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

October 10, 1989

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Request No. 3-89-005
Allegation No. RIII-88-A-0174

MEMORANDUM FOR: Eugene T. Pawlik, Director, Office of Investigations
Field Office, Region III

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

SUBJECT: REQUEST FOR INVESTIGATION

University of Cincinnati
Licensee/Vendor/Applicant

34-06903-05
License No.

University of Cincinnati
Facility or Site Location

Carl J Paperiello

A. Bert Davis
Regional Administrator

Oct 10, 1989
Date

A. Request

What is the matter that is being requested for investigation (be as specific as possible regarding the underlying incident).

In December 1988, a Region III inspector received an anonymous allegation that some records (no further information) may have been hidden from the NRC during an August 1988 inspection. In January 1989 this individual recontacted Region III with some additional information and agreed to provide further information in the future. No further information was forthcoming. During followup on other allegations in September 1989, the Region III inspection obtained information that the University RSO and Assistant RSO may have been involved in withholding sealed source inventory and leak test records from NRC review during an inspection to avoid the discovery of several sources that had been missing for two years.

B. Purpose of Investigation

1. What is the basis for the belief that the violation of a regulatory requirement is more likely to have been intentional or to have resulted from careless disregard or reckless indifference than from error or oversight? (be as specific as possible).

3-89-011

EXHIBIT 1

A/3

Eugene T. Pawlik October 10, 1989

An NRC inspector conducting a review of Allegations RIII-88-A-0174 and RIII-89-A-0084 during an onsite inspection the week of September 18, 1989, was presented with documentation (Enclosures 1-3) that sealed source records were intentionally concealed from an NRC inspector in 1988.

2. What are the potential regulatory requirements that may have been violated?

Materials License Conditions 12.c. and d. - Sealed Source Leak Test and Record Requirements
Materials License Condition 14 - Physical Source Inventories and Record Requirements
10 CFR 30.9(a) - Completeness and Accuracy of Information
10 CFR 30.51(b) - Record Retention Requirements
10 CFR 30.52(b) - Inspections

3. If no violation is suspected, what is the specific regulatory concern?

N/A

4. Why is an investigation needed for regulatory action and what is the regulatory impact of this matter, if true?

The investigation is needed in order to determine the culpability of the licensee in the intentional concealment of records. Investigative effort is also needed to determine the level of licensee management involvement. This effort is required to evaluate what action to take against the licensee and/or individuals.

C. Requestor's Priority

1. Is the priority of the investigation high, normal, or low?

High (A.3)

2. What is the estimated date when the results of the investigation are needed?

January 2, 1990

3. What is the basis for the date and the impact of not meeting this date? (For example, is there an immediate safety issue that must be addressed or are the results necessary to resolve any ongoing regulatory issue and if so, what actions are dependent on the outcome of the investigation?)

The date selected was based on allowing 90 days to conduct the investigation and prepare the report. While the sources have not yet been recovered, no immediate safety significance is attached since the sources do not represent a substantial safety hazard unless

they are dismantled and ingested (Nickel-63) and the licensee has administratively suspended the individuals allegedly involved. The significance may change if the licensee determines that it wants to reinstate the individuals.

D. Contact

1. Staff members:

Wayne J. Slawinski, Division of Radiation Safety and Safeguards

2. Allegers identification with address and telephone number if not confidential. (Indicate if any confidential sources are involved and who may be contacted for the identifying details.)

Anonymous

E. Other Relevant Information

See enclosures.

Carl J. Paperiello Jr

A. Bert Davis
Regional Administrator

Enclosures:
1. August 2, 1989 ltr from P. Jason to Dr. J. F. Wiot
2. August 18, 1989 ltr from Dr. J. F. Wiot to P. Jason
3. August 21, 1989 ltr from P. Jason to Dr. J. F. Wiot
4. August 22, 1989 Dr. B. Mallett handwritten mtg notes
5. August 13, 1984 University of Cincinnati application for renewal of Byproduct License No. 34-06903-05
6. U. of C.'s Materials License Amendment No. 55 Pages 6 of 6
7. D. R. Gibbons Inspection Field notes Inspection Report No. 88001 and NRC Form 591

cc w/enclosures:
J. M. Taylor, DEDR
R. M. Bernero, NMSS
J. Lieberman, OE
J. Goldberg, OGC
B. B. Hayes, OI

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UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 558-4110

234 Goodman Street
Old Operating Pavilion Basement
Cincinnati, Ohio 45267-0581

August 2, 1989

Dr. Jerome F. Wiot
Chairman Radiology
Professor
M.L. 742

Dear Dr. Wiot:

This memo serves to certify that I do have knowledge of various documents which were intentionally concealed from a Nuclear Regulatory Commission inspector during an on-site inspection of our broad license. Kenneth M. Fritz, the University of Cincinnati's Radiation Safety Officer, directly ordered me to do so and I felt as if I had no other choice but to follow that directive. Enclosed you will find other documents on sealed radioactive sources that have been "missing" for some time now as is evidenced by the dates of their last being tested for leakage. To the best of my recollection, Mr. Fritz has seen this information. This report is freely and willing furnished to you with the hope that it will help to rectify the problems with which we all are currently confronted. My signature below verifies the aforesaid.

Respectfully yours,

Prince Jason

Prince Jason
Deputy Radiation Safety Officer
University of Cincinnati

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University of Cincinnati
Radiation Safety Committee

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mail Location #591
Telephones:
Radiation Safety Office 558-4110
Administration 558-9061

513/558-4396

August 18, 1989

Mr. Prince Jason
Deputy Radiation Safety Officer
University of Cincinnati
Cincinnati, Ohio 45267-0591

Dear Mr. Jason:

Thank you for your letter. Please be assured that the matters to which you refer will be thoroughly investigated. In that regard, could you please provide me with the following supplemental information:

1. Can you identify the documents (specifically or by category) which were "intentionally concealed from a Nuclear Regulatory Commission inspector during an on-site investigation of our broad license?"

2. When did the concealment occur? How long did it last? What on-site inspection did it affect?

3. How was the concealment accomplished - were the documents removed from the files, misfiled so they wouldn't be noticed, or never filed at all? Were the document logs altered in any way so as to assist the concealment?

4. Are the "other documents" you enclosed with your letter different from the ones that were concealed from the NRC inspector?

5. What do you mean when you say the documents have been "'missing' for some time now"? Have they also been deliberately concealed? If so, how and by whom were they concealed? If not, were the documents "missing" because they were lost or misfiled? If so, who is responsible?

I appreciate your assistance in our continuing efforts to achieve full and complete compliance with all Nuclear Regulatory Commission requirements.

Sincerely,

Jerome F. Wiot, M.D.
Chairman
Radiation Safety Committee

JFW/kam

cc: F. Trejo

EXHIBIT 1

UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 558-4110

234 Goodman Street
Old Operating Pavilion Basement
Cincinnati, Ohio 45267-0591

August 21, 1989

Dr. Jerome Wiot
Chairman Radiology
Professor
University of Cincinnati
Cincinnati, Ohio 45267-0742

Dear Dr. Wiot:

I appreciate your concerns and actions in regard to the information which has been given to you. I shall here commence to answer the questions posed in your letter dated August, 18, 1989. In doing so, there are a few corrections and/or clarifications which I must make.

1. The incident whereupon sealed source documents were "concealed" from the NRC inspector did not actually occur while he was on-site. My technical staff made me aware of this as they, too, are knowledgeable of the happening. It was the Friday before the inspector arrived (August 19, 1988) that Mr. Fritz reviewed all of the sealed source documents and sorted out those that he could see had any type of discrepancy. He then handed those documents to me and told me to "... here, do something with these" , or "... here, put these somewhere." I then took the documents from his office, brought them out to the office area where our technicians' desks are and gave them to one of our staff members who placed them in the back of a desk drawer. All of us - myself, Mr. Fritz and the technicians - knew that the inspector was due to arrive the following Monday, August 22, 1988. I can identify these documents as I have them in my possession. I sent you photocopies of most or all of them in my original letter.

2. As stated in item 1 above, this action took place on Friday, August 19, 1988 and has endured until the present. It affected the inspection of August 22-25, 1988. A copy of that inspection report is enclosed.

3. There was no alteration of the documents and item 1 above describes the manner in which they were withheld.

4. No. Those are the ones. As stated, I have them. There may be more; I do have others.

5. I do not believe that I said any documents were missing. If I did, it was erroneous wording on my part. Yet, this also, is probably the case as is

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5. (cont.)
evidenced by the fact that we could find no records in our office of the three tritium foils which were found in room 524 of the IDR building on Wednesday, July 26, 1989. Nonetheless, what I did say (or meant to) was that the sources have been "missing for some time now". This is what the documents attest to. I have these documents, but since they show that there has not been a leak test performed since 1986, and there is no notation as to their disposition, then the question becomes, "Where are these sources?"

I hope these responses represent a clear understanding of what occurred. If I may be of further assistance, please let me know.

Sincerely,

Prince Jason

Prince Jason
Deputy RSO

PJ/pj
enclosure

cc: F. Trejo

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Mallick's Notes of 8/22/89 meeting with Wiot of U of C

JMG 9/29

② August 1989

8/22/89

Mtg on Staffing resources:

- Space
✓ - Stear = availability
- Sept 1 - 15 in [illegible]
- back to [illegible] — until Oct. 15.

Mtg. w/ Univ. of Cin: Polkey, Nelson
were Mallick, Swierawski, + Francisco Trep.
Licensee: Dr. Wiot, Chairman of Radiology, Senior VP [illegible]
- Senior VP = [illegible] RSO - w/ Don Brewer.
- he chairs RSC.

Bkgd:
- Brewer called Francisco Trep b/c: tech. approached him (4 total in Rad. Safety Office)
- Jan '89 - techs. no problem w/ [illegible] & w/ RSO
- w/ [illegible] - communication [illegible] & personality problems
- [illegible] Jan 89 - [illegible] ([illegible]) felt discrimination job
- [illegible] re what was going on
- then on 8/[illegible] - Jeff [illegible] - called him [illegible] & said one of techs [illegible] & info went to NRC office (NRC). [illegible] in Rad. Safety office [illegible]
- felt wouldn't [illegible] [illegible]. [illegible] "Double [illegible]" to accompanied NRC.
- NRC = started on 8/1[illegible]/89 onsite

- they plan to put RSO & deputy on admin. leave until Stringfellow [illegible] [illegible] interim RSO.

—— they want to use Howard Elson in effect this Friday. on Elson
- Does he have respect of staff in Rad. safety office?
answer: Yes.

- techs: [illegible] from [illegible] [illegible].

- can Wiot make change to license — answer: He has correspondence from VA's office where position [illegible]

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(3)

8/22/89 August 1989

Univ. of Cin. - contd (contd)

? — what experience Elson had w/ Univ. of Cin. program
answer: reviewed license last week

? — he's not familiar w/ program.
answer: - George Alexander familiar & back him
- techs have been there a long time
- NES will work with him.
- techs respect him & he has capability/exp. operating as manager of program.

? availability — this will be his full time program & he will relieved of duties in oncology.

— they also plan to revamp Rad. Safety Program
- ? problems noted. answer: coverage.
- Final audit rpt. 8/4/89. — they will provide to us.

- ? audits in past
- necessarily to see program working outside Rad. Safety office
- told them this was a concern — & we will want to see what doing in future as oversight so Dr. Elson not out there alone.

— we asked them functions needed: — if get two, we will approve.
1. availability
2. assistance to RSO.
- alternate RSO ~~[illegible]~~, assistant RSO
— management oversight.
- support RSO staff. whoever will fcn. in a capacity.

— or Does RSO & Assist. currently know?
— no — they plan to tell after this Friday.
Discussed if ~~[illegible]~~ they are "OK" — they will reinstate.

— Discussed — we have issues at Univ of Cin. & will be in touch about.

compensation / informed of the dilemma } - discussed license renewal & what the NRC & don't want to interfere w/ that process. — we may not have — at same time we have to answer concerns.

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MATERIALS LICENSE

Amendment No. 55

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, ode of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer by product, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. University of Cincinnati	In accordance with application dated August 13, 1984 3. License number 34-06903-05 is amended in its entirety to read as follows:
2. Mail Location 569 Cincinnati, OH 45267-0569	4. Expiration date: May 31, 1991
	5. Docket or Reference No.: 030-02764

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 25 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 10 curies total for all sources authorized in Subitem 6.E.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-06903-05

Docket or Reference number: 030-02764

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
F. Xenon-133	F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	F. 5000 millicuries
G. Uranium (Depleted in Uranium 235)	G. Cadmium plated metal	G. 160 kilograms
H. Any byproduct material with Atomic Nos. 3 thru 83, inclusive	H. Any Hydrogen-3 Iodine-129	H. 3 curies of each isotope, 1000 curies total except as noted below: 500 curies 1 curie
I. Cesium-137	I. Any sealed source approved by the NRC or an Agreement State for licensing purposes	I. 6 curies
J. Americium-241	J. Any sealed source approved by the NRC or an Agreement State for licensing purposes	J. 1 curie
K. Californium-252	K. Any sealed or foil source approved by the NRC or an Agreement State for licensing purposes	K. 15 millicuries
L. Americium-241	L. Sealed source (Troxler Dwg. No. A-102700)	L. 10 millicuries

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MATERIALS LICENSE
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9. Authorized Use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. To be used as shielding in linear accelerator and technetium 99m generators.

H. through K. To be used for medical research, research and development as defined in 10 CFR Part 30, Section 30.4 (q), instruction of students, animal studies and calibration of instruments.

L. To be used in a Troxler Electronics, Inc. Model 3220 portable gauge for measurement of soil moisture.

CONDITIONS

10. A. Licensed material listed in Subitems 6.A., 6.B. and 6.F. below shall be used only at the licensee's facilities located at:

Longview State Hospital
6600 Paddock Road
Cincinnati, Ohio

Highland District Hospital
1275 North High Street
Hillsboro, Ohio

Daniel Drake Memorial Hospital
Galbraith and Vine Street
Cincinnati, Ohio

B. Licensed material listed in Subitems H. through K. shall be used only at the licensee's facilities located at:

The Main Campus of the
University of Cincinnati
Cincinnati, Ohio

Kettering Laboratory
University of Cincinnati
Cincinnati, Ohio

Raymond Walters College
9555 Plainfield Road
Cincinnati, Ohio

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C. Licensed material listed in Subitems 6.A. through 6.K. shall be used only at the licensee's facilities located at:

University Medical Center and Hospitals
234 Goodman Street
Cincinnati, Ohio

Shriner's Burn Institute
202 Goodman Street
Cincinnati, Ohio

Children's Hospital Medical Center
Elland and Bethesda
Cincinnati, Ohio

D. Licensed material listed in Subitem 7.L. may be stored at the Main Campus of the University of Cincinnati, Cincinnati, Ohio, and may be used at temporary job sites of the licensee's throughout the State of Ohio.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, E. L. Saenger, M.D., Chairman. The committee's core membership shall consist of E. L. Saenger, M.D., K. M. Fritz, J. G. Kereiakes, Ph.D., and H. Bruce Bosmann, Ph.D. No member shall be deputized to act in the absense of the Committee Chairman or the Radiation Safety Officer without the specific approval of the Commission.

B. The use of licensed material in or on humans shall be by a physician as defined in Section 35.3(b) of 10 CFR Part 35.

C. The Radiation Protection Officer for the activities authorized by this license is K. M. Fritz.

D. Licensed material listed in Subitem 6.L. shall be used by, or under the supervision and in the physical presence of, individuals who have completed the device manufacturer's training course and have been designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of the individuals who have been designated as authorized users.

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicting that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be field within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, describing the equipment involved, the test results, and the corrective action taken.

13. Sealed sources containing licensed material shall not be opened.

14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.

15. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-06903-05

Docket or Reference number: 030-02764

Amendment No. 55

16. Patients containing iodine-131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of gold-198) shall remain hospitalized until the residual activity is 30 millicuries or less.

17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

18. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

19. Pursuant to Sections 20.106(b) and 20.302 of 10 CFR Part 20, the licensee is authorized to dispose of isotopes specified in Item 14 of application dated August 9, 1984, by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 of 10 CFR Part 20 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR Part 20.

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated August 13, 1984 including attachments dated August 9, 1984; and

    B. Letter dated April 11, 1986.

For the U.S. Nuclear Regulatory Commission

EXHIBIT 1

Date MAY 21 1986

Original Signed
By William J. Adam
Materials Licensing Section, Region III

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COPY

UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 872-4115

M.L. 569
J Pavilion
Cincinnati, Ohio 45267-0569

August 13, 1984

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Materials Licensing Section
U.S. Nuclear Regularatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

Pursuant to your correspondence of July 6 and enclosed in duplicate is our application for renewal of byproduct license 34-06903-05.

Sincerely,

Kenneth M. Fritz
Radiation Safety Officer
University of Cincinnati

KMF:bb

RECEIVED
AUG 17 1984
REGION III

AUG 17 1984

B70B 00215 860521
REG3 LICO
34-06903-05 PDR

Control No. 77319

Item #5: See item 8E for uses at each area.

Item #6

Licensed material used by and under supervision of individuals (Principle Investigators) designated by Radiation Safety Committee,

E.L. Saenger M.D., Chairman

J.G. Kereiakes, Ph.D., Vice Chairman

K.M. Fritz, Radiation Safety Officer

Other committee members selected from the College of Medicine and other Colleges of the University, Nursing, and Administration. Resumes for those listed above are enclosed.

EXHIBIT J

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Responsibilities of the Radiation Safety Committee

a. Review and approve or disapprove applications for the use of radioisotopes within the University and keep records of such actions.

b. Prescribe special conditions that may be necessary for the safe handling of radioisotopes, including additional training, limitation of dosage in humans, designation of limited areas of use, proper disposal methods, and procedures to be followed for spills or other radiation accidents.

c. Receive and review periodic and/or urgent reports of the Radiation Safety Officer regarding:

1. Results of area monitoring.

2. Personnel exposures as measured by suitable dosimeters.

3. Accidents in handling, storage or use of radioisotopes.

d. Take remedial action if safe procedures are not being observed such as ionizing radiation hazard exists or if these procedures are not in compliance with government regulations.

e. Keep department chairmen and other radioisotope users advised of current rules and recommendations of the various government agencies concerned with radiation protection and the safe use of radioisotopes.

f. ALARA responsibilities (see Appendix C)

Applications for routine uses of radioisotopes are given provisional approval by the Chairman or Vice-Chairman of the RSC and Radiation Safety Officer. These applications are then included in the agenda for the next Radiation Safety Committee meeting for Committee discussion and final approval. All new uses of radioisotopes are presented to the Committee and require unanimous approval by members present. Applications for administration to humans for research purposes require written approval from the Radiation Safety Committee. Meetings of the Radiation Safety Committee are held four times yearly. Other meetings can be held on petition of any member of the Committee. Fifty percent of the members constitute a ~~Quorum~~ quorum for voting. Minutes of meetings are kept on permanent file.

The interim business of the Radiation Safety Committee shall be conducted by the Chairman or the Radiation Safety Officer and shall be subject to the eventual approval of the Committee. In the absence of these two individuals those persons deputized may serve in their place.

Principle Investigator is a person named as responsible investigator in an approved protocol.

User is a person working under a Principal Investigator; a physician using radioactive material in the practice of medicine and/or the Principle Investigator.

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Decay - When practicable, radioactive material is held until decayed to background levels. Such determination is made either by direct monitoring (shielding removed) with suitable survey meter or by calculation. Material for decay is kept either in the laboratory of the Principle Investigator or in the Radiation Safety waste storage room. A sketch of this area is enclosed. Criteria for a suitable storage area include the following items: adequate shielding; adequate ventilation, security; proper posting of area; and limiting exposure in adjacent unrestricted areas pursuant to 10CFR20, section 20.105.

ITEM #15 - Radiation Protection Program

Radiation Safety Officer (RSO): The Radiation Safety Officer will be responsible to the Radiation Safety Committee for:

1. Compiling and disseminating information on radiation safety and health physics to physicians, researchers, technologists and nurses involved in handling radioactive materials or caring for patients receiving radionuclides, brachytherapy and other forms of ionizing radiation.
2. Consulting with users of ionizing radiation and giving advice concerning radiological safety.
3. Preparing all NRC license applications and State and municipal registrations for the University of Cincinnati.
4. Reviewing all proposals for uses of ionizing radiation including radionuclides and external sources of radiation, e.g., x-rays, accelerators and other devices.
5. Ordering, receiving and recording all radioisotopes and maintaining all records pertinent thereto.
6. Maintaining personnel exposure records and providing personnel and area monitoring, including film badge service.

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7. Suspending immediately any operation causing a radiation hazard.

8. Performing routine and special radiation surveys as deemed necessary for radiation safety.

9. Approving construction and remodeling of all facilities intended for radioisotope or ionizing radiation use.

10. Supervising disposal of all radioactive wastes.

11. Administering the Radiation Safety Program.

12. Making available courses for training persons in the safe use of radioisotopes and radiation producing devices.

13. Supervising calibration and maintenance of instruments used in the Radiation Safety Program.

14. Supervising decontamination and preventing the spread of contamination in case of accidents.

15. Notifying NRC and other agencies as required.

Deputy Radiation Safety Officer (DSRO): Routine operation of the University Radiation Safety Program under supervision of the Radiation Safety Officer. The DSRO assumes responsibility of the RSO in his absence and is therefore responsible to the Radiation Safety Committee. The DSRO is instructed to consult with the Committee Chairman, Vice-Chairman, or other Committee members in the event of the absence of the RSO when problems arise.

EXHIBIT 1
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Area Survey Program - Each protocol approved by the RSC has a required wipe test frequency to be followed by the users. Compliance in following this frequency is verified during inspection of laboratory procedures and radioactive material users by Radiation Safety Office personnel. The required wipe test frequency varies for different radioactive material uses. The

UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 872-4115

M.L. 569
J Pavilion
Cincinnati, Ohio 45267-0569

August 13, 1984

EXHIBIT 1
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Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

Pursuant to your correspondence of July 6 and enclosed in duplicate is our application for renewal of byproduct license 34-06903-05.

Sincerely,

Kenneth M. Foltz
Radiation Safety Officer
University of Cincinnati

RECEIVED
AUG 17 1984
REGION III

AUG 17 1984

8708100215 860521
REG3 LICBO
34-06903-05 PDR

Control No. 77319

Item #5: See item 8E for uses at each area.

Item #6

Licensed material used by and under supervision of individuals (Principle Investigators) designated by Radiation Safety Committee,

E.L. Saenger M.D., Chairman

J.G. Kereiakes, Ph.D., Vice Chairman

K.M. Fritz, Radiation Safety Officer

Other committee members selected from the College of Medicine and other Colleges of the University, Nursing, and Administration. Resumes for those listed above are enclosed.

Responsibilities of the Radiation Safety Committee

a. Review and approve or disapprove applications for the use of radioisotopes within the University and keep records of such actions.

b. Prescribe special conditions that may be necessary for the safe handling of radioisotopes, including additional training, limitation of dosage in humans, designation of limited areas of use, proper disposal methods, and procedures to be followed for spills or other radiation accidents.

c. Receive and review periodic and/or urgent reports of the Radiation Safety Officer regarding:

1. Results of area monitoring.

2. Personnel exposures as measured by suitable dosimeters.

3. Accidents in handling, storage or use of radioisotopes.

d. Take remedial action if safe procedures are not being observed where ionizing radiation hazard exists or if these procedures are not in compliance with government regulations.

e. Keep department chairmen and other radioisotope users advised of current rules and recommendations of the various government agencies concerned with radiation protection and the safe use of radioisotopes.

f. ALARA responsibilities (see Appendix C)

Applications for routine uses of radioisotopes are given provisional approval by the Chairman or Vice-Chairman of the RSC and Radiation Safety Officer. These applications are then included in the agenda for the next Radiation Safety Committee meeting for Committee discussion and final approval. All new uses of radioisotopes are presented to the Committee and require unanimous approval by members present. Applications for administration to humans for research purposes require written approval from the Radiation Safety Committee. Meetings of the Radiation Safety Committee are held four times yearly. Other meetings can be held on petition of any member of the Committee. Fifty percent of the members constitute a ~~Forum~~ Quorum for voting. Minutes of meetings are kept on permanent file.

The interim business of the Radiation Safety Committee shall be conducted by the Chairman or the Radiation Safety Officer and shall be subject to the eventual approval of the Committee. In the absence of these two individuals those persons deputized may serve in their place.

Principle Investigator is a person named as responsible investigator in an approved protocol.

User is a person working under a Principal Investigator; a physician using radioactive material in the practice of medicine and/or the Principle Investigator.

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Decay - When practicable, radioactive material is held until decayed to background levels. Such determination is made either by direct monitoring (shielding removed) with suitable survey meter or by calculation. Material for decay is kept either in the laboratory of the Principle Investigator or in the Radiation Safety waste storage room. A sketch of this area is enclosed. Criteria for a suitable storage area include the following items: adequate shielding; adequate ventilation, security; proper posting of area; and limiting exposure in adjacent unrestricted areas pursuant to 10CFR20, section 20.105.

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NRC FORM 591 (12-84) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

DMB COPY

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
University of Cincinnati Mail Location 569 Cincinnati, Ohio 45267	U.S. NUCLEAR REGULATORY COMMISSION REGION III 799 ROOSEVELT RD. GLEN ELLYN, IL 60137

3. DOCKET NUMBER(S)		4. LICENSE NUMBER(S)		5. DATE OF INSPECTION
030 18949	030 02764	34-06903-09	34-06903-05	August 22-25, 1988
030 20526	030 11331	34-06903-12	34-06903-11	
	030 19588		34-06903-13	

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. This inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

[ ] 1. Within the scope of this inspection, no violations were observed.

[X] 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

[X] 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

[ ] A. _____ was not properly posted to indicate the presence of a _____, 10 CFR 20.203(b), (c), (d), (e) or 34.42.

[ ] B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

[ ] C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

[X] D. Records of Monthly spot checks for July 1987 of a Co-60 Teletherapy unit were not properly maintained. 10 CFR 35.654 (f) or License Condition Number For license No. 34-06903-12.

[ ] E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

[ ] F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

[X] H. License No. 34-06903-05 Radiation survey instruments were not calibrated annually as required 10 CFR 35.51, License Condition 20

[X] I. Weekly wipe tests at one of the licensee's locations were not done at the proper intervals and records of wipe test at two other locations were not properly maintained. 10 CFR 35.70 (h) License Condition 20

[X] J. Records of semiannual ventilation check for 1987 and 1988 and annual air flow measurements of hoods were not properly maintained. 10 CFR 35.205 (e) and License Condition 20

[X] K. The licensee failed to maintain on file the certification required for packages declared DOT 7A Type A used to ship radioactive material from December 19, 1987 to August 19, 1988. 10 CFR 71.5; 49 CFR 173.415(a)

I/we state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above, and the requirements of 10 CFR 2.201. No further response will be submitted unless required by statement of correct ERC.

8809060103 880822
REG3 LIC30
34-06903-05 PNU

EXHIBIT 1

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Kenneth M Fitz — SIGNATURE – LICENSEE — 8/26/88 DATE

D. R. Gibson — SIGNATURE – NRC INSPECTOR — 8/29/88 DATE

IE07 c/1

Broad Medical

NUCLEAR MEDICAL INSPECTION FIELD NOTES

Inspection Report No. 88001 License No. 34-06903-05

Licensee (name and address) Docket No. 03002764

UNIVERSITY OF CINCINNATI,

MAIL LOCATION 564

CINCINNATI, OH 45267

Licensee Contact K. M. FRITZ Telephone No. 513-872-4115 (558-4110)

Last Amendment No. 58 Date of Amendment Nov. 20, 1987

✓Priority 2 Category C.I

Program Codes:
- (✓) 02110 - Broad
- ( ) 02120 - Group Hospital
- ( ) 02121 - Non-Group Hos.
- ( ) 02200 - Private Practice - Group
- ( ) 02201 - Private Practice - Limit
- ( ) 02220 - N.M. Van
- ( ) 02209 - InVivo Testing
- ( ) 02500 - Pharmacy
- ( ) 02210 - Eye Application
- ( ) Other

Date of Inspection AUGUST 22-25, 1988

Type of Inspection: ( ) Announced (✓) Unannounced (✓) Normal
( ) Initial ( ) Special (✓) Reinspection

Next Inspection Date 08 90

(✓) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No Violation, Clear 591 issued
(✓) Violation(s), 591 issued
( ) Action on Previous Violation
( ) Regional Action
( ) Headquarters Action

Persons contacted: KENNETH M FRITZ - RSO
DR. J. G. KERRIGAN - VICE CHAIRMAN RSC
DR. J.W. VESTER - ASSOCIATE DEAN
DR. K.W. ROWE - V.P.
GEORGE ALEXANDER - DIR. MEDICAL AND RADIATION SAFETY OFFICER
CARL HARRIS - DIRECTOR OF RISK MANAGEMENT

Those present at exit interview: ALL OF ABOVE

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Inspector D. R. Gilbert (Signature) August 29, 1988 (Date Signed)

Approved M. D. Ludeman (Signature) 8/30/88 (Date Signed)

1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No (L/C)
Remarks: JOSEPH STEGER - PRES. OF THE UNIV.
KENNETH ROWE - V.P. OF UNIV. PRES OF THE UNIV MED. CENTER
JOHN W. VESTER - WILL BE TAKING DR. ROWE'S POSITION
J.F. WIOT - CHAIRMAN RSC
GEORGE ALEXANDER - ADMINISTRATIVE DIRECTOR
K.M. FRITZ - RSO

b. Use by authroized individuals. (✓) Yes ( ) No (L/C)
Remarks: THE RSC APPROVES EACH USER (APPROX 150) AND MANY ARE BOARD CERTIFIED. THE USERS ARE CONSIDERED THE PRINCIPLE INVESTIGATOR. THEY TRAIN AND SUPERVISE PERSONNEL WHO HAVE COMPLETED A SAFETY COURSE PRESENTED BY THE RADIATION SAFETY OFFICE

c. Radiation Safety Committee meets at required intervals. (✓) Yes ( ) No (35.22 (a)(2)) 4 TIMES EACH YEAR - REVIEWED RECORDS TO 8-12-86
THEY ALSO HAVE TWO SUBCOMMITTEES, ONE FOR X-RAY AND ONE FOR TELETHERAPY
Membership in accordance with 35.22 (a)(1) L/C (✓) Yes ( ) No
INCLUDES UPPER MANAGEMENT AND NURSING STAFF
RECORDS INDICATE ABOUT 0F THE COMMITTEE ATTENDS THE MEETINGS

d. Record of Committee meetings. (✓) Yes ( ) No (L/C or 35.22 (a)(4))
Remarks:

2. INSPECTION HISTORY

a. Item(s) of violations or deviations noted during last inspection conducted on Nov. 17-21, 1986 (X) Yes ( ) No.

Response letter dated JANUARY 21, 1987

b.

Requirement	Type of Violation	Corrective Action Taken (X) Yes ( ) No	Status Oper. Clos
10CFR 20.207 b	A 100 MCi TC99m GENERATOR WAS LEFT UNATTENDED - CLOSED		
✓ L/C 20	SURVEY INSTRUMENTS DID NOT HAVE CORRECTION FACTORS ATTACHED WHEN REQUIRED. - CLOSED		
L/C 20	SEVERAL GENERAL PURPOSE LABS WERE NOT WIPE TESTED - MONTHLY - C		
10CFR 35.48	THE LICENSEE FAILED TO SUBMIT THE PROPER NOTIFICATION OF SEVEN MISADMINISTRATIONS - CLOSED		
10 CFR 20.203 (f)(1)(2)	A BARREL WAS NOT PROPERLY LABELED.		

(continue b. paragraph 20, if needed)

c. If any item(s) of violations or deviations noted during last inspection were not corrected, explain.

EXHIBIT 1

3. SCOPE OF PROGRAM

This is a large University engaged in academic and medical Research. They provide various other nuclear medical services. Most of the Research labs are located in the West Campus. The Children's Hospital, The Holmes Hospital use doses from the 2.7 Ci Mo-99 Generator located at the University Hospital. They do Tissue studies with various isotopes, mainly H-3, C-14, I-125, P-32 and Sm-153.

4. INTERNAL AUDITS OR INSEPCTIONS

THERE ARE ABOUT 150 protocols on file at present, or 450 uses that can be conducted. few of these are used.

a. Required by license condition. (✓) Yes ( ) No

b. Audits or inspections conducted (✓) Yes ( ) No (L/C)
PERFORMED BY RAD. SAFE OFFICE PERSONNEL (ASST. RSO AND 4 TECHNOLOGIST)

c. Records maintained. (✓) Yes ( ) No (L/C)
Remarks: The licensee has instituted a questionnaire for each user, and for each protocol. The questions concern the use, who build-ups and the training, WIPE SCHEDULES AND SURVEYS ETC.
THEY PERFORMED 478 AUDITS IN 1981 AND 2285 ROOMS SURVEYED.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. Training program required by license condition. (✓) Yes ( ) No

b. Training program implemented. (✓) Yes ( ) No (L/C)
Remarks: ANY STUDENTS, OR STAFF PERSONNEL WITH NO PREVIOUS TRAINING WHO PLAN TO USE RPM, ARE REQUIRED TO COMPLETE A TRAINING COURSE CONDUCTED AT LEAST TWICE EACH YEAR. THE RAD. SAFE. OFFICE PERSONNEL THE COUNCIL. MEDICAL STAFF ARE TRAINED WHEN HIRED.

c. Retraining program required by license condition. (✓) Yes ( ) No

d. Retraining program implemented. (✓) Yes ( ) No (L/C)
Remarks: PERIODIC NEWLETTER AND ANNUAL RETRAINING FOR NURSING STAFF AND HOSPITAL PERSONNEL

e. Instruction to workers in accordance with 10 CFR 19.12 (✓) Yes ( ) No (19.12)
Remarks:

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There is no more work at the Critical station at the present time.

All of the RAM used at the University is ordered through the Radiation safety office (Ram Serv. Org.) is delivered to that office, and the Consignee picks up the material from that office.

The univ. has 10-15 nuclear Med. Techs.

EXHIBIT 1

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6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedure referenced in license condition. (✓) Yes ( ) No

b. Used in accordance with referenced procedure. (✓) Yes ( ) No
Remarks:

c. Individuals understanding of procedures adequate. (✓) Yes ( ) No
Remarks:

d. Examples of key procedures:

(1) ordering and accepting packages RAM (✓) Adequate ( ) Inadequate

(2) general rules for safe use of RAM (✓) Adequate ( ) Inadequate

(3) emergency procedures (✓) Adequate ( ) Inadequate
POSTED IN MOST AREAS.

(4) survey procedures (✓) Adequate ( ) Inadequate
THE LICENSEE HAS A NEW FORM THAT WILL, HOPEFULLY, HELP RAD. SAFE. PERSONNEL GET BETTER REPORTS

(5) handling of volatile RAM (e.g., Xe-133, I-131)
(✓) Adequate ( ) Inadequate
USED UNDER, OR IN HOODS

(6) precautions for use of RAM (sealed and unsealed) for therapy
(✓) Adequate ( ) Inadequate

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (✓) Yes ( ) No (L/C)
Remarks: SURVEYED AND INSPECTED VARIOUS LAB AREAS AND THE THREE HOSPITALS THAT DO MOST OF THE NUCLEAR MEDICINE

b. Isotope, chemical form, quantity and use as authorized. (✓) Yes ( ) No (L/C
Remarks:

EXHIBIT 1

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c. Tests required by license condition or regulations.

(1) molybdenum-99 breakthrough. (✓) Yes ( ) No (35.204(a))

(2) performed as required. (✓) Yes ( ) No
(L/C and/or 35.204(b))

(3) records maintained. (✓) Yes ( ) No (35.204(c))
Remarks: DONE AT THE UNIV. HOSPITALS

(4) leak tests (✓) Yes ( ) No

(5) leak tests performed as required. (✓) Yes ( ) No (L/C)
(35.59 (b)(1), 35.59 (b)(2), 35.59 (c)(1))
Remarks:
RECORDS IN RAD. SAFE. OFF.

(6) other tests required (e.g., physical inventories; surveys to ensure that patients contain 30 millicuries of Au-198, I-131 before leaving hospital) (L/C or 35.75)
MOST PATIENTS RECEIVE LESS THAN 30 MCi

d. Inventory of sealed sources.

(1) Inventory of Group VI sources. (✓) Yes ( ) No (35.59 (g))
DONE QUARTERLY

(2) Inventory of calibration sources. (✓) Yes ( ) No (35.59 (g))

e. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (✓) Yes ( ) No

(2) Radioactive material secured to prevent unauthroized removal from an unrestricted area. (✓) Yes ( ) No (20.207)
Remarks: THE THREE HOSPITALS HAVE THEIR AREAS BOTH CONTROLLED ACCESS. THE AREA IS USUALLY OCCUPIED AND/OR LOCKED.

f. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those decribed in license application. (✓) Yes ( ) No (L/C or 35.120, 35.220, 35.330, or 35.420)
Remarks:

(2) Capability of radiation survey instruments is adequate for program (✓) Yes ( ) No
Remarks:

EXHIBIT 1

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(3) Calibration of survey instruments required. (✓) Yes ( ) No
6 MO. AND ANNUAL

(4) Performed as required. ( ) Yes (✓) No (L/C or 35.51)
Remarks: CSM-5 SN 2835 LAST DONE 12-86
E120A SN 9321 DONE 7-21-86 AND 2-8-87 MAY NOT BE USED DURING THIS TIME
CSM-5 SN 2627 DONE 6-26-86 6-12-87
↓ 2787 DONE 8-14-86 7-7-87
OVER

The survey instruments not Calibrated (as required, may not have been used, may not be used under the license, or may have been sent back to Vendor for repair. The license will try to determine which of the Category fits the instruments. We were able to determine 5 or 6 others were damaged and not used, Calibrated elsewhere, or ~~did not~~ was not used.

✓ all of the Radiation Safety instrument are done at 6 mo. intervals, and are used for most of the surveys at labs

EXHIBIT 1

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5A

(5) Dose calibrator checks required. (✓) Yes ( ) No
Daily, Quarterly annually at each hospital

(6) Performed as required. (✓) Yes ( ) No (L/C or 35.50)

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

Where stored? all deliveries are during normal hours or RSO staff notified at time

Security? locked storage Vault inside locked room.

a. Survey of incoming packages. (✓) Yes ( ) No (20.205(b)(1)) - L/C)
Remarks: most packages exempt from surface survey but all are wipe tested opened and wipe test of inner container

b. Record of survey. (✓) Yes ( ) No (20.401(b))
Remarks:

c. Procedure for opening packages. (✓) Yes ( ) No (L/C; 20.205(d))
Remarks:

d. BPM transferred in accordance with 10 CFR 30.41. (✓) Yes ( ) No (30.41)
Remarks:

e. Records of receipt and transfer maintained. (✓) Yes ( ) No (30.51)
Remarks:

EXHIBIT 1

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9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier LANDAUER Frequency MONTHLY

b. Reports reviewed by RSO AND STAFF Frequency AS RECEIVED
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 9-15-86 to 8-14-87

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes (*) No Complete: ( ) ~~Yes~~ ( ) No

(2) NRC-5: (*) Yes ( ) No Complete: (*) Yes ( ) No
(20.401 (a)) SOCIAL SEC. NO. AND D.P. WERE NOT ON ALL OF LANDAUER
Remarks: REPORTS, BUT ARE LISTED ON THE UNIV. FILE. FOR THOSE MISSING THE RSO HAS REGISTERED EACH BADGE HOLDER (APPROX 1400) ON A COMPUTER FILE. THE FILE IS USED TO DETERMINE WHO DOESN'T RETURN BADGES ON TIME. THESE PEOPLE ARE CONTACTED TO SEE IF THEY NEED, WANT, OR REQUIRE BADGES. SOME MAY BE TAKEN OFF LIST IF BADGES ARE NOT NEED

e. Maximum ~~quarterly~~ annual whole-body exposure.

1985	1987	1988
G 312	H 129	G 490
W4 312	W-2-329	W2 2570

f. Maximum ~~quarterly~~ annual extremity exposure.

W3 912	W4 277	W4 2560

EACH PERSON WHO WEARS FINGER TLDS - GETS ONE FOR EACH HAND.

g. Licensee has implemented an ALARA program. (*) Yes ( ) No (35.20)
Remarks: REVIEWED DURING RSC MEETINGS

h. Radiation survey of unrestricted areas. (*) Yes ( ) No
(20.201(b) to show compliance with 20.105 (b), 35.415(a)(4), 35.315(a)(4)
Remarks:

i. Record of surveys maintained. (*) Yes ( ) No (20.401 (b) to show compliance with 20.105(b) 35.315(a)(4) or 35.415(a)(4))
Remarks:

EXHIBIT 1

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j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.). (_) Yes ( ) No (L/C or 35.70, 35.59(h), 35.315(a)(4))
Remarks: DRUM STORAGE AREA SURVEYED QUARTERLY 1-22-87 6-5-87 8-
AND DOSE DURING SHIPMENTS OF WASTE DURING AUGUST 1987 AND JAN. APR. AUG 1
WIPING SURVEY OF CHILDRENS MEDICAL CENTER (WIPE TESTS) NOT PERFORMED
7-8-88 TO 7-22-88. AND ROOM G-507 OF MICRO BIOLOGY AND CHEM
IS FAILED TO RECORD WIPE TESTS
PERFORMED SINCE JAN. 1986

the person who performed, or [illegible] wife test at CHMC was on Vacation. The person wife test results were found in another location (drawer). The licensee will be told with the person when she returns to see if she misplaced the other results, or forgot to do the test. The licensee will impress on the tech to record the results.

Room 6409 - The technician in charge then did not realize the wife test results were required to be maintained. She would discard them during routine clean up. There is a language barrier there that licensee personnel are going to try to get through.

Room 6507 - There is a language problem there, also. Records for wife visit on Jan. 20, 1988 were not available during the inspection, because the results were sent to the wrong person and apparently misfiled. That person was on Vacation. Personnel will try to locate them (if not discarded) and ~~[illegible]~~ the people to get the records them or forward to Rad. Safe. Office.

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k. Record of survey maintained. (✓) Yes ( ) No (L/C, 35.70(h), 35.415(a)(4)) except for the note.

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (✓) Yes ( ) No
Remarks: The licensee receives four 10 mCi Vials Xe-133 and five 20 mCi Vials weekly. The xenon traps have a ✓ xenolert alarm. I-131 less than 30 mCi usually in liquid form is given inside hoods under negative pressure

b. Monitoring for airborne radioactivity conducted. (✓) Yes ( ) No (20.201(b)) to show compliance with all sections of 20.103 - (L/C, or 35.205)
Remarks: SEMI ANNUAL TESTS OF THE XENON HOODS AND I-131 AREA. ANNUAL CHECKS OF HOODS.
PERSONNEL IN MAINTENANCE HAVE BEEN DOING THE HOODS AND SOME OF THE HOSPITAL AREAS, BUT RECORD ONLY IF WORK IS REQUIRED. ALL HOODS IN THE UNIV. ARE CHECKED.

c. Records of monitoring maintained. (✓) Yes ( ) No (20.401(b) or L/C or 35.205(d)) EXCEPT FOR THE HOODS IN 1987, MAINTENANCE DID NOT
Remarks: KEEP RECORDS FOR 1987. RAD SAFE DID THIS ONES THEY WERE RESPONSIBLE FOR IN 1988 AND RECORDED. RAD SAFE PERSONNEL WILL DO THESE, OR HAVE MAINTENANCE RECORD OF THE PROPER FORM. (OVER)

d. Bioassay program implemented as described in correspondence with NRC (✓) Yes ( ) No (L/C or 35.315(a)(8))
Thyroid Counts on personnel who use I-131 or I-125 above 2 mCi's
Revised 11-86 To 9-15-88 386 COUNTS ✓ MAX 7.9 NCi I-125
11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL ✓ MAX. 30 NCi I-131

a. Radioactivity in effluents to unrestricted areas. (✓) Yes ( ) No

b. Release in accordance with regulatory limits. (✓) Yes ( ) No (20.106(a))
Remarks: The licensee did incinerate, but has discontinued late 1986. all waste is held.

c. State solid waste disposal method. 235 barrels in 1987 4 SHIPMENTS
166 DRUMS in 1988 3 SHIPMENTS

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d. State liquid waste disposal method. SEWER OR HOLD FOR DECAY. RECORDS INDICATE THAT THE LICENSEE MAY BE APPROACHING 1 Ci/YR. PROGRAM HAVE PUT ~~DOWN THE DRAIN~~ A LOT MORE OF S-35 THIS YEAR THAN OTHER YEARS. USERS HAVE BEEN CAUTIONED ABOUT THIS DISPOSAL

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (✓) Yes ( ) No (L/C or 35.92)
Remarks:

The Xenon rooms were tested for negative pressure at one of the hospitals (HIGHLAND)

on 1-30-87
9-21-87
2-22-88
6-29-88

and Holmes on 1-11-88. These were recorded. The Holmes hospital did not check negative. a new system was installed there, and tested by maintenance, but they did not record or inform Rad Safe of the results.

There were no records of the Univ. hospital xenon rooms being done, but these are checked by hospital personnel. The person doing the study and maintaining the records is on Vacation. Rad Safe personnel will get the records and maintain them and all of the other Ventilation records.

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f. Records of disposal. (✓) Yes ( ) No (30.51 or 35.92(b))
Remarks:

g. Survey of waste prior to disposal. (✓) Yes ( ) No
(20.201(b) to show compliance with 20.301 35.92(a)(2))
Remarks: RECORDS OF HOLMES, CHMC AND HIGHLAND AT THE UNIV. HOSPITALS OTHER LAB AREAS HAVE THE RECORDS IN THEIR LABS, OR IS PART OF WASTE SHIPMENTS ORDERS

h. Records of surveys maintained. (✓) Yes ( ) No (20.401(b) or 35.92(b))
Remarks:

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).
(✓) Yes ( ) No (19.13)
Remarks:

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
(✓) Yes ( ) No (20.405(a))
Remarks: LICENSEE HAS RECORDED AND KEPT RECORDS OF INVESTIGATIONS INTO ALARA LIMITS AND TWO INCIDENTS OF BADGES EXPOSED. ONE WAS PUT IN THE IRRADIATOR AT THE BLOOD CENTER. THE PERSON WHO DID THAT WAS REPRIMANDED

c. Licensee in compliance with 10 CFR 20.403 (incidents).
(✓) Yes ( ) No (20.403)
Remarks: THE LICENSEE REPORTED FEB. 15, 1988 THAT HE HAS SOURCE LEAKING Co-57 ON 9-1-87 AND Sm-153 8-17-87. ALL DETECTED DURING 6 MO. CHECKS. ALL TAKEN OUT OF SERVICE, PROPERLY PACKAGED AND RETURNED TO VENDOR ~~FOR~~ OR WASTE DISPOSAL

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
(✓) Yes ( ) No (20.402(a) or 20.402(b))
Remarks: JAN. 4, 1988 REPORTED A THEFT OF 3 # micro Ci of I-125 in morphine. licensee has taken corrective action. BPM is locked in freezer inside locked room.

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e. Licensee in compliance with 10 CFR 35.33 and 35.44 (misadministration). (✓) Yes ( ) No (35.33a,b,c or d) and 35.44)
Remarks: Notified RIII Sept. 28, 1987 of 3 that happened on 9-17-87
They also record those that do not fall under the reportable area of new part 35? I think they do

13. POSTING OF NOTICES

Notices to workers posted. (✓) Yes ( ) No (19.11(a) or (b)) (19.11(c))
Remarks: in all lab areas.

14. CONFIRMATORY MEASUREMENTS/INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument Ludlum 14C NRC Serial No. 017306

c. Describe type and results of measurements and compare with licensee's measurements. Surveyed 45 labs and three hospital areas. All areas were BKG a max of 3 mr/h.
RM 2227 Co-implant 0.5 MR/HR MAX OUTSIDE
RM 2224 Co implant ADJACENT ROOM WAS IS LOCKED POSTED AS RADIATION AREA.

15. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. (✓) Yes ( ) No (20.203 or 35.60 or 35.66)
Remarks: The licensee and inspector located two labs no longer using material, but were posted. The posting will be removed. ~~Rad~~ Rad Safe personnel will be going to go throughout the areas and remove posting that is no longer required.

16. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (✓) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report (✓) Yes ( ) No

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17. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licnesee. (✓) Yes ( ) No.
Remarks: info

c. Licensee took appropriate action in response to Bulletins and Information Notices. (✓) Yes ( ) No
Remarks: info Only.

18. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

	Yes	Violation
a. License makes shipments of RAM? If "Yes", complete the following items.	(✓)	( )

b. Such shipments consisted of:
(✓) radwaste
(✓) sources/products USUALLY BACK TO VENDORS
( ) other _____

c. For radwaste, shipments are:
( ) by licensee, using common carrier
(✓) through Radwaste Broker
name of Broker RADIATION SERVICES ORGANIZATION

d. Licensee is aware of 10 CFR 61:

Radwaste requirements for generators?	(✓)	( )
Licensee has classified and characterized its radwaste? (20.311(d)) THEIR	(✓)	( )

BROKER PERFORMS THE PAPER WORK

✓ LICENSEE DOES NOT HAVE THE TEST RESULTS DECLARING A SHIPPING CONTAINERS DOT7A TYPE A. The Vendors were called during the inspection, and will send copies of the test to the licensee

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19. LIST OF VIOLATION(S)

20. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

Trial Program for Materials Performance Indicators

1. Failure of Radiation Safety Committee (or certain key members of) to meet or discuss meaningful issues. ( ) Yes (✓) No ( ) N/A

2. RSO unable to perform his or her duties due to other unrelated tasks assigned to him or her. ( ) Yes (✓) No ( ) N/A

3. Licensee does not have sufficient technologist/authorized user/radiation staffing for licensed program workload. ( ) Yes (✓) No ( ) N/A
   may increase staff soon by one

4. Numerous customer complaints regarding manufacturers or distributors (AMS, SUMMA, SYNCOR, Mallinckrodt, etc.) ( ) Yes (✓) No ( ) N/A

5. Numerous safety-related allegations which have been substantiated. ( ) Yes (✓) No ( ) N/A

6. Significant number of diagnostic misadministrations (greater than one per thousand procedures). ( ) Yes (✓) No ( ) N/A

7. Radiation exposures approaching 10 CFR Part 20 limits. ( ) Yes (✓) No ( ) N/A

8. Frequent or excessive contamination within restricted areas (greater than 10 x NMSS guidance for release to unrestricted areas). ( ) Yes (✓) No ( ) N/A

9. Excessive missed surveillances (leak testing, inventories, surveys, etc., greater than 50% per year). ( ) Yes (✓) No ( ) No

10. Financial instability of licensee (shoe-string operation, one or two-man operation such that cost of cleanup is significant to continued operations of the facility). ( ) Yes (✓) No ( ) N/A

11. Lack of senior management involvement in licensed activities. ( ) Yes (✓) No ( ) N/A

12. Inadequate consulting services (consultant not findings problems but NRC does). ( ) Yes (✓) No ( ) N/A

13. Radiation Safety Committee give "rubber stamp approvals" to users and/or uses of licensed materials or issues permits for indefinite periods of time. ( ) Yes (✓) No ( ) N/A

Violation No. K (Taken from NOV or 591 Form)

Xerox Additional Sheets For Each Violation

The facts documented in the inspection report should address the following questions for each violation as applicable (MC 0400-05.02.a and b and MC 0610-05.03.e):

1. What was the requirement and, if the requirement was conditional, how were the conditions satisfied which made the requirement applicable ? 10 CFR 71.5 : 49 CFR 172.4. REQUIRED TO HAVE DOT 7A CERTIFICATION

2. How the requirement was violated ? NO DOT 7A CERTIFICATION ON FILE

3. When was the requirement violated and what was the duration of the violation ? 1992 /

4. What was the apparent root cause and contributing casual factors for the violation ? LICENSEE UNAWARE OF REQUIREMENT

5. How and by whom (be specific if an NRC inspector) was the violation discovered ? NRC INSPECTOR DURING RECORD REVIEW

6. Was the violation required to be reported and, if so, what was the applicable reporting requirement ? No

7. Was the violation reported and, if so, when and by whom was it reported ? N/A

8. If the violation was reported, but the report was late, why was the report late ? N/A

9. was the report complete and accurate ? N/A

10. Were there multiple examples of the violation ? No

11. What were the opportunities and when did they exist for licensee staff and management to be aware of the violation ? 1992 TO 1988

12. What were the cirucumstances surrounding the violation which effect the significance of the violation ? LICENSEE UNAWARE OF REQUIREMENT

13. Is the violation indicative of programmatic problems or is it an isolated case ? N/A

14. What short term corrective and remedial action was taken and when was it taken ? LICENSEE CONTACTED VENDORS TO GET CERTIFICATES

15. Did NRC have to intervene to accomplish satisfactory short term correction and remedial action ? N.

16. Were there previous similar NRC inspection or licensee audit findings and, if so, should the corrective actions from those findings have prevented this violation ? NO

The inspection report details should include times, dates, titles of persons types of equipment, and specific factual information responsive to the above listed questions, as applicable. Potential severity level and enforcement options will not be discussed in the inspection report.

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Violation No. J (Taken from NOV or 591 Form)

Xerox Additional Sheets For Each Violation

The facts documented in the inspection report should address the following questions for each violation as applicable (MC 0400-05.02.a and b and MC 0610-05.03.e):

1. What was the requirement and, if the requirement was conditional, how were the conditions satisfied which made the requirement applicable ? 10 C.F.R. 20.1101(b) AIR VENTILATION CHECKS - RECORDS
2. How the requirement was violated ? PERFORMED, BUT RECORDS WERE NOT SENT TO RSO
3. When was the requirement violated and what was the duration of the violation ? 1987 AND 1988
4. What was the apparent root cause and contributing casual factors for the violation ? LICENSEE PERSONNEL WERE NOT SENDING RESULTS TO RSO
5. How and by whom (be specific if an NRC inspector) was the violation discovered ? INSPECTOR AND RSO DURING A REVIEW OF RECORDS AND TOUR
6. Was the violation required to be reported and, if so, what was the applicable reporting requirement ? No
7. Was the violation reported and, if so, when and by whom was it reported ? N/A
8. If the violation was reported, but the report was late, why was the report late ? S/A
9. was the report complete and accurate ? N/A
10. Were there multiple examples of the violation ? No
11. What were the opportunities and when did they exist for licensee staff and management to be aware of the violation ? 1987 AND 1988 DURING AUDITS AND INSPECTIONS
12. What were the cirucumstances surrounding the violation which effect the significance of the violation ? RECORDS WERE NOT SENT TO THE RIGHT PERSONNEL
13. Is the violation indicative of programmatic problems or is it an isolated case ? N.
14. What short term corrective and remedial action was taken and when was it taken ? RECORDS WILL BE SENT TO RSO
15. Did NRC have to intervene to accomplish satisfactory short term correction and remedial action ? No
16. Were there previous similar NRC inspection or licensee audit findings and, if so, should the corrective actions from those findings have prevented this violation ? No

The inspection report details should include times, dates, titles of persons types of equipment, and specific factual information responsive to the above listed questions, as applicable. Potential severity level and enforcement options will not be discussed in the inspection report.

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Violation No. E (Taken from NOV or 591 Form)

Xerox Additional Sheets For Each Violation

The facts documented in the inspection report should address the following questions for each violation as applicable (MC 0400-05.02.a and b and MC 0610-05.03.e):

1. What was the requirement and, if the requirement was conditional, how were the conditions satisfied which made the requirement applicable ? WRITTEN WORK PROCEDURE
2. How the requirement was violated ? RECORDS NOT MAINTAINED 10 CFR 35.70 & L/C 20 AND TESTS NOT DONE WEEKLY AND YEARLY
3. When was the requirement violated and what was the duration of the violation ? JANUARY 20, 1988 TO AUGUST 25, 1988 RECORDS 7-6-88 TO 7-21-88 NOT PERFORMED
4. What was the apparent root cause and contributing casual factors for the violation ? USERS DID NOT REALIZE THEY WERE REQUIRED TO MAINTAIN RECORDS OR FORWARD TO RSO
5. How and by whom (be specific if an NRC inspector) was the violation discovered ? INSPECTOR AND LICENSEE'S RSO DURING TOUR
6. Was the violation required to be reported and, if so, what was the applicable reporting requirement ? No.
7. Was the violation reported and, if so, when and by whom was it reported ? N/A
8. If the violation was reported, but the report was late, why was the report late ? N/A
9. was the report complete and accurate ? N/A
10. Were there multiple examples of the violation ? No.
11. What were the opportunities and when did they exist for licensee staff and management to be aware of the violation ? SINCE JAN 88 AND DAILY
12. What were the cirucumstances surrounding the violation which effect the significance of the violation ? PERSONNEL WERE NOT INFORMED OF THE RECORD REQUIREMENTS. THE TESTS WERE NOT DONE BECAUSE THE PERSON WAS ON VACATION AND USUALLY DOES THE TEST AND THE PERSON OF REPLACEMENT WAS OFF THE DAY OF THE TESTS. THE PERSON MAY HAVE THE RECORDS
13. Is the violation indicative of programmatic problems or is it an isolated case ? No.
14. What short term corrective and remedial action was taken and when was it taken ? PERSONNEL WILL FORWARD RECORDS TO RSO AND KEEP COPIES
15. Did NRC have to intervene to accomplish satisfactory short term correction and remedial action ? No.
16. Were there previous similar NRC inspection or licensee audit findings and, if so, should the corrective actions from those findings have prevented this violation ? NO

The inspection report details should include times, dates, titles of persons types of equipment, and specific factual information responsive to the above listed questions, as applicable. Potential severity level and enforcement options will not be discussed in the inspection report.

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Xerox Additional Sheet For Each Violation

The facts documented in the inspection report should address the following questions for each violation as applicable (MC 0400-05.02.a and b and MC 0610-[illegible].03.e):

1. What was the requirement and, if the requirement was conditional, how were the conditions satisfied which made the requirement applicable ? L/C ANNUAL SURVEY INSTRUMENT CALIBRA.
2. How the requirement was violated ? SOME INSTRUMENTS WERE NOT DONE ANNUALLY
3. When was the requirement violated and what was the duration of the violation ? DURING 1986 AND 1987
4. What was the apparent root cause and contributing casual factors for the violation SOME USERS DID NOT GET THEIR SURVEY INSTRUMENTS TO THE RSO
5. How and by whom (be specific if an NRC inspector) was the violation discovered ? INSPECTOR DURING A REVIEW OF RECORDS
6. Was the violation required to be reported and, if so, what was the applicable reporting requirement ? No
7. Was the violation reported and, if so, when and by whom was it reported ? N/A
8. If the violation was reported, but the report was late, why was the report late ?
9. was the report complete and accurate ? N/A
10. Were there multiple examples of the violation ? 4 of 5 INSTRUMENTS OUT OF 165
11. What were the opportunities and when did they exist for licensee staff and management to be aware of the violation ? DURING 1987 AND 1988 THE LICENSEE COULD HAVE CALCULATED THE UNITS
12. What were the cirucumstances surrounding the violation which effect the significar of the violation ? USERS WERE NOT FORWARDING THE UNITS TO THE RSO
13. Is the violation indicative of programmatic problems or is it an isolated case ? ISOLATED
14. What short term corrective and remedial action was taken and when was it taken ? THE LICENSEE IS TRYING TO DETERMINE IF THE UNITS WERE USED, ARE PART OF THE, OR WHEN THE LICENSEE ACQUIRED AND WILL CALCULATE
15. Did NRC have to intervene to accomplish satisfactory short term correction and remedial action ? No
16. Were there previous similar NRC inspection or licensee audit findings and, if so, should the corrective actions from those findings have prevented this violation ? YES.

The inspection report details should include times, dates, titles of persons types of equipment, and specific factual information responsive to the above listed questions, applicable. Potential severity level and enforcement options will not be discussed the inspection report.

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