V

Release as bracketed E.t.b

March 10, 1990

MEMORANDUM FOR: David Williams
Inspector General

FROM: Peter Crane Peter Crane

SUBJECT: CINCINNATI AND RELATED INVESTIGATIONS

In a memorandum to Bill Kennedy dated yesterday, I set out the essentials of my position (which the agency has decided to treat as a differing professional opinion/differing professional view) on those aspects of the University of Cincinnati matter that are under the jurisdiction of the Office of Investigations. I sent you a copy of that memo. As I tried to make clear, I was constrained in what I could say in that memo by the need to avoid compromising investigations now under way in your office.

The purpose of this memorandum is not to rehash my views on all the matters now before the IG's office in this area, but rather to provide what might be called a road map to the links, as I see them, between the matters discussed in yesterday's memorandum to Bill Kennedy and the various investigations now pending in OIG.

1. 1984 -- The Staff Encourages or Tolerates the Submission of an Inaccurate Factual Account by the Licensee

Briefly, I believe that in October, 1984, after Tom Dorian of the Office of the Executive Legal Director advised the NRC staff that a misadministration had occurred at the Univesity of Cincinnati Medical Center, NRC staff and licensee personnel agreed upon a fictitious rationale for a contrary finding, that is, a finding that no misadministration had occurred. That rationale was to be the following scenario: the hospital implants the seed in the patient; then discovers that the seed is leaking; recognizes that there may be some deposition of radioactive iodine in the patient's thyroid; decides that the need to treat the patient's brain tumor outweighs any possible harm to the thyroid; and therefore makes a medical decision to allow the treatment to continue. The letter of November 2, 1984, from Dr. Bernard Aron, if read reasonably, makes just these assertions. I/16

(To make my position quite clear, I believe that this "medical decision" would not necesarily have been unreasonable, had it actually occurred; as described in my memo of yesterday, my difficulty is that I believe that no such "medical decision" was made, because the hospital failed to recognize until after the treatment period was concluded that the seed had been leaking in

the patient. My allegation regarding the hospital is directed not at the quality of its medical decisionmaking but at the honesty of its reporting to NRC.)

With regard to the role of the NRC staff, my contention is that the NRC staff knew full well that Dr. Aron's letter greatly overstated the extent to which the hospita understood the event while it was taking place. It turns out that there is documentary evidence of the communications between the NRC staff and hospital personnel that led up to Dr, Aron's letter. (This evidence first came to light on May 3, 1989, when an OI investigator, an OIA investigator, and I visited the hospital and requested its records on the incident. OI had not previously sought these records.) That evidence -- two sets of handwritten notes, made by two hospital employees, on the same telephone call with an NRC staff member -- indicates that the staff member advised the hospital that it should describe its "medical decision" in a letter to NRC, and that the NRC would find that no misadministration had occurred.

As a subsidiary matter, all of these factual representations were essentially irrelevant, because the incident was a misadministration under the NRC's rules regardless of whether the licensee discovered it and allowed it to continue.

It may be relevant that Dr. Eugene Saenger, then Chairman of the Radiation Safety Committee at the University of Cincinnati Medical Center, was at that time a consultant to the NRC staff, used in cases where expert advice was needed as to whether a reportable misadministration had occurred within the meaning of the NRC's rules. For the NRC staff, it was apparently no bar to using Dr. Saenger in this capacity that he had -- as he told the OI investigator -- written editorials denouncing the NRC's misadministration reporting rule as an improper interference in the practice of medicine.

2. 1986 -- The Staff Potentially Compromises the OI Investigation and Provides Misinformation to the Commission

After my memorandum of August 27, 1986 challenged the accuracy of the licensee's account, the Commission referred the matter to OI, which reported back to the Commission that an investigation was warranted. On November 28, 1984, the EDO sent the Commission a memo which purported to provide the real facts of the incident, based upon the licensee's submission and a November 24, 1986 telephone call with the licensee. I believe that it was inappropriate for the staff, knowing of the upcoming OI investigation, to make such a telephone call. In addition, I believe the facts presented in the November 28, 1986 memorandum were not an accurate statement of what occurred at the hospital in 1984. (The staff did not now assert that the hospital knew of the leaking seed while the incident was in progress, but rather that it suspected it. This is true up to a point; the hospital

suspected the seed was leaking, but then performed a wipe test and decided, as it wrote in the patient's chart, that the sources were "intact.") The EDO's memorandum also quoted from Dr. Aron's November 2, 1984 letter.

I do not claim that the EDO personally knew the memorandum to be inaccurate, but I believe that it was incumbent on all connected with the preparation of that memo to have made sure of its accuracy, especially since the memorandum's conclusion was that there was no basis for any investigation of the licensee. (This memorandum, incidentally, agreed that the incident should have been called a misadministration. However, if the May 3, 1989 testimony of Dr. Saenger is accurate, no one from the staff ever advised the licensee that the incident had been reclassified as a misadministration.)

3. 1987 -- The Staff Causes the Commission to Send Congress an Abnormal Occurrence Report of Borderline Accuracy

In mid-1987, the staff sent the Commission a quarterly abnormal occurrence report, for submission to the Congress, that included an update on the University of Cincinnati incident. This report did not claim that the licensee knew of the leak during treatment or even suspected it. However, it said that when the seed was removed, radioactivity was found in the patient's neck, and that this "confirmed" that the seed had been leaking. The use of the word "confirmed" implies, to me, confirmation of an existing suspicion. In fact, according to OI's interview with Dr. [redacted] what evidence the licensee had at the time of removal of the seed indicated that the seed was <u>not</u> leaking. "Revealed" would therefore have been a more accurate word than "confirmed." To make myself clear, I am not claiming that the staff caused the Commission to deceive the Congress, but I believe that the use of the word "confirmed" had the potential to mislead and therefore should have been avoided.

4. 1989 -- The Surreptitious Rule Change Comes to Light

In the spring of 1989, in the course of discussing a draft staff paper on Part 35 (medical licensees) with Marjorie Rothschild, I became aware that there was a difference between the misadministration rule as printed in the 1986 copy of 10 CFR that I was using and the 1989 copy that she was using. This seemed odd, since to my knowledge the Commission had not changed the misadministration rule in a number of years. Thus the two texts should have been the same. On checking further, I discovered that late in 1984 (November, I believe), the staff sent the Commission a paper which purported to be a rewrite and consolidation of Part 35. The paper represented that no change whatsoever had been made in the misadministration rule. The Commission issued the rule for public comment, adding a paragraph that said that although the Commission was not changing the misadministration rule, it would

appreciate public comment on the subject of it. In fact, the proposed and final rules altered the provisions dealing with notification of patients after a misadministration. The effect of the change is, in my view, to make it harder ever to take enforcement action against a licensee for failing to notify a patient of a misadministration. It thus appears that the Commission was induced to relax its misadministration reporting rules without either the Commissioners or the public knowing that such a rule change had occurred.

It may be relevant that in the summer of 1989, when the staff sent a Part 35 package to the Commission for action, the Commissioners responded with a staff requirements memorandum to the staff directing that those events which were currently misadministrations should continue to be treated as misadministrations. The staff thereupon prepared a rulemaking package that purportedly followed the directives of the SRM. A review of the fine print revealed that in one respect, however, events previously treated as misadministrations would become non-misadministrations if the staff's package were adopted: events involving seeds that leak or become lost during treatment. Thus five years after the Cincinnati incident, the staff apparently saw the need to reclassify leaking seed events as non-misadministrations, and this need apparently took precedence over obedience to the Commission's directive.

5. 1990 -- The Staff Collaborates with the Regulated Industry on a Petition to the NRC

Early in 1990, I believe, I received a call from Dr. Carol Marcus, a nuclear physician practicing in California. Dr. Marcus planned to file comments with EPA regarding a rule on radionuclide emissions which the nuclear medicine community believed -- quite rightly, in my view -- could seriously interfere with the treatment of patients without providing any countervailing benefit to the public. Hugh Thompson had asked her to call me, suggesting that my familiarity with administrative processes might make me a source of advice as to how such comments should be framed (i.e., should she be writing to an audience of scientists, doctors, lawyers, or lay persons?) Our discussion turned from the EPA rule to the NRC's regulation of nuclear medicine, a subject on which Dr. Marcus has strong views. She mentioned the petition that she had filed with the NRC, and volunteered -- four times, I believe -- that Richard Cunningham of the NRC had asked her to file the petition. She further mentioned that Norm McElroy of the NRC had helped draft the petition. Dr. Marcus did not seem aware in the slightest that there might be any impropriety or appearance of impropriety in the staff's suggesting that a petition be filed and then purporting to act on that petition impartially. It was my impression that Dr. Marcus felt that she was giving credit where credit was due by commending the role of the two NRC staff members. I passed this information on to the IG's office. (It is my understanding that

Dr. Marcus subsequently made similar assertions regarding the role of the two staff members to other NRC personnel, again in the context of praising them -- but this is purely hearsay.)

SUMMARY

I suggested at the outset that I would try to offer a road map as to the links among the various matters now before the IG. In a nutshell, I believe that the common thread is a deepseated hostility on the part of the NRC staff (or portions of it) toward the regulation of nuclear medicine in general and the misadministration reporting requirement in particular. The misadministration rule was imposed over the objections of the NRC staff; retained over the objections of the NRC staff; and kept stringent despite repeated staff attempts to water it down.

In 1984, the staff did two things, in my view. First, it collaborated with a licensee to paper over a particular misadministration, in the face of advice from its own lawyer that a misadministration had occurred. Second, it set in motion a rule change -- unbeknownst to the Commissioners or the public -- that would make it more difficult for the NRC ever to take enforcement action against a licensee for failing to report a misadministration to a patient. In 1986, when the 1984 coverup of the Cincinnati misadministration began to unravel, the staff misrepresented the facts to the Commission and compromised OI's investigation by contacting the licensee. In 1987, it caused the Commission to make representations to the Congress about the Cincinnati incident that walked a fine line between accuracy and misrepresentation. In 1989, when repeated staff efforts to weaken the regulation of nuclear medicine had proved unavailing (because of Commission resistence), the staff mobilized the regulated community to file a petition that could be used to persuade the Commission that it was necessary to back off from regulating the nuclear medicine community. In my view, therefore, all these areas of investigation are, to a greater or a lesser degree, connected.

I should add that I am writing from memory, not with the documents in question before me. I regret any minor factual errors that may inadvertently have crept into the above account. I feel confident, however, that in all significant respects, the foregoing is accurate in its factual representations. Whether there is validity to the hypotheses and opinions I draw from those facts is for others to judge.

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
The General Counsel

W.C. — 3 pm outline. C.

(taken on Fri. 8/31

(1) When bioassays were performed? 9/4 (urine)
How performed — bioassays?
Thyroid [illegible] 2

(2) When samples taken? 8/31 (Friday)
When etc? 9/4 (urine Tuesday)
9/5, 9/12, 9/24, 10/19
Pt. follow up info?

Were contamination wipe tests etc.? (Sat) (9/1)
No — taken a [illegible] on pig
thyroid showed 1st [illegible] I 125 counts
wipe taken off pig

Release

I/18

Ex 6

University of Cincinnati
Medical Center

University Hospital

234 Goodman Street
Cincinnati, Ohio 45267-0677

Eugene L. Saenger Radioisotope Laboratory
Mail Location #577
TELEPHONE (513) 872-4282

August 30, 1984

TO: [redacted] Dr Saenger

FROM: [redacted]

RE: ^{125}I seeds

I would like to make the following suggestions concerning the use of all ^{125}I seeds:

1. I believe it is universally agreed that all loading, unloading and cleaning of seeds be done in a fume hood;

2. The high speed "flash autoclave" in surgery operates at 30-35 psi steam pressure (270-280°F) which is the maximum pressure limit for loose seeds. As noted, seeds in plastic tubing should not be autoclaved at all. I would think that until it can be shown that this procedure can be done safely, that seeds be autoclaved using ethylene oxide only;

3. I am not terribly convinced that air sampling is going to show anything other than a catastrophic leaker. I would suggest that the following procedure be used when seeds are removed from a catheter after use:

   a. work in hood;

   b. as seeds are removed, they are placed in a small bottle of disinfectant (1:750 dilution of Zephiran, for instance) and tightly capped;

   c. approximately 24 hours later, a sample of the Zephiran will be counted in a well counter;

   d. seeds will not be re-used unless the Zephiran is shown to be free of activity.

This should be a more rigorous test for leakers with liquid in contact with the excised seeds rather than just air. Also, if a leaker is discovered, the activity will be localized in the bottle rather than through a large volume of air.

4. Ideally, these seeds will not be used in more than one patient.

II/19

Chronology of 125I Incident

8/10/84 Ten 125-I seeds ~~are~~ were received in Radiation Safety. Mean activity of the seeds ~~is~~ was 40 mCi per seed. Routine wipe testing indicates little contamination (46 net cpm). Seeds ~~are~~ were taken to brachytherapy room in Radiation Oncology. Manipulation and autoclaving trials ~~are~~ were carried out using dummy seeds.

8/13/84 Seeds ~~are~~ were loaded into two ~~Heyman~~ Henschke coaxial catheters (4 per catheter). The two remaining seeds ~~are~~ were stored in a sealed pig in the a brachytherapy room. Seeds ~~are~~ were taken to the operating room in a pig for flash sterilization and implantation into patient KW. Thin - window monitoring of instruments used ~~is~~ was negative (Equal to background in brachytherapy room).

8/17/84 Catheters ~~are~~ were unloaded in the patients room and placed in a transport pig. Survey of the tools and environs with thin window counter at this time ~~is~~ was negative. The seeds ~~are~~ were returned to Radiation Oncology where they ~~are~~ were stored on the bench in a sealed pig.

8/20/84 Preparations ~~are~~ were made for insertion of seeds into patient J.F. The catheters from the previous case ~~are~~ were opened using a scissors, razor blade, and needle. All seeds ~~are~~ were combined in the original shipping pig. Five ~~are~~ were then withdrawn and placed in a new catheter. The loaded catheter ~~is~~ was stored on the bench in the brachytherapy room in a closed transport pig. The balance of the seeds ~~are~~ were stored in the sealed, original shipping pig. No activity ~~is~~ was found on the tools using the thin-window counter (in the brachytherapy room).

8/27/84 The sources ~~are~~ were once again removed from the catheter in preparation for implantation into patient JH. The same tools ~~are~~ were used. The sources ~~are~~ were loaded and sent to the OR for autoclaving and insertion. A postoperative survey of tools and pig ~~is~~ was negative. The patient returns to her room.

8/28/84 Routine wipe-testing of iridium-192 buckets for shipment reveals contamination of the surfaces with iodine-125. The contamination ~~is~~ was traced to the brachytherapy room, which ~~is~~ was sealed off.

Oncology and Radiation Safety ~~are~~ were notified. Decontamination ~~is~~ was begun. Wipe testing of the brachytherapy room reveal~~s~~ed ~~relatively low~~ levels of contamination. ~~Whole body counter technician is ill.~~ Thyroid counts ~~are~~ were scheduled for following day.

8/29/84

Wipe testing of patient's lead hat and bandage reveal~~s~~ed no leakage, and it ~~is~~ was therefore decided not to remove the sources.

8/30/84

Thyroid counting reveal~~s~~ed 209 nCi of 125I in gland of technician FE. Decontamination ~~is~~ was suspended and thyroid counts ~~are~~ were commenced for all personnel at risk.

8/31/84

Thyroid counting ~~is~~ was continued and investigation of ventilatory patterns in Radiation Oncology ~~is~~ was begun. ~~It is determined that~~ the brachytherapy room ~~is~~ was under positive pressure. Maintenance ~~is~~ was called in to correct the problem. Urine and blood samples are obtained on the patient and technicians FE and PJ, who ~~are~~ were examined by Dr. Maxon.

1/84

The sources ~~are~~ were removed from patient JE. Although no contamination is detected outside the patient's body, thin window counting indicate~~s~~d a substantial amount of Radioactive Iodine ~~to be~~ present in the thyroid gland of the patient. Monitoring by Radiation Safety indicate~~s~~d a level of 1.5 mR/hr at 2". The patient ~~is~~ was OK'ed for discharge with instructions to return for whole-body counting.

9/4/84

Repeat thyroid scanning show~~s~~ed declining levels of radioiodine in FE and PJ. Wipe testing confirm~~s~~ed absence of contamination in OR and in patient's room.

7/5 →

9/6

Ex. 6

Chronology of 125I Incident

8/10/84 — Ten 125-I seeds are received in Radiation Safety. Mean activity of the seeds is 40 mCi per seed. Routine wipe testing indicates little contamination (46 net cpm). Seeds are taken to brachytherapy room in Radiation Oncology. Manipulation and autoclaving trials are carried out using dummy seeds.

8/13/84 — Seeds are loaded into two ~~Boyman~~ Heyman-Schultz coaxial catheters (4 per catheter). The two remaining seeds are stored in a sealed pig in the a brachytherapy room. Seeds are taken to the operating room in a pig for flash sterilization and implantation into patient RW. Thin - window monitoring of instruments used is negative (Equal to background in brachytherapy room).

8/17/84 — Catheters are unloaded in the patients room and placed in a transport pig. Survey of the tools and environs with thin window counter at this time is negative. The seeds are returned to Radiation Oncology where they are stored on the bench in a sealed pig.

8/20/84 — Preparations are made for insertion of seeds into patient ~~J.F.~~ JF. The catheters from the previous case are opened using a scissors, razor blade, and needle. All seeds are combined in the original shipping pig. Five are then withdrawn and placed in a new catheter. The loaded catheter is stored on the bench in the brachytherapy room in a closed transport pig. The balance of the seeds are stored in the sealed, original shipping pig. No activity is found on the tools using the thin-window counter (in the brachytherapy room).

8/27/84 — The sources are once again removed from the catheter in preparation for implantation into patient JH. The same tools are used. The sources are loaded and sent to the OR for autoclaving and insertion. A postoperative survey of tools and pig is negative. The patient returns to her room.

8/28/84 — Routine wipe-testing of iridium-192 buckets for shipment reveals contamination of the surfaces with iodine-125. The contamination is traced to the brachytherapy room, which is sealed off.

Oncology and Radiation Safety are notified. Decontamination is begun. Wipe testing of the brachytherapy room reveals relatively low levels of contamination. ~~Whole body counter technician is ill.~~

8/29/84 Thyroid counts are scheduled for following day. Wipe testing of patient's lead hat and bandage reveal no leakage, and it is therefor decided not to remove the sources.

8/30/84 Thyroid counting reveals 209 nCi of 125I in gland of technician FH. Decontamination is suspended and thyroid counts are commenced for all personnel at risk.

8/31/84 Thyroid counting is continued and investigation of ventilatory patterns in Radiation Oncology is begun. ~~It is determined that the brachytherapy room is under positive pressure.~~ Maintenance is called in to ~~correct the problem~~. Urine and blood samples are obtained on the patient and technicians FH and PJ, who are examined by Dr. [redacted]

9/1/84 The sources are removed from patient JH. Although no contamination is detected outside the patient's body, thin window counting indicates a substantial amount of Radioactive Iodine to be present in the thyroid gland of the patient. Monitoring by Radiation Safety indicates a level of 1.5 mR/hr at 2". The patient is OK'ed for discharge with instructions to return for whole-body counting.

9/4/84 Repeat thyroid scanning shows declining levels of radioiodine in FH and PJ. Wipe testing confirms absence of contamination in OR and in patient's room.

Chronology of 125I Incident

8/10/84 — Ten 125-I seeds are received in Radiation Safety. Mean activity of the seeds is 40 mCi per seed. Routine wipe testing indicates little contamination (46 net cpm). Seeds are taken to brachytherapy room in Radiation Oncology. Manipulation and autoclaving trials are carried out using dummy seeds.

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.20/84 — Preparations are made for insertion of seeds into patient J.F. The catheters from the previous case are opened using a scissors, razor blade, and needle. All seeds are combined in the original shipping pig. Five are then withdrawn and placed in a new catheter. The loaded catheter is stored on the bench in the brachytherapy room in a closed transport pig. The balance of the seeds are stored in the sealed, original shipping pig. No activity is found on the tools using the thin-window counter (in the brachytherapy room).

8/27/84 — The sources are once again removed from the catheter in preparation for implantation into patient JB. The same tools are [illegible]. The sources are loaded and sent to [illegible]R for autoclaving and insertion. A post-operative survey of tools and pig is negative. The patient returns to her room.

8/28/84 — Routine wipe-testing of iridium-192 buckets for shipment reveals contamination of the surfaces with iodine-125. The contamination is traced to the brachytherapy room, which is sealed off.

Oncology and Radiation Safety are notified. Decontamination is begun. Wipe testing of the brachytherapy room reveals relatively low levels of contamination. Whole body counter technician is ill.

8/29/84 — Thyroid counts are scheduled for following day. Wipe testing of patient's lead hat and bandage reveal no leakage, and it is therefor decided not to remove the sources.

8/30/84 — Thyroid counting reveals 209 nCi of 125I in gland of technician PE. Decontamination is suspended and thyroid counts are commenced for all personnel at risk.

8/31/84 — Thyroid counting is continued and investigation of ventilatory patterns in Radiation Oncology is begun. It is determined that the brachytherapy room is under positive pressure. Maintenance is called in to correct the problem. Urine and blood samples are obtained on the patient and technicians PE and PJ, who are examined by Dr. [redacted]

Ex 6

9/1/84 — The sources are removed from patient JE. Although no contamination is detected outside the patient's body, thin window counting indicates a substantial amount of Radioactive Iodine to be present in the thyroid gland of the patient. Monitoring by Radiation Safety indicates a level of 1.5 mR/hr at 2". The patient is OK'ed for discharge with instructions to return for whole-body counting.

9/4/84 — Repeat thyroid scanning shows declining levels of radioiodine in PE and PJ. Wipe testing confirms absence of contamination in OR and in patient's room.

Aug 27, 28 — Sept 5   Chronological Facts

9AM → lunch — 3PM or 4:30

Ex 6

[redacted]

Each person's job
What was to test containment

Who was surgeon who removed
seeds from head

[redacted] Ex 6

Major Figures
— Who investigated Containment?

Oct 3, 1984 EW Report
Aug 12 1986 NRC Report
8/30 versus 9/5

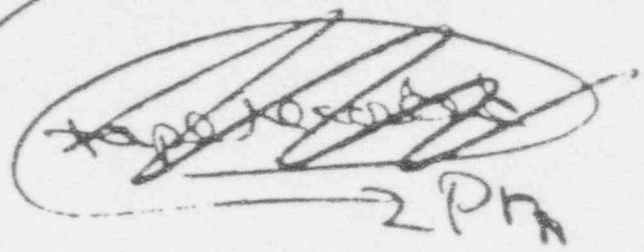
2/84 - 12/85 — [redacted] Ex 6

I/21

Release as bracketed

[redacted]

weekly appt w/ Dr.



Mr axelson

(312) 790-5612

Results of pt. follow up (show progress)
Any minutes of follow up meetings
Therapists discussed

I

URINE COUNTS

[redacted] – 5M count on 9-4-84 69 cts over
of 24 hr urine sample
8-30 to 8-31

[redacted] –
5M count on 9-4-31
of 24 hr urine sample 14 cts over B
8-30 to 8-31

9/4 de

Jennifer Heeg (patient) 3 oz (88.71 ml) urin

57.6 μCi ± 10% / 30
(counted in dose calibrator

Rad. Detr 2" from neck read 1.5 mR

Is scheduled by Dr [redacted] for WBC on
9-5-84 @ 10 AM.

Ext

1/23

University of Cincinnati
Medical Center

University Hospital

234 Goodman Street
Cincinnati, Ohio 45267-0577

Eugene L. Saenger Radioisotope Laboratory
Mail Location #577
TELEPHONE (513) 872-4282

J

September 17, 1984

TO: [redacted] Ph.D.
M.D.
Ph.D.

EX-6

FROM: Eugene L. Saenger, M.D. E.L.S

RE: Attached correspondence re Radiation Therapy Division, Holmes

Please review Dr. [redacted] letter of 9/17/84 and my draft reply. I would appreciate your comments, suggestions, etc. regarding these issues by Friday, September 21 so that I may finalize and mail my response.

Thank you for your assistance in this matter.

LS/sck
enclosures

Release as bracketed

I/24

UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 872-4115

ML 569
J Pavilion
Cincinnati, Ohio 45267-0569

September 18, 1984

[redacted] M.D.
Assistant Professor
Division of Radiation Oncology
ML #757

Dear Dr. [redacted]

Thank you for your letter of September 17. I will try to respond to the specific points you raised.

1. At the moment, I have no immediate suggestion for the layout of the brachytherapy room. At the time of the last remodeling of the Radiation Therapy Division - namely the addition of the room for the 10 MeV therapy unit - it would have been an excellent time for such a proposal to have been entertained. It would be somewhat difficult to make a change now but perhaps the Radiation Therapy Division could consider its existing space and the remodeling of the Radiation Safety Department an interim solution and one might then be able to review such proposals for improvement.

Also within the budget of the Radiation Therapy Division a continuous air flow hood should be estimated along with appropriate gas monitoring devices if you find it necessary to use radium and 125-I sealed sources. It is unclear from this letter as to the volume of the work and the scheduling procedures utilized in Radiation Therapy. If the average use is not in excess of two cases per day, perhaps some compromise in scheduling might improve this situation.

2. As you may recall we have discussed at some length the use of personnel from the Radiation Safety Office to load and unload radioactive sources. It continues to be my expressed feeling that such loading should be carried out by Radiation Therapy technologists who have career training in this function rather than by Radiation Safety personnel. The monitoring which is undertaken within the Radiation Therapy facility should also be done both by the Radiation Therapy technologists and physics personnel as well as the physicians. If the persons from the Radiation Safety Office require additional training in regard to monitoring and handling of sources, it is my feeling that such training should be supplied by personnel from the Radiation Therapy Division since persons working there are more familiar with the specific conditions pertaining to the use of these sources than are others in the Radiation Safety laboratory.

Along this line, the Radiation Safety Office is to provide only monitoring and clean-up in the event of a spill. The record of the

Radiation Therapy Division over the last year indicates that there has been one mishandling of iridium, probably not due to an error on the part of the University, and the one I-125 incident.

3. In regard to loading and unloading radioactive sources, it would again seem to me that this is a function of the Division of Radiation Therapy. This subject has been raised at several meetings of the Radiation Safety Committee and I believe that I have written you in this regard on several previous occasions.

I trust that these matters will continue to receive the full attention of the Radiation Therapy service. We shall plan to discuss your letter, my reply and the subsequent handling of these incidents at the succeeding meetings of the Radiation Safety Committee.

Thank you for your interest.

Sincerely,

Eugene L. Saenger, M.D., Chairman
Radiation Safety Committee

ELS/sck

University of Cincinnati
Medical Center

College of Medicine
Christian R. Holmes Division

Division of Radiation Oncology

Eden and Bethesda Avenues
Cincinnati, Ohio 45219
Phone (513) 872-7706

September 17, 1984

Eugene L. Saenger, M.D.
Chairman
Radiation Safety Committee
M.L. 577

Dear Dr. Saenger:

In view of the recent incident regarding ^{125}I contamination in our radiation therapy department, probably as a result of damage to a high activity sealed ^{125}I seed, we have identified several deficiencies in our department.

1. Our brachytherapy room and handling area is situated in the mist of our treatment area where there is a lot of traffic. We have large amounts of brachytherapy sources including radium, which may present a potential hazard if there is a radon leak. Our brachytherapy room is also of extreme small size to work in safely. We definitely need a continuous airflow hood with radioactive gas monitoring devices, if we are to continue using the radium and radioactive ^{125}I sealed sources safely.

2. Although we have two parttime helpers to assist us in loading and unloading of radioactive sources and monitoring patients which is more than adequate as far as man power is concerned, we feel that these two helpers need more training as far as monitoring radioactive contamination and handling of sources that may potentially be damaged and leak radioactive substances.

3. We need to closely examine our procedures for loading and unloading these radioactive sources and compare them with other centers to see what is the safest way of handling these sources.

It is the hope of the Radiation Therapy Department that eventually we can find an isolated room with the proposed improvements away from a high volume traffic area to store our radioactive sources and to load and unload afterloading device somewhere within the hospital. We hope that the Radiation Safety Committee and Department in conjunction with the hospitals' Space Utilization Committee and Dr. [redacted] can help us to achieve our goals.

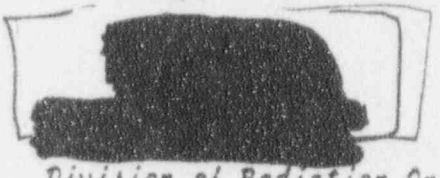
We are currently trying to set up a program in which the personnel handling of radioactive sources are to be better informed and trained to handle them safely.

We will be contacting U.C., San Francisco, who have handled these high activity ^{125}I sources over many years time, to share our experiences and further learn of their handling techniques.

4. We have contacted the 3M Company who manufactures these sealed high active ^{125}I sources, and they will be sending us a container to ship back these high activity radioactive ^{125}I seeds for investigation to see if there is a production defect in the titanium shell and what can be further done to prevent future leakage of ^{125}I.

I believe we can work closely together in achieving our future goals in safely handling all radioactive substance in our department. We will be using Iridium seeds instead of the high activity ^{125}I seeds in our future brain implants until some of the above problems can be solved.

Sincerely,



Division of Radiation Oncology
University Hospital

PYCH/pas

Dear Dr. [redacted]

E/16

M

Thank you for your letter of September 17, 1984 which identifies several deficiencies in your department. Although not indicated on the letter, I trust that this information was also copied to your Department Director.

Specifically

Your specific concerns have been discussed with several members of the Radiation Safety Committee and the following comments are offered that adhere to stipulations of our "Procedures and Codes of The University of Cincinnati - Radiation Safety Manual"

1. Page8, E. "All radiation areas shall be properly labeled and shall be restricted to authorized personnel only."

   Page 6, IV. "Storage sites for large amounts of radioactive materials should be as remote from occupied areas as practical."

   Page 6, IV. "Radioactive solutions that emit gases should be labeled and kept in approved hoods which are provided with filters and have adequate ventilation".

2. Page 3, E. Principal Investigators Responsibility:
   " #2, Insuring that personnel under their control have received sufficient training, as determined by the Radiation Safety Officer, to use radioactive materials safely."

Page 3, F. #11. It is the responsibility of the Individual users to " Conduct significant decontamination procedures as supervised by the Radiation Safety Committee".

3. Page 3, E. #4. It is the responsibility of the Principal Investigator to " Adequately plan an experiment or procedure to assure that safety precautions are taken".

In view of your determination that your department has in some instances not completey complied with the afore mentioned Procedures and Codes, it is advised that use of the Brachytherapy Room and its surroundings are not be used until this matter has been resolved within your department.

I/27

Release

CC:

Dr.