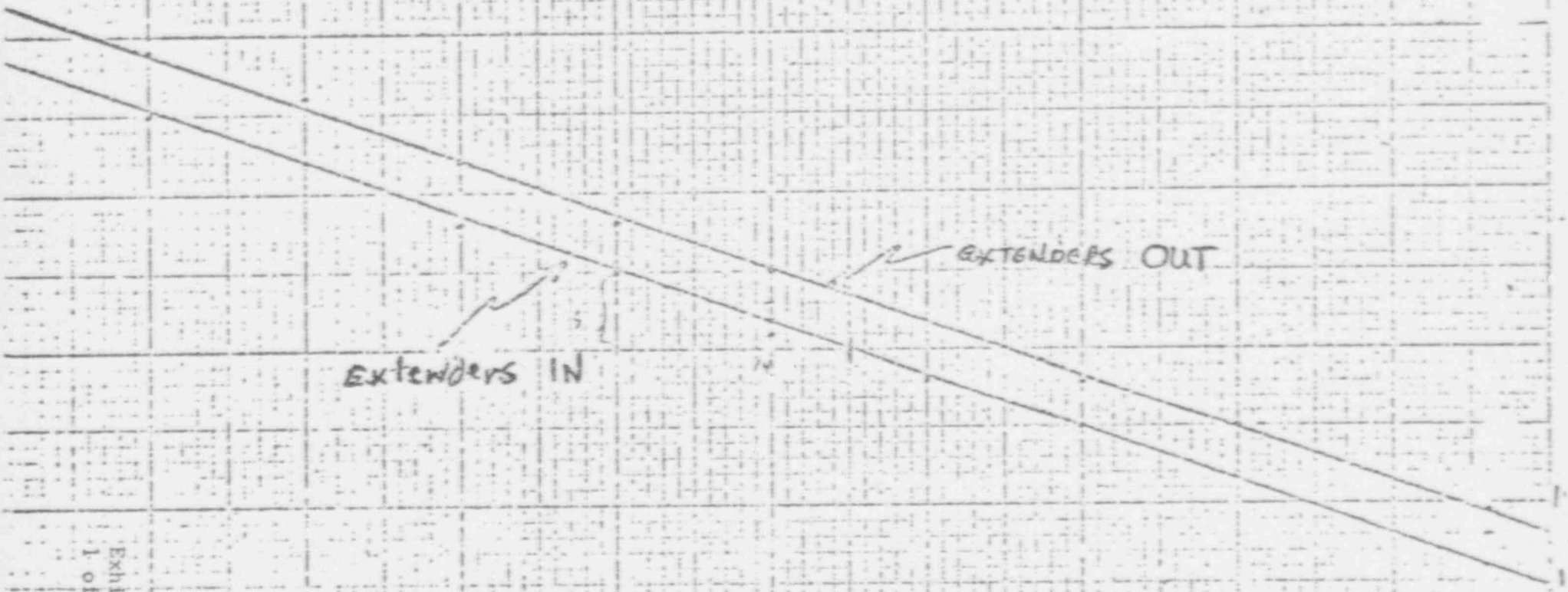
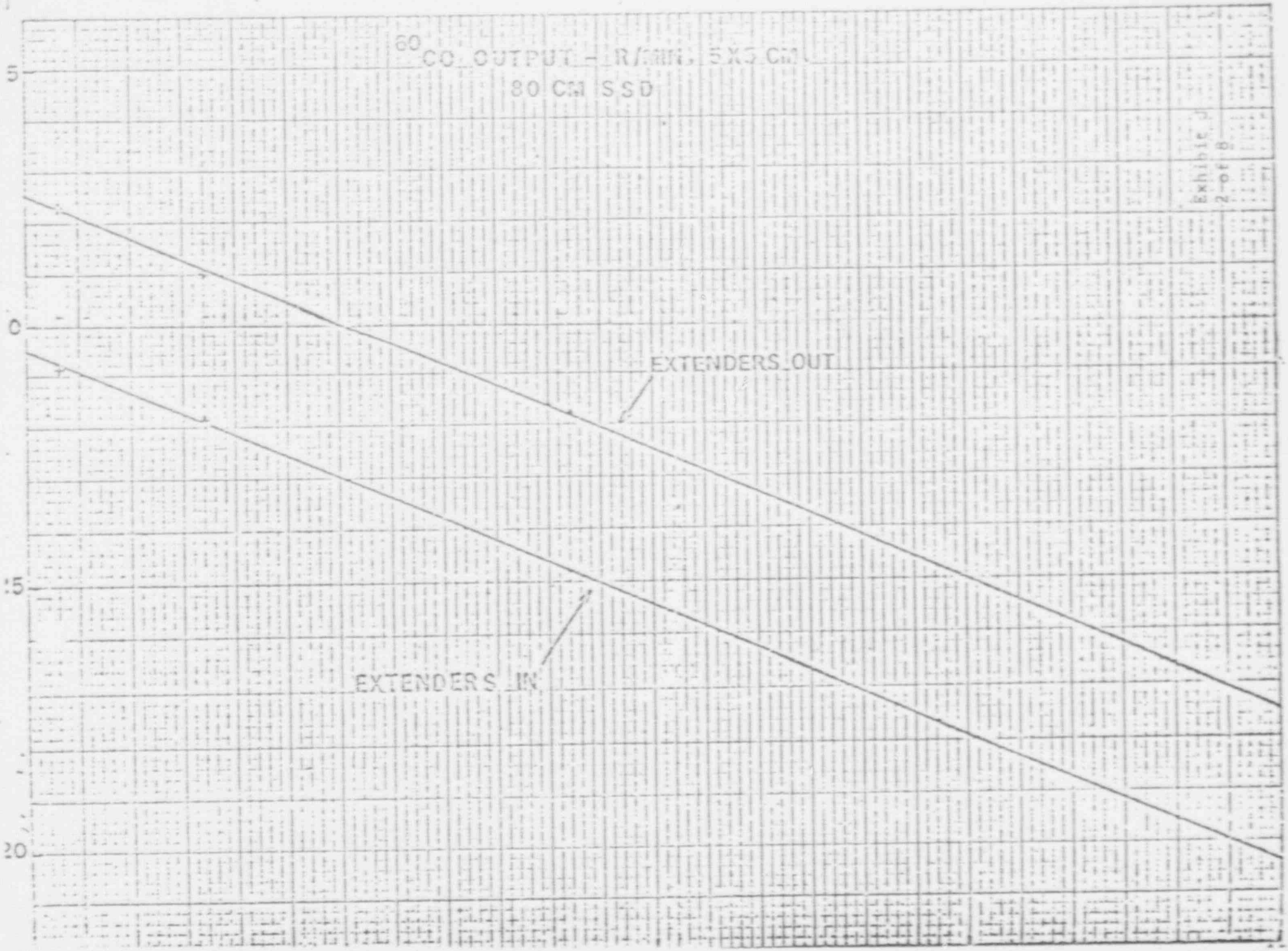
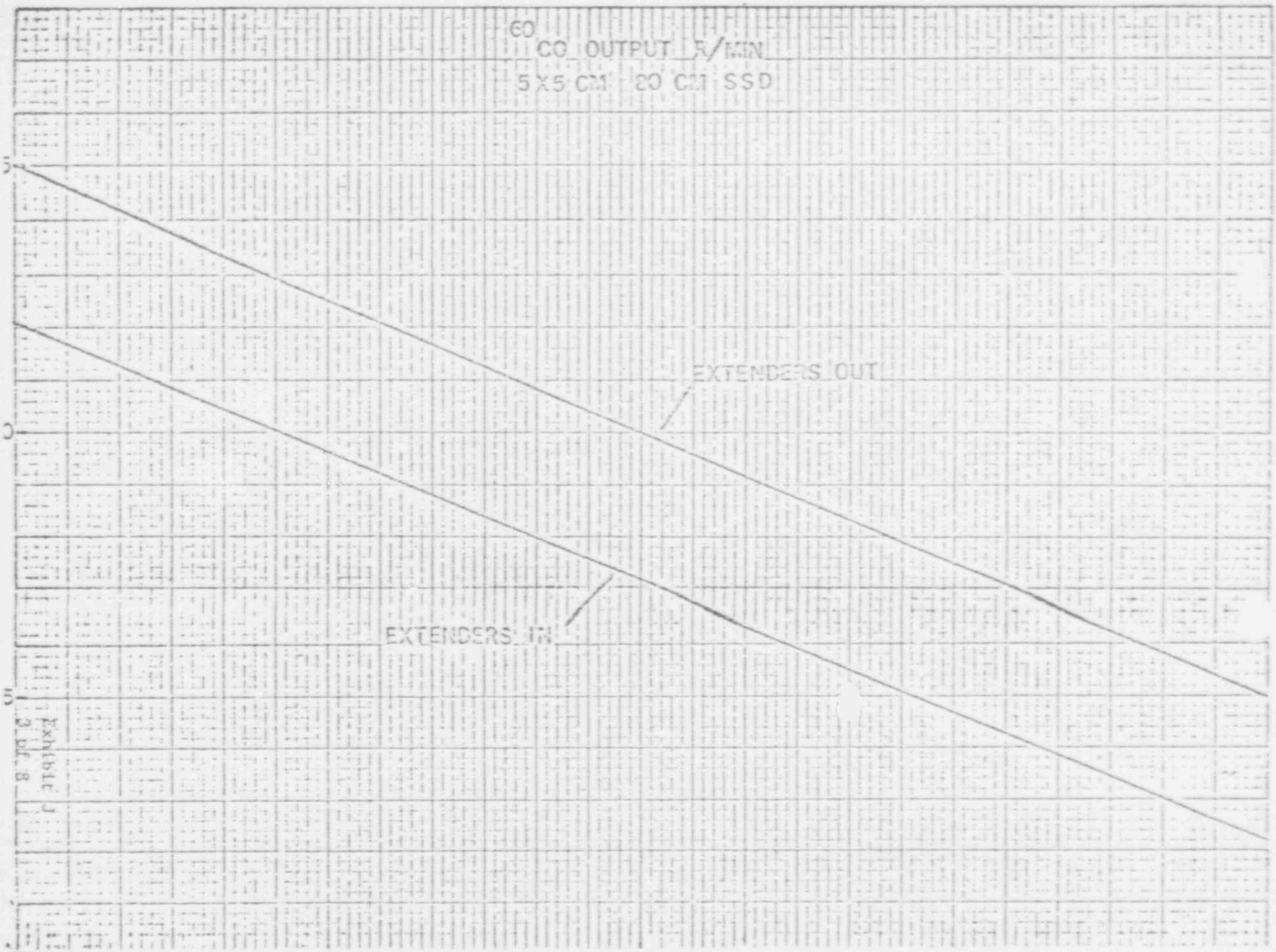


Exhibit J
1 of 8

1974


60 CO OUTPUT - R/MIN, 5X5 CM
80 CM SSD
5
0
EXTENDERS OUT
EXTENDERS IN
20


60
CO OUTPUT L/MIN
5X5 CM 20 CM SSD
EXTENDERS OUT
EXTENDERS IN

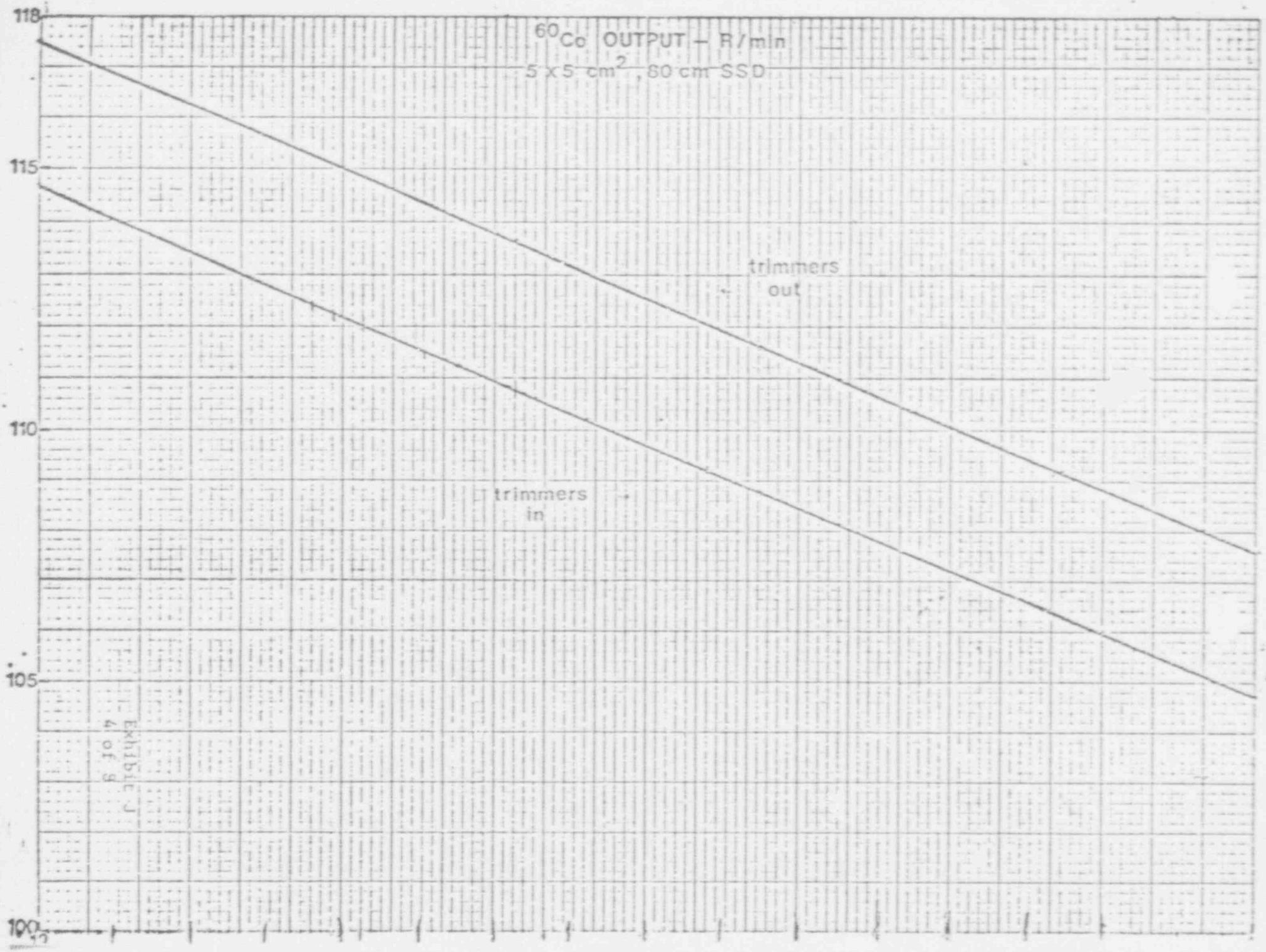


Exhibit J
4 of 9

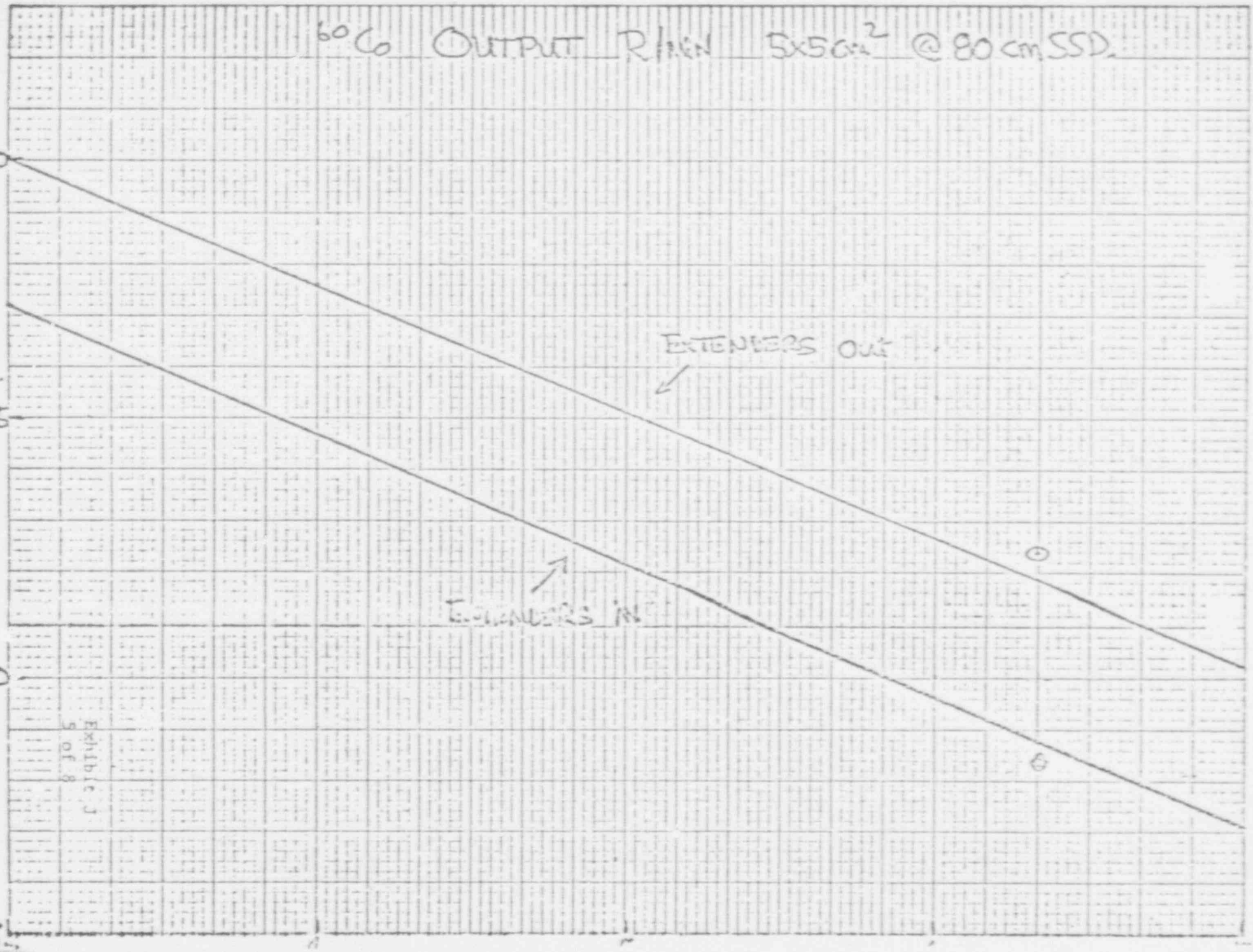
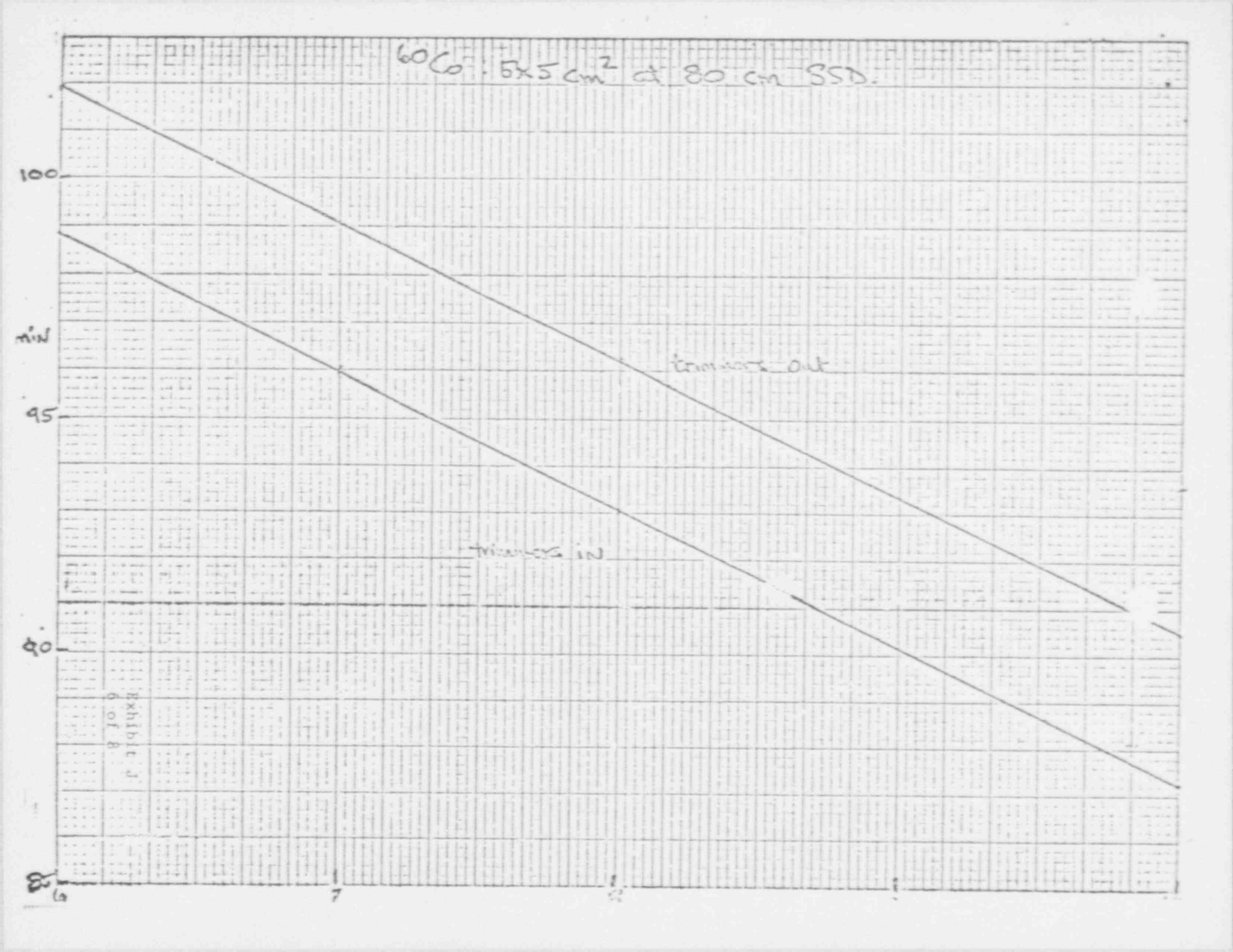


Exhibit J
5 of 8


60Co : 5x5 cm² at 80 cm SSD.
100
95
90
80
min
timer's out
timer's in
0
1/2
1
Exhibit J
9 of 9

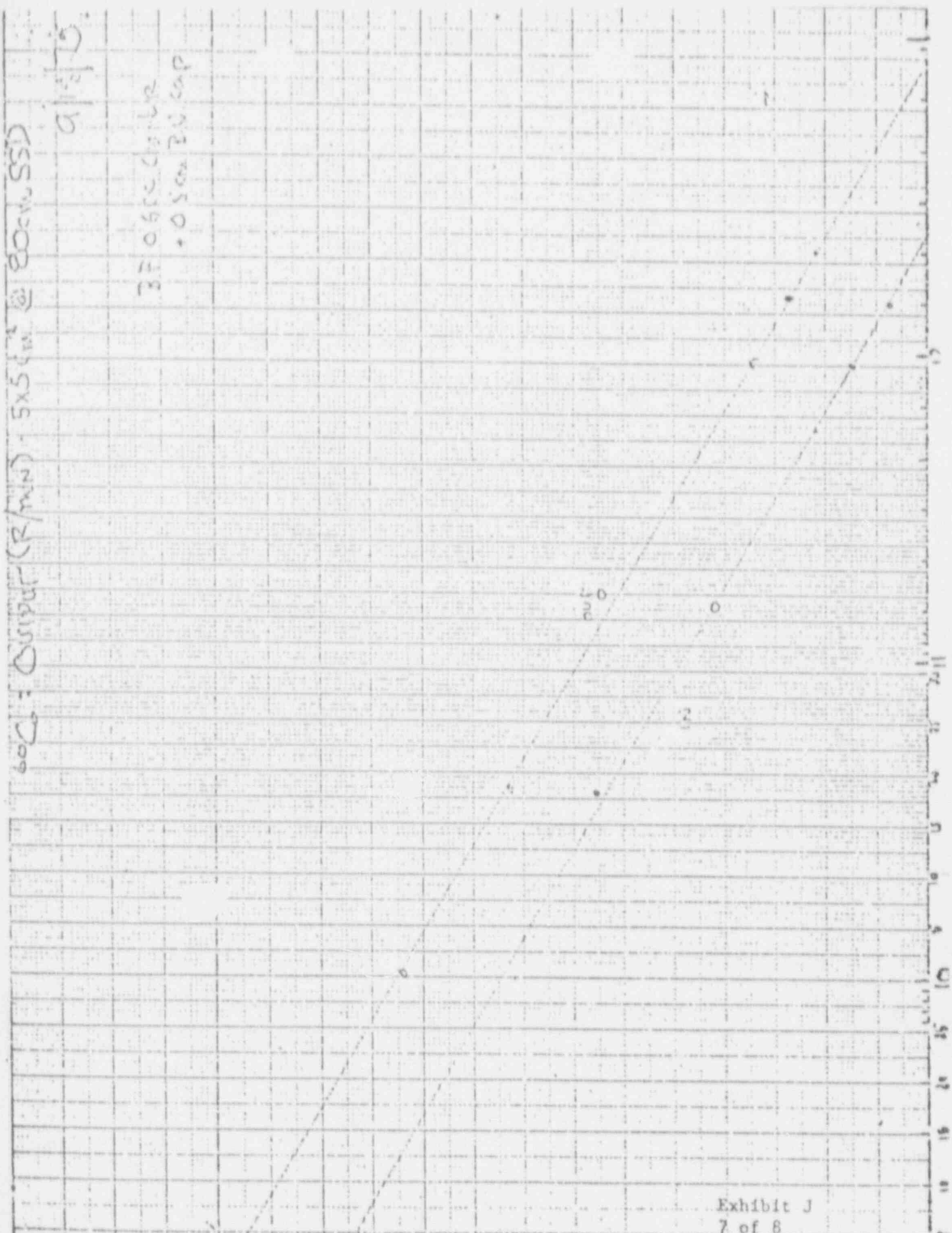


Exhibit J
7 of 8

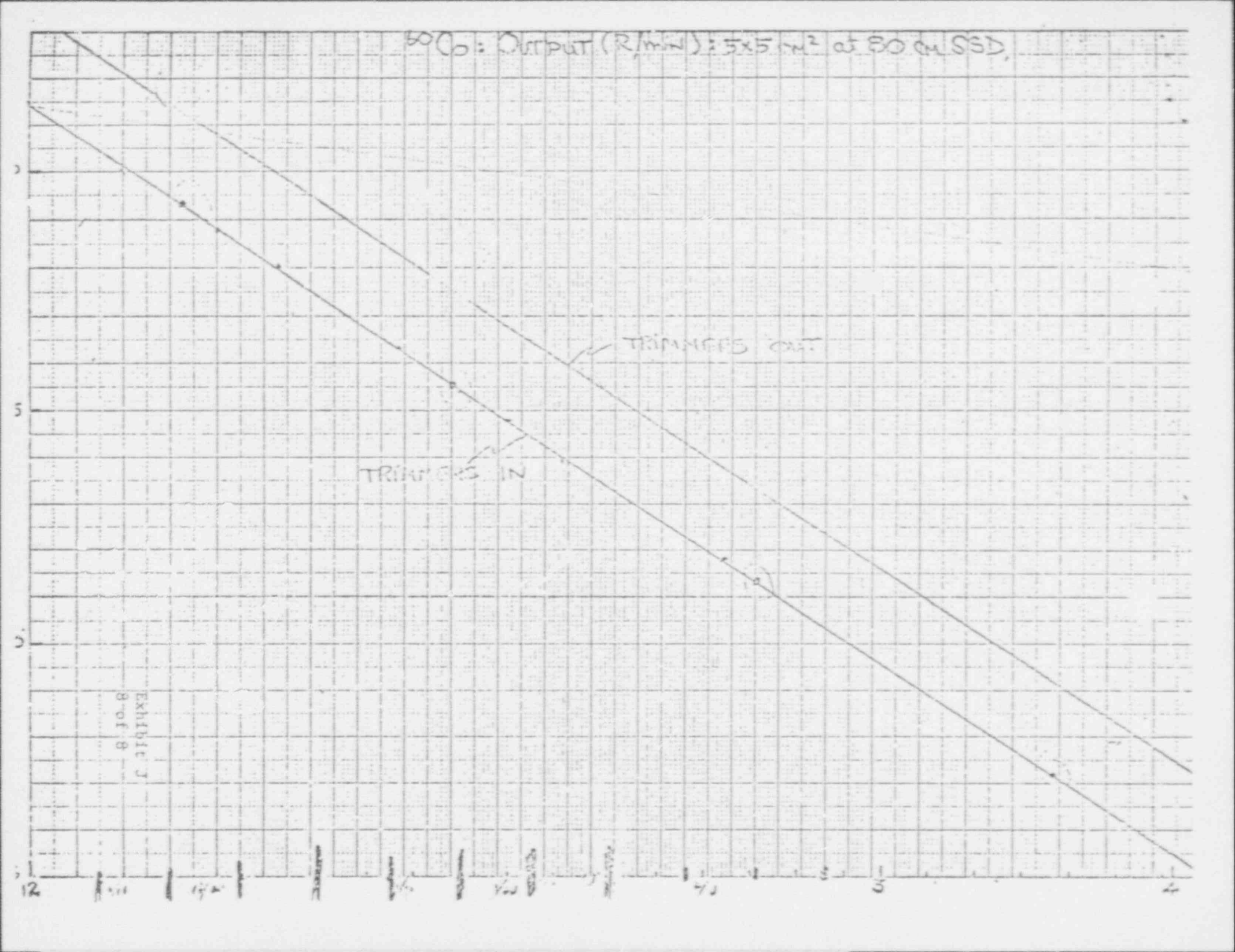


Exhibit J
8 of 8

UNITED STATES DEPARTMENT OF COMMERCE
National Bureau of Standards
Washington, D.C. 20234

28 May 1976

Larry R. Pilot, Director
Division of Compliance, HFK-100
Bureau of Medical Devices
and Diagnostic Products
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Mr. Pilot:

This is a report on the examination of an ionization chamber and electrometer, performed at NBS in accord with the request in your letter of May 12th, 1976.

Electrometer: Keithley Model 616, Serial Number 25112. This electrometer was transferred to me at the Victoreen Instrument Company in Cleveland, during my visit there on May 13, 1976. It was carefully packed by Victoreen, and hand-carried by me to NBS. On arrival at NBS it was examined and tested essentially as outlined in my letter of May 7, 1976 to Harry Sauberman. The electrometer functioned in an entirely normal manner in all characteristics that we examined. The memorandum of May 12th, 1976 from Michael Odlaug stated that the 10^{-8}-coulomb charge-collecting mode was used in measurement with this electrometer, and this mode was found to measure charge correctly to better than 1%.

Ionization chamber: Farmer chamber, Model 2505/3, Serial Number 1108, with collector's identification on seal "76-81-044 5-12-76 MD." The shipment arrived at NBS on May 19th via air freight from Columbus, Ohio. There was no indication of damage to the carton or its contents, which had been very carefully packed. On opening the carton we found a conventional Farmer ionization-chamber assembly. This chamber assembly consists of a measuring volume defined by a graphite thimble, supported on an aluminum stem about 10 cm long, permenently connected to a tri-axial cable about 10 meters (33 feet) long, terminating in a tri-axial BNC connector which mates with the signal input on the electrometer. The measuring volume is defined by the outer graphite thimble and an inner aluminum electrode, as is shown on the attached photocopy of a radiograph.

On opening the shipping carton, the ionization chamber was covered with the protective cap which is standard equipment with these Farmer chambers. On removing the protective cap, it was found that the graphite thimble was broken at its base. The break was just inside the shoulder of the aluminum stem, so that when the graphite thimble was replaced in its normal position, it was not apparent to the eye that it was broken. In the radiograph taken with the thimble in its normal position, the break is not visible because it is inside the aluminum stem.

The first tests performed on the chamber were to test for electrical continuity between the three contacts on the BNC connector and the appropriate parts of the ionization chamber. These were all normal except for the absence of electrical continuity between the center conductor of the BNC connector and the aluminum collecting electrode. Under normal circumstances it is not possible to measure continuity between these two parts, but since the graphite thimble was loose, this measurement was made, and it was found that the resistance was greater than 10^{14} ohms. This open circuit renders the chamber inoperable.

It was observed that about one-third of the distance from the BNC connector to the ion chamber there was a small piece of black plastic electrical tape wound around the cable. When this was removed, the outer braid was visible on one side, indicating that somehow the outer insulation of the cable had been in part worn or abraded. We suspected at this time that the open circuit would be found at this position, and I so informed Harry Sauberman of the BMDDP in a telephone conversation. Subsequent examination showed this to be an erroneous inference. The abraded section of the cable was radiographed, and no evidence of a break in the central conductor was seen. Additional radiographs were taken at a few other places in the cable, particularly near the ionization chamber and the connector, but there was no evidence of a broken center conductor on any of the radiographs. The BNC connector was disassembled, found to be normal in appearance, and reassembled. The capacitance between the center conductor and the inner braid was found to be 725 picofarads measured from the connector end, and 15 picofarads measured from the ionization chamber end, which indicates that the open circuit in the central conductor is at the ionization-chamber end of the assembly.

Radiation measurements confirmed that the chamber is inoperable. The response to radiation was approximately 1000 times lower than would be expected with this instrument. This observation was made using both an NBS electrometer, and the Keithley electrometer which is the subject of this report.

If the open circuit in the central conductor were found and repaired, it probably would be possible to calibrate the ionization chamber. The calibration factor (in roentgens per coulomb) would be smaller than the calibration factor before the thimble was broken, assuming that the volume is increased due to the fact that the broken thimble will not quite go back into its original position. Since the thimble is 25 millimeters long, a change in length of 1 millimeter would produce a volume change of 4%, which is a fair estimate of the uncertainty in reproducing the calibration factor of the chamber before it was broken.

As can be seen on the radiograph, the wall of the graphite thimble is very thin and it is not uncommon that these thimbles are broken. It is not possible to repair such a thimble, but it can be replaced by a new thimble.

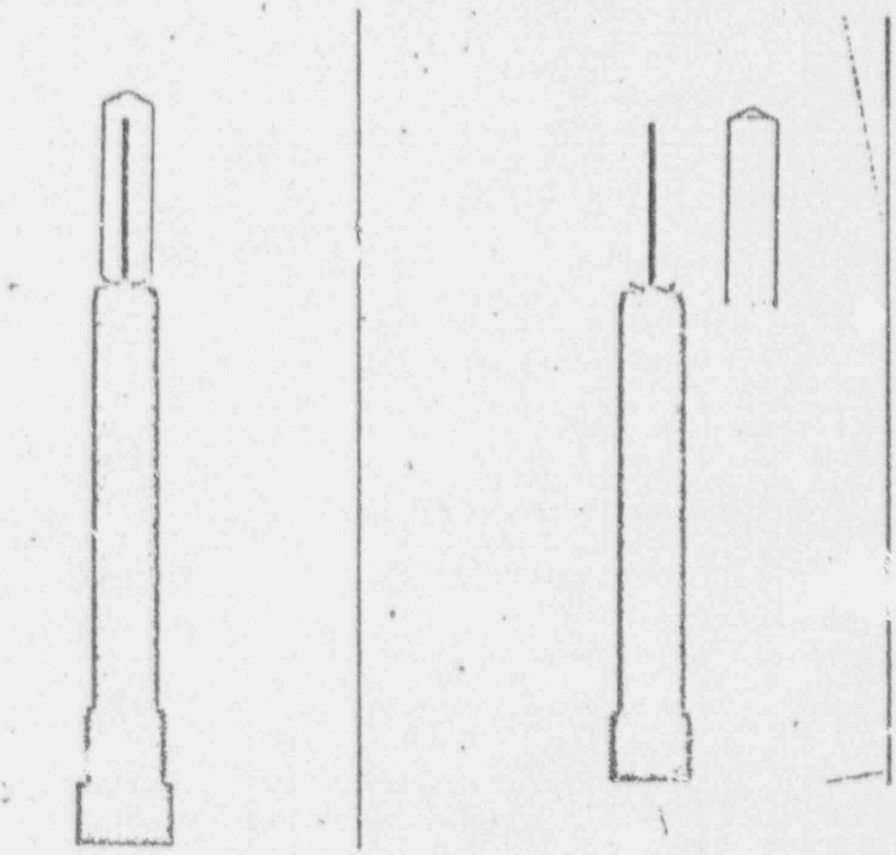
I hope this report of our examination meets the needs of your agency. We are holding the equipment until we are informed to whom it should be sent.

Sincerely yours,

Robert Loevinger

Robert Loevinger
Chief, Dosimetry Section
Center for Radiation Research

cc: Harry Butts, BMDDP
Harry Sauberman, BMDDP
David Link, BMDDP
Don Thompson, BRH
J. E. Leiss, CRR



Radiographs of Farmer Chamber Model 2505/3, Serial Number 1108
28 May 1976

July 29, 1977

Franklin County Coroner's Office
ATTN: Dr. William Adrion
Coroner
520 King Avenue
Columbus, OH 42310

Dear Dr. Adrion:

Enclosed is a copy of a report prepared by Dr. Eugene L. Saenger concerning [redacted] of Columbus, Ohio, who died at Riverside Methodist Hospital, Columbus, Ohio, on December 30, 1975.

As you are aware, Dr. Saenger is the NRC's Medical Consultant.

Sincerely,

James G. Keppler
Director

Enclosure:
Medical Report

cc w/enclosure:
Mr. James Flynn, Associate
Administrator
Riverside Methodist Hospital
Central Files

OFFICE ▶	RIII	RIII	RIII			
SURNAME ▶	Lonergan/jg	Allan	Keppler			
DATE ▶	7/14/77					

REPORT ON [redacted]

Eugene L. Saenger, M.D.
University of Cincinnati
Medical Consultant
Nuclear Regulatory Commission

1. Clinical Course

[redacted] a 25 year old pregnant female who entered Riverside Methodist Hospital for initial admission on December 1, 1975 and died on December 30, 1975.

The patient noted a lump in her neck in February 1975. The diagnosis of Hodgkin's disease was made in September 1975 and was considered to be limited to the neck. On September 9, 1975 abdominal exploration, liver biopsy and splenectomy revealed no evidence of Hodgkin's disease in the abdomen. The patient was approximately 4 1/2 months pregnant. Radiation therapy was begun on September 30, 1975 and concluded on October 31, 1975. Treatment was planned to the mediastinum, bilateral supraclavicular, and axillary areas and the neck - a mantle technique using Cobalt 60 teletherapy. There were 19 treatments administered in 33 days and the doses initially calculated and subsequently recalculated are shown in the following table:

Total Doses to Treatment Areas (rads)

	Mediastinum	Supraclavicular	Axillary
Initial Calculated dose (10-31-75)	3420	3708	3519
Recalculated dose (6-8-76)	4708	5546	4314
Ratio of Recalculated to initial dose	1.38	1.5	1.22

At the beginning of treatment, September 30, 1975, the position of trimmer blocks to protect the lungs was checked by port films and appeared "essentially correct". Midway through treatment, October 15, the patient complained of severe sore throat and increased nausea. On examination "her throat still appears markedly reddened and there are areas of patchy pseudomucinous formation". On a follow-up visit of November 24, 1975, she developed a severe skin reaction over the upper portion of the mantle field after October 31 but the skin peeled and at that visit looked "virtually normal". "Overall she is doing well with good appetite and slow weight gain".

Seven days prior to her final admission on December 1 she noted gradual onset of progressive dyspnea and non-productive cough with substernal pleuritic chest pain. On the day after admission she spontaneously aborted a 7 1/2 month fetus.

Her subsequent course was steadily downhill with increasing respiratory difficulty, characteristic of a severe form of the adult respiratory distress syndrome (Hopewell and Murry, Ann. Rev. Med. 1976). There was increasing abnormalities of blood gases and increasing pulmonary infiltrates by x-ray culminating in bilateral pneumothoraces. On the third hospital day there was clinical evidence of thrombophlebitis of the left lower extremity and laboratory evidence of pulmonary emboli.

In spite of vigorous therapy directed to the many manifestations of respiratory difficulty the patient failed to respond. Death occurred December 30, 1975 which was 92 days from the beginning of radiation therapy and 60 days from its completion.

A copy of the necropsy record of the patient from the Department of Pathology, Riverside Methodist Hospital is appended (attachment 1).

2. Evaluation of the clinical course and autopsy findings

The rapidly progressing course involving primarily the lungs leading to death within 60 days after completion of treatment is characteristic of a severe reaction to ionizing radiation. As noted by Rubin and Casarett the typical acute response begins after a latent period of weeks to months before the onset of symptoms and signs. They further state that typically the onset occurs one to three months after the completion of a four to six week course of x-irradiation (Rubin and Casarret, p. 423). An earlier report of Whitfield, Bond and Arnott (Quart. J. Med. New Series 25: 67-86, 1956) lists 3 cases of Hodgkin's disease with very similar courses and fatal outcomes in which deep x-ray therapy was used. Radiographic changes were similar to those experienced in [redacted] case. Schwarz, Whitcomb and Goldman (Chest 64: 88-93, 1973) describe similar roentgenographic changes including the fact that radiographic changes can extend beyond the confines of the treatment portals.

In his review of this case, Clarence C. Lushbaugh, M.D. of Oak Ridge Associated Universities, our consulting pathologist, described as the cause of death "the severe pneumonitis which at the time of her death was actively extending, undergoing scarring and progressively thickening alveolar walls and filling alveolar spaces with cellular detritis, multinucleated giant epithelial cells, masses of loose epithelium, macrophages, proteinaceous edema fluid and mucin".

Lushbaugh continues as follows: "While it is true that sections from the periphery of the lungs are not as extensively involved as the more hilar ones, they have increased fibrosis and even in atelectatic areas have not collapsed normally. There is also pleural fibrosis...".

The rapid termination of life with severe pulmonary involvement following so quickly the radiation therapy given at an excessively high dose indicate that her death was due to acute radiation pneumonitis.

Eugene L. Saenger, M.D.
Medical Consultant

ELS/swh

REFERENCES

Hopewell PC, Murray JF: The Adult Respiratory Distress Syndrome, in Annual Review of Medicine: Selected Topics in the Clinical Sciences, W.P. Creger, ed., Annual Reviews, Inc., Palo Alto California, Vol. 27, 1976.

Rubin P, Casarett GW; Clinical Radiation Pathology, W.B. Saunders Company, Vol. 1, 1968.

Whitfield AGW, Bond WH, Arnott WM; Radiation Reactions in the Lung, Quarterly Journal of Medicine, New Series XXV, No. 97, January 1956.

Schwarz MI, Whitcomb ME, Goldman AL; The Spectrum of Diffuse Pulmonary Infiltration in Malignant Disease, Chest, Vol. 64, No. 1, July 1973.