

University of Cincinnati
Medical Center



Office of Administrative Services

Health Professions Building
Eden and Bethesda Avenues
Cincinnati, Ohio 45267-0553

October 13, 1989

Bruce S. Mallett, Ph.D.
Chief
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Docket No. 030-02764

Subject: Protocol Review Change Request

- Reference: I. Telecon F. Trejo (NES)/W. Slawniski (NRC)
on October 10, 1989
- II. NRC's confirmatory action letter (CAL),
dated August 30, 1989
- III. NRC's License Number 34-06903-05

Dear Dr. Mallett:

We are hereby confirming the request made by Mr. Trejo during the above referenced telecon, regarding a change to the CAL's requirement for the review of protocols.

Specifically, Item 3 of the CAL states that affected protocols and dormant protocols shall be reviewed by a quorum of the Radiation Safety Committee by October 30, 1989. We are requesting a change to the CAL's requirements with respect to the review of dormant protocols to the effect that we review only those dormant protocols when a purchase requisition is processed.

For your information and as a backup to our request, the following items are presented.

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REG3 LIC30
34-06903-05 PNU

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a) Protocols Review Status:

| | | |
|--|------------|------------|
| Total # of protocols | | <u>746</u> |
| # of protocols reviewed per CAL & have procured RAM | 210 | |
| # of dormant protocols reviewed by RSO only with no procurement activity | 119 | |
| # of dormant protocols yet to be reviewed with no procurement activity | <u>417</u> | <u>746</u> |

b) PIs response to the CAL's Item 2:

Attached herewith are the memos sent to all PIs on September 1, 1989 and on September 13, 1989. The latter one was hand-delivered to all delinquent PIs.

| | | |
|---|-----------|------------|
| # of PIs (non-human use) | | <u>220</u> |
| # of PIs w/sign-off sheet completed and on file | 177 | |
| # of PIs delinquent and with RAM purchasing rights suspended | <u>43</u> | <u>220</u> |

c) Radiation Safety Program Revisions:

One of the many program revisions will institute an isotope(s) possession limit with annual review for each authorized user (AU/formerly PI). This program change will require that all AUs reapply using a new isotope use application form. The revised procedure will replace the current "protocol" approach some time in January 1990 and it will make of no use the 746 protocols that are currently on file.

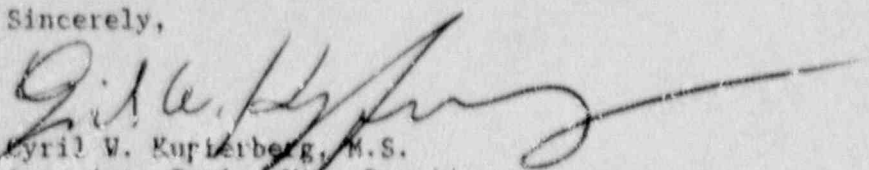
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Based on a), b), and c) above, the Radiation Safety Committee members have petitioned to use their time reviewing and approving the revisions to our Radiation Safety Program instead of reviewing dormant protocols which will become obsolete under the revised program.

The administration of this University firmly believes that the committee members are making a reasonable request.

We would appreciate your prompt review and response to our request. If you need additional information, please do not hesitate to contact me at 513-558-2484.

Sincerely,



Cyril W. Kupferberg, M.S.
Associate Senior Vice President
for the Medical Center, and
Associate Dean for the College of Medicine
Management and Finance

Enclosures

cc: Jerome F. Wiot, M.D. (Chairman, RSC)
Howard R. Elson, Ph.D. (RSC)
Wayne Slawinski (NRC)
Donald Sreniawski (NRU)
Francisco Trejo (NES)



**University of Cincinnati
Radiation Safety Committee**

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mail Location #591

Telephones:

Radiation Safety Office 558-4110
Administration 558-9081

August 31, 1989

TO: All Principal Investigators

FROM: Jerome F. Wiot, M.D.
Chairman, Radiation Safety Committee (RSC)

SUBJECT: Radiation Safety Office Organization Appointments

RE: (1) U.S. Nuclear Regulatory Commission (NRC) License
Amendment No. 61, dated August 24, 1989

(2) U.S. Nuclear Regulatory Commission License 34-06903-05

Please be informed that the referenced license amendment authorized the appointments of Howard E. Elson, Ph.D. to serve as the Radiation Safety Officer (RSO) for this institution, and Edward B. Silberstein, M.D. to serve as the Assistant Radiation Safety Officer for the activities authorized in our NRC license. Both of these appointments became effective on August 25, 1989.

It is your responsibility to inform your radiation workers of these changes in the Radiation Safety Office.

The Radiation Safety Committee and the University Administration request your support and full cooperation be given to Dr. Elson and Dr. Silberstein.

cc: Howard R. Elson, Ph.D.
Donald C. Harrison, M.D.
Cyril W. Kupferberg
Edward B. Silberstein, M.D.
Joseph A. Steger, Ph.D.
RSC Members



UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 558-4110

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

September 13, 1989

TO: Howard R. Elson, Ph.D.
Radiation Safety Officer

FROM:

RE: Memo of September 13, 1989

I acknowledge receipt of the letter of September 1, 1989 from
Jerome F. Wlot, M.D. pertaining to the NRC-CAL.

P.J.'s Signature _____



UNIVERSITY OF CINCINNATI • RADIATION SAFETY OFFICE

Telephone (513) 558-4110

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

September 13, 1989

TO: Delinquent Principal Investigators
FROM: Howard R. Elson, Ph.D. *HRE*
Radiation Safety Officer
RE: Sign-Off Sheet for NRC Confirmatory Actions Letter (CAL)

On September 1, 1989 you received a letter from Jerome F. Wiot, M.D. requiring the Evaluation of Protocols and the return of a Sign-Off Sheet. With this letter, I am supplying an additional copy of this letter. Until this Sign-Off Sheet is returned to this office, no isotopes may be purchased for your protocols as mandated by the NRC-CAL.

HRE:ch
cc: Jerome F. Wiot, M.D.
Cyril W. Kupferberg, M.S.



University of Cincinnati
Radiation Safety Committee

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mail Location #591

Telephones:

Radiation Safety Office 558-4110
Administration 558-9081

September 1, 1989

TO: All Principal Investigators

FROM: Jerome F. Wiot, M.D.
Chairman, Radiation Safety Committee (RSC)

SUBJECT: Action Items

Presented below are several important items for your information and that require your prompt attention and timely response to the Radiation Safety Office.

Item No. 1: Independent Evaluation of UC's Radiation Safety Program

Nuclear Energy Services (NES) has been contracted by this University to perform an in-depth audit of our radiation safety program. Part of the audit includes the walk-through inspection and radiation and contamination survey of all laboratories and areas where radioactive materials are being used. NES personnel will be stopping by your labs asking to see your records of activities required by your protocols and/or our radiation safety manual. Please give them your full cooperation.

Action: Complete Item No. 1 of the Sign-Off Sheet (attached).

Item No. 2: Tc-99 Contamination in Rooms 300 and 309, Crosley Tower

On August 23, 1989, NES personnel discovered high levels of loose Tc-99 contamination in the above-mentioned locations. The apparent causes for this incident were lack of proper performance of contamination survey, lack of proper training of lab personnel and lack of PI supervision of authorized activities. The NRC Region III was notified within 24 hours of the incident discovery in accordance with 10 CFR 20. 403. NRC inspectors from Region III were on campus on Friday, August 25, 1989, reviewing the actions taken by the Radiation Safety Office as a result of the incident.

Action: Complete Item No. 2 of the Sign-Off Sheet.

Item No. 3: Evaluation of Protocols Adequacy

As a result of Item No. 2 above, you are hereby requested to:

- 3.1 review and evaluate your protocol(s) for adequacy in contamination controls requirements, personnel instruction and training requirements and facility/equipment requirements.

- 3.2 ensure that your protocol(s) contain accurate information for authorized personnel, authorized room(s) and sink(s), authorized isotope(s), authorized isotope amount per purchase and authorized isotope amount for sink disposal.
- 3.3 review and ensure that your radiation and/or contamination survey records are current and that all of your authorized areas are either free of contamination or within the levels of contamination stated on your protocol and/or radiation safety manual.
- 3.4 ensure that each protocol names an acting PI responsible for the supervision of the authorized activities in your absence (i.e., sabbatical, vacation, sickness, etc.).

Action: Complete Items No. 3 of the Sign-Off Sheet.

Item No. 4: Sign-Off Sheet

It is important for this University that the attached Sign-Off Sheet be properly executed and returned to the Radiation Safety Office (Mail Location No. 591) no later than September 9, 1989.

If you have any questions or require addition information, please contact Howard Elson, Radiation Safety Office, at 558-4110.

Attachment

cc: Howard R. Elson, Ph.D.
Donald C. Harrison, M.D.
Cyril W. Kupferberg
Edward B. Silberstein, M.D.
Joseph A. Steger, Ph.D.
RSC Members



University of Cincinnati
Radiation Safety Committee

234 Goodman Street
Cincinnati, Ohio 45267-0591

Mall Location #591

Telephones:

Radiation Safety Office 558-4110
Administration 558-9081

September 1, 1989

TO: All Authorized Users of Radioactive Materials

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

The attached sign-off sheet is being sent to each authorized user of radioactive materials throughout the University of Cincinnati and Children's Hospital Medical Center.

The sheets must be completed and returned to the Radiation Safety Office (Howard R. Elson) no later than September 8, 1989.

Failure to comply with this request will result in your inability to procure radioactive materials in the future.

Attachment

SIGN-OFF SHEET

TO: Howard R. Elson, Ph.D.
Radiation Safety Office
Mail Location 591

FROM:

SUBJECT: Dr. J. F. Wiot's Memo/ACTION ITEMS

Item No. 1: Independent Evaluation of UC's Radiation Safety Program

I am fully aware of the contents stated in Item No. 1. I have also informed all my workers of it.

Principal Investigator's Signature Date

Item No. 2: Tc-99 Contamination in Rooms 300 and 309, Crosley Tower

I read the description of the incident and its apparent causes. My radiation workers have been informed of it.

Principal Investigator's Signature Date

Item No. 3: Evaluation of Protocols Adequacy

3.1 I have reviewed and evaluated my protocol(s) in accordance with the requirements stated in Subsection 3.1 of this memorandum. (Contamination controls, training, equipment, etc.) My protocol(s) listed below is (are) adequate and applicable.

Protocol No. _____, No. _____, No. _____

No. _____, No. _____, No. _____

Principal Investigator's Signature Date

3.2 I have ensured that each of my protocol(s) contain accurate information per Subsection 3.2 of this memorandum. The information listed below is to the best of my knowledge correct and accurate.

● Names of radiation workers under my supervision:

● List of authorized rooms: Room/sink Nos. _____ / _____
 No. _____ / _____, No. _____ / _____, No. _____ / _____
 _____, No. _____ / _____, No. _____ / _____.

● List of authorized isotopes, balance-on-hand per isotope and maximum isotope amount per purchase. (Note: balance-on-hand includes waste not yet turned over to the RSO.)

Isotope _____; Bal. on-hand _____; Max P/purch _____
 Isotope _____; Bal. on-hand _____; Max P/purch _____
 Isotope _____; Bal. on-hand _____; Max P/purch _____

● The following Principal Investigator has accepted to supervise my radiation workers and their authorized activities during my absences:

Acting PI's Name _____ Phone No. _____

Acting PI's Signature _____ Date _____

Principal Investigator's Signature _____ Date _____

Item No. 4: Miscellaneous Information

Please check the following items and sign at the bottom:

● All of my authorized rooms have been surveyed for radiation and/or contamination. Records are kept and can be audited by the RSO and/or his designee: Yes _____, No _____.

Principal Investigator's Signature _____

● My survey instruments and/or analytical equipment has current calibration status: Yes _____, No _____.

Principal Investigator's Signature _____

● All of my radiation workers have recently reviewed with me all of my protocols authorized by the Radiation Safety Committee:

Yes _____, No _____,
 Review Completion Date: _____

Principal Investigator's Signature _____