U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-03444/90002(DRSS)

Docket No. 030-03444

License No. 48-04193-01 Category G(1) Priority 1

Licensee: Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, WI 53226

Enforcement Conference At: NRC Region III office, Glen Ellyn, IL

Enforcement Conference Conducted: October 29, 1990

Inspectors: Wayne Slawinski 11-5-90
Wayne Slawinski, Senior Radiation Specialist — Date

William H. Schultz/sw 11-5-90
Jamnes Cameron
Radiation Specialist — Date

Reviewed By: William H. Schultz 11-5-90
William Schultz, Chief
Nuclear Materials Safety
Section 1 — Date

Approved By: John A. Grobe 11-21-90
John A. Grobe, Chief
Nuclear Materials Safety
Branch — Date

Meeting Summary

Enforcement Conference on October 29, 1990 (Report No. 030-03444/90002(DRSS))
Areas Discussed: A review of the findings from the September 26-28, 1990 inspection, including a discussion of each apparent violation and concern, the accuracy of the facts, causal factors, the corrective actions taken or planned by the licensee, and the NRC enforcement policy. The licensee's actions in satisfying the commitments in a Confirmatory Action Letter dated October 12, 1990, were also reviewed.

DETAILS

1. Conference Attendees

Milwaukee County Medical Complex

S. Buhr, Standard Nuclear Consultants (Licensee Consultant)
B. D. Collier, M.D., Chairman, Radiation Safety Committee and Nuclear Medicine Division
C. Haavik, Ph.D., Associate Dean, Research and Graduate Studies
J. Hanser, Hospital Administrator
J. Lato, Assistant Hospital Administrator
R. Stiglitz, Director, Nuclear Medicine Services
C. Wilson, Ph.D., Radiation Safety Officer

Nuclear Regulatory Commission, Region III

W. Axelson, Deputy Director, Division of Radiation Safety and Safeguards
B. Berson, Regional Counsel
J. Cameron, Radiation Specialist, Nuclear Materials Safety Section 1
A. Davis, Regional Administrator
P. Lougheed, Enforcement Coordinator
C. Pederson, Director, Enforcement and Investigation Coordination Staff
W. Schultz, Chief, Nuclear Materials Safety Section 1
W. Slawinski, Senior Radiation Specialist, Nuclear Materials Safety Section 1

2. Enforcement Conference Summary

An enforcement conference was held in the NRC Region III office on October 29, 1990, between members of the NRC Region III and Milwaukee County Medical Complex staffs. The conference was conducted to (1) review the apparent violations and other concerns identified during the September 26-28, 1990 inspection; (2) discuss root and contributing causes including the licensee's apparent lack of management control and oversight exercised over its broad scope program; (3) discuss the accuracy of the inspection findings and the licensee's corrective actions; (4) determine whether there were any aggravating or mitigating circumstances; and (5) obtain other information that would help determine the appropriate enforcement action. NRC inspection findings are documented in Inspection Report No. 030-03444/90001(DRSS), transmitted to the licensee by letter dated October 25, 1990.

The NRC started the meeting by explaining the purpose of an enforcement conference, and that this conference was held to discuss the findings of our inspection which identified numerous apparent violations and disclosed that:

(a) The Radiation Safety Officer is not effectively implementing the license conditions and applicable NRC regulations.

(b) Management, including the Radiation Safety Committee, does not provide adequate program oversight.

(c) Licensed material is allowed to be used by researchers who do not appear to meet the minimum training and experience requirements, as defined in the license.

The NRC presented 15 apparent violations and several other concerns. The licensee did not contest the apparent violations and indicated general agreement with the information presented in Inspection Report No. 030-03444/90001(DRSS). The licensee, however, indicated that it had not verified the accuracy of all the information (dates of material use, etc.) included in the apparent violations and inspection report.

The licensee presented its corrective actions for each apparent violation and concern, and provided the NRC staff with a two volume preliminary written response to the inspection findings.

The corrective actions taken by the licensee included an audit and survey of all research laboratories and a commitment to continue these required quarterly audits and report the results to the Radiation Safety Committee. The licensee also committed to audit the nuclear medicine section monthly and the brachytherapy source log book quarterly. The licensee continues to evaluate the necessity for additional radiation safety office staff and has temporarily assigned the Nuclear Medicine Services Director to assist the radiation safety office until staff needs are fulfilled. The licensee's response to a CAL issued on October 12, 1990, is described in section 3 below.

3. Confirmatory Action Letter Followup

Due to the numerous apparent violations and other concerns identified during the inspection, Region III management contacted the licensee on October 11, 1990 to discuss the necessity for the licensee to self-evaluate its present overall radiation safety program. Consequently, Region III issued a Confirmatory Action Letter (CAL) dated October 12, 1990. The licensee's efforts at satisfying the commitments in part A of the CAL were discussed during the enforcement conference and are summarized below. The licensee's CAL response is also documented in Volume I of its two volume response to the inspection findings. Excerpts from Volume I are attached to this conference report. The licensee's actions for parts B and C of the CAL, which require that the licensee retain a consultant to audit/evaluate all licensed activities and submit the audit findings to the NRC, will be evaluated during future inspections.

CAL Item A(1): Review the training and qualifications of all current authorized users and immediately withdraw authorization for all individuals who do not meet the minimum training requirements, as specified in the license.

Licensee Actions: All non-medical authorized users were reevaluated by the radiation safety committee (RSC). As a result, certain users previously approved by the RSC were restricted to possession and use of material with which they demonstrated adequate training and experience pursuant to 10 CFR 33.15(b). The licensee also committed to reevaluate its RSC protocol review procedures to ensure that future authorized users satisfy 10 CFR 33.15(b) requirements.

CAL Item A(2): Perform direct reading surveys and surveys for removable contamination in all research laboratories and facilities where licensed material is or has been used.

Licensee Actions: Direct beta/gamma swipe test of all facilities where licensed material is or has been used were performed. Swipe samples were counted for beta and gamma contamination. GM survey results were reportedly all within acceptable limits. No removable beta or gamma contamination was found that exceeded 220 dpm/100 cm^2.

CAL Item A(3): Assure that authorized users do not possess and use licensed material in quantities exceeding their individual possession limits.

Licensee Actions:

The inventories of all authorized users were reviewed to verify that activities possessed were within limits authorized by the RSC. Three additional researchers were discovered to possess quantities of licensed material 5-10 times greater than authorized by the RSC. Material exceeding authorized amounts has been removed from the researchers' possession and transferred to the radiation safety office's storage area pending special authorization for the additional material.

CAL Item A(4): Secure the services of a consultant whose qualifications will be evaluated and approved by the NRC.

Licensee Actions: The licensee has contracted the services of Standard Nuclear Consultants to assist the licensee.

CAL Summary: It appears the licensee has satisfied the commitments in Items A(1)-A(4) of the CAL dated October 12, 1990.

Attachments:
1. Ltr dtd 10/29/90, to A. B. Davis, "Response to Confirmatory Action Letter"
2. Licensee Presentation at Enforcement Conference

Attachment 1

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 29, 1990

A. Bert Davis
Regional Administrator, Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Sir:

Response to Confirmatory Action Letter
dated October 12, 1990 from A. Bert Davis

1. **Review the training and qualifications of all current authorized users and immediately withdraw authorization for all individuals who do not meet the minimum training requirements, as specified in your license.**

All non-medical authorized users were asked to re-submit their credentials for evaluation. (Item #1-LCA) All users were reviewed and their previous authorizations were restricted to material with which they demonstrated experience. For example, individuals authorized in category B2 with no experience with gamma emitters were restricted to use of beta emitters only. Similarly, most users authorized in category B4 were restricted to radiolabeling with iodine only because of a lack of training or experience with labeling with tritium. Letters were sent to all users notifying them of the restrictions or reduction in category of authorization. A copy of one such letter is enclosed as an example. (Item #2-LCA)

The following actions have been taken for the individuals specifically identified in the inspection report dated October 25, 1990.

a. M. L. Haasch, Ph.D: Use restricted to beta emitter only in categories B2 and B3. (Item #3-LCA) No gamma emitters are in her possession. Her revised training and experience form is included. (Item #4-LCA)

b. H. Bienert, Ph.D.: Authorization to perform radiolabeling was revoked. (Item #5-LCA) H-3 (for radiolabeling) in his possession will be placed in storage in the Radiation Safety office. His revised training and experience form is included. (Item #6-LCA)

c. C. Lai, Ph.D.: Authorization to use material was revoked. (Item #7-LCA) He has no material in his possession.

d. A. Haas, Ph.D.: Authorization has been restricted to use of beta emitters and to gamma emitters of less than 50 keV. (Item #8-LCA) Letter from A. Haas is included. (Item #9-LCA)

The procedures previously followed by the Radiation Safety Committee for review of training and experience will be re-evaluated to insure that authorized users meet the requirements of 10 CFR 33.15(b). The radiation safety consultant that is engaged will be asked to address this issue and to aid the committee in revising its procedures. Our categories of use will also be re-examined and revised to insure that individuals are authorized for only materials and activities which are appropriate for their training and experience.

2. Perform direct reading surveys and surveys for removable contamination in all laboratories and facilities where licensed material is or has been used.

Laboratory audits of all laboratories were performed. GM surveys and swipe test of all facilities where licensed material is or has been used were performed. Swipe samples were counted for beta and gamma contamination. GM survey results were all within acceptable limits. No removable beta or gamma contamination was found that exceeded 220 dpm/100 cm^2.

3. Assure that authorized users do not possess and use licensed material in quantities exceeding their individual possession limits.

The inventories of all authorized users were reviewed to verify that activities possessed were within limits authorized by the committee. The following investigators were found to have more activity than permitted by the Radiation Safety Committee.

1. William Cashdollar, Ph.D

An order for 5 mCi of H-3 was approved and processed in August, 1990. The activity delivered was 25 mCi. The manufacture was notified but they did not want the material returned and the material was given to the investigator with instructions to request authorization for one-time possession of the 25 mCi from the Radiation Safety Committee. This request had not been initiated by the time of the inspection. The material has been removed from the investigator's lab and is in storage in the Radiation Safety office. (Item #10-LCA)

2. Michael Gillin, Ph.D.

An order for 50 mCi of S-35 was approved and the material delivered to the user. This material was not used and has been removed from the user's lab and is in storage in the Radiation Safety office. (Item #11-LCA)

3. William Cowley, Ph.D.

Dr. Cowley is authorized for RIA kits with a total activity not to exceed 0.2 mCi. He is now preparing his own kits and on several occasions he obtained shipments of 1 mCi of H-3. Two vials each containing less than 1 mCi were removed from his possession. A third (0.5 mCi) was left in his lab because of special storage requirements. (Item #12-LCA)

At the time of the inspection it was noted that on two occasions, one in 1988 and the other in September 1990, two authorized users, Drs. L. Ryan and Miziorko, each received 25 mCi of tritium in single vials. Although neither purchase exceeded the user's total possession limit, their individual vial possession limits of 5 mCi were exceeded.

Both investigators were notified and the vials in question were immediately removed from their laboratories. (Items #13-LCA and #14-LCA) Dr. L. Ryan (Item #15-LCA) requested emergency approval from the Radiation Safety Committee to resume use of this material because he was in the middle of an experiment. His request was granted by the Radiation Safety Committee and the material was returned to his lab. Dr. H. Miziorko also requested his possession limit be increased (Item #16-LCA) but the committee has not yet acted on his request and the material is in storage in the Radiation Safety office.

To avoid a reoccurrence of this violation a daily inventory summary will be prepared which gives the total activity of each radioactive material in the possession of each authorized users. This daily inventory summary will be used to verify that the activity of a given purchase order is in compliance with the user's total authorized possession limit and the amount of material in his current inventory.

4. Secure the services of a consultant whose qualifications will be evaluated and approved by the NRC.

Standard Nuclear Consultants, Ltd. have been engaged to provide consulting services. Their proposal is included. (Item #17-LCA)

Sincerely,

Julie Hanser, FACHE
Hospital Administrator

Attachment 2

TO: NUCLEAR REGULATORY COMMISSION

FROM: LICENSE NO: 48-04193-01

DATE: OCTOBER 29, 1990

RESPONSE BY THE MILWAUKEE COUNTY MEDICAL COMPLEX AND THE MEDICAL COLLEGE OF WISCONSIN TO THE NUCLEAR REGULATORY COMMISSION

ORDER OF PRESENTATION

Julie Hanser, FACHE
Hospital Administrator
Milwaukee County Medical Complex

Coryce Haavik, Ph.D
Associate Dean, Research and Graduate Studies
Medical College of Wisconsin

B. David Collier, M.D.
Director of Nuclear Medicine
Chairman Radiation Safety Committee
Milwaukee County Medical Complex

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Milwaukee County Medical Complex

a. Summary of Responses to Confirmatory Action Letter Dated October 12, 1990 from A. Bert Davis
b. Summary of Corrective Actions Taken and to be Implemented to Remedy the Apparent Violations Contained in the Letter Dated October 17, 1990 from Charles E. Norelius

Correspondence Initiated by the Associate Dean for Research and Graduate Studies of the Medical College of Wisconsin

MEDICAL COLLEGE OF WISCONSIN

Division of Research and Graduate Studies
Office of Associate Dean

October 10, 1990

MEMO TO: Basic Science Chairmen

FROM: Coryce O. Haavik, Ph.D.
Associate Dean for Research and Graduate Studies

REGARDING: Radioisotopes

I mentioned to you last week that during a recent audit by agents of the Nuclear Regulatory Commission, a number of areas of noncompliance with NRC regulations were identified. Although it is likely that none of the items for which we will be cited involve life-threatening situations, it is clear that the standard laboratory operating procedures of MCW faculty, students, and staff are not fully up to the expected standards.

Please emphasize to your faculty the importance of adhering to the procedures described in the MCW Radiation Safety manual for the proper ordering, storing, handling, and disposal of radioisotopes. In addition, particular attention should be given to ensuring that (1) food is not stored in radioactive areas, (2) that wipe tests are done with the required frequency, even during weeks in which radioisotopes were not used, and (3) that the faculty provide the required training to those who work under their supervision.

If you have any questions about the NRC requirements, please contact our Radiation Safety Officer, Dr. Charles Wilson, Chief of medical Physics, Department of Radiology

cc: Charles Wilson, Ph.D.

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8218
FAX (414) 257-8215

MEDICAL COLLEGE OF WISCONSIN

Henry M. Miziorko, Ph.D.
Professor

Department of Biochemistry

MEMORANDUM

TO: Dr. Coryce O. Haavik
Associate Dean, Research & Graduate Studies

FROM: Dr. Henry Miziorko
Interim Chairman, Biochemistry Department

DATE: October 25, 1990

RE: Radiation Safety/NCR Regulations

This memorandum will confirm that I have discussed with authorized users in the Biochemistry Department their obligations under our licensing agreement with the Nuclear Regulatory Commission. They will ensure that all personnel in their laboratories are trained in safe use, storage, and disposal of radioisotopes. In addition, they will eliminate any problems in maintaining up-to-date records of radiation surveys and disposal of licensed material.

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8435 / 8257 / 8259
FAX (414) 257-2008

MEDICAL COLLEGE OF WISCONSIN

Department of Microbiology

MEMORANDUM

TO: Coryce O. Haavik, Ph.D.
Associate Dean, Research and Graduate Studies

FROM: Sidney E. Grossberg, M.D.
Walter Schroeder Professor and Chairman

DATE: 24 October 1990

RE: Observance of radiation safety regulations

Please be advised that we have notified the faculty and asked them to instruct their laboratory personnel concerning the need for rigorously observing the institutional rules that relate to radioisotopes, specifically the maintenance of records for the receipt, utilization, and disposal of radioisotopes; strict avoidance of storing food and drink anywhere near areas that radioisotopes are stored or used; and the necessity for doing wipe tests on surfaces where radioisotopes are used at least one a month as well as immediately after the isotopes are handled. The faculty recognized the importance of complying with these rules and will communicate this to their laboratory personnel.

SEG:mcw

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8253
FAX# (414) 257-8427

MEDICAL COLLEGE OF WISCONSIN

Allen W. Cowley Jr., Ph.D.
Professor and Chairman

Department of Physiology

October 25, 1990

MEMO TO: Coryce O. Haavik, Ph.D
Associate Dean
Division of Research and Graduate Studies

FROM. Allen W. Cowley Jr., Ph.D.
Professor and Chairman
Dept. of Physiology

Recently it was called to my attention that the regulations regarding the use of radioisotopes were not being complied with by all members of the MCW research community and that this has caused some serious concerns for the institution. I have addressed these concerns with the Department of Physiology faculty, staff, and students and expect compliance with all regulations. We will make every effort to use these isotopes in a safe and careful manner according to the guidelines clearly stated in the Medical College of Wisconsin Radiation Safety Manual.

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8264
FAX (414) 257-8570

Correspondence from Chairman of the Radiation
Safety Committee, Milwaukee County Medical Complex

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 25, 1990

Memorandum

To: Charles R. Wilson, Ph.D.
Radiation Safety Officer

From: B. David Collier, M.D.
Director of Nuclear Medicine
Medical College of Wisconsin

Subject: Services of Robert Stiglitz, B.S. to the Radiation Safety Program

Robert Stiglitz is a knowledgable and experienced Radiation Safety officer having served in that capacity for over 20 years at the Milwaukee VA Medical Center. Approximately 2 years ago, Mr. Stiglitz retired from the VA and thereafter assumed the position as Director of Nuclear Medicine Services for the Medical College of Wisconsin. Recognizing the importance of radiation safety activities at this time, the services of Mr. Stiglitz to your Radiation Safety program under license no. 48-04193-01 are being contributed by the Nuclear Medicine section within the Department of Radiology of the Medical College of Wisconsin.

BDC:mb

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 25, 1990

B. David Collier, M.D.
Director of Nuclear Medicine
Medical College of Wisconsin

Dear Dave:

Thank you for making the sevices of Robert Stiglitz available to me at this time. I have known Bob for a long time and I value his expertise and his assistance is greatly appreciated.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D
Radiation Safety Officer

Response to the Confirmatory Action Letter
Dated October 12, 1990 from A. Bert Davis

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

CAL-RIII-90-20

OCT 12 1990

Milwaukee County Medical Complex
ATTN: Julie Hanser, FACHE
Hospital Administrator
8700 West Wisconsin Avenue
Milwaukee, WI 53226

License No.: 48-04193-01
Docket No.: 030-03444

Gentlemen:

This refers to the conversation on October 11, 1990, between Ms. Janice Lato, Assistant Hospital Administrator, and John A. Grobe, Chief, Nuclear Materials Safety Branch. The purpose of this call was to discuss concerns that were identified during an inspection of your licensed facilities on September 28-30, 1990. As a result of this inspection, we have concluded that: (1) licensee management including the Radiation Safety Committee does not provide adequate oversight of your licensed program, (2) the Radiation Safety Officer (RSO) is not effectively implementing the conditions of your license and applicable NRC regulations, and (3) licensed material is routinely used by individuals who do not meet the minimum training requirements, as defined in your license.

A. Based on the October 11, 1990 conversation, it is our understanding that within 2 weeks you will:

1. Review the training and qualifications of all current authorized users and immediately withdraw authorization for all individuals who do not meet the minimum training requirements, as specified in your license.

2. Perform direct reading surveys and surveys for removable contamination in all laboratories and facilities where licensed material is or has been used.

3. Assure that authorized users do not possess and use licensed material in quantities exceeding their individual possession limits.

4. Secure the services of a consultant whose qualifications will be evaluated and approved by the NRC.

B. Within 30 days after approval by the NRC, your consultant will complete an audit and evaluation of all licensed activities with particular emphasis on the Research and Development and Brachytherapy programs.

C. Within 20 days after completing the audit and evaluation of your facilities and licensed activities, the consultant will prepare and submit to the NRC a report of the audit findings.

CONFIRMATORY ACTION LETTER

If your understanding differs from that set forth above, please call this office by telephone at (708) 790-5500 immediately. Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of Milwaukee County Medical Complex. Nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter.

Sincerely,

A. Bert Davis
Regional Administrator

cc: State of Wisconsin
DCD/DCB (RIDS)

MILWAUKEE COUNTY
medical complex

8700 Wes isconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 29, 1990

A. Bert Davis
Regional Administrator, Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Sir:

Response to Confirmatory Action Letter dated October 12, 1990 from A. Bert Davis

1. **Review the training and qualifications of all current authorized users and immediately withdraw authorization for all individuals who do not meet the minimum training requirements, as specified in your license.**

All non-medical authorized users were asked to re-submit their credentials for evaluation. (Item #1-LCA) All users were reviewed and their previous authorizations were restricted to material with which they demonstrated experience. For example, individuals authorized in category B2 with no experience with gamma emitters were restricted to use of beta emitters only. Similarly, most users authorized in category B4 were restricted to radiolabeling with iodine only because of a lack of training or experience with labeling with tritium. Letters were sent to all users notifying them of the restrictions or reduction in category of authorization. A copy of one such letter is enclosed as an example. (Item #2-LCA)

The following actions have been taken for the individuals specifically identified in the inspection report dated October 25, 1990.

a. M. L. Haasch, Ph.D: Use restricted to beta emitter only in categories B2 and B3. (Item #3-LCA) No gamma emitters are in her possession. Her revised training and experience form is included. (Item #4-LCA)

b. H. Bienert, Ph.D.: Authorization to perform radiolabeling was revoked. (Item #5-LCA) H-3 (for radiolabeling) in his possession will be placed in storage in the Radiation Safety office. His revised training and experience form is included. (Item #6-LCA)

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To avoid a reoccurrence of this violation a daily inventory summary will be prepared which gives the total activity of each radioactive material in the possession of each authorized users. This daily inventory summary will be used to verify that the activity of a given purchase order is in compliance with the user's total authorized possession limit and the amount of material in his current inventory.

4. Secure the services of a consultant whose qualifications will be evaluated and approved by the NRC.

Standard Nuclear Consultants, Ltd. have been engaged to provide consulting services. Their proposal is included. (Item #17-LCA)

Sincerely

Julie Hanser, FACHE
Hospital Administrator

Item #1-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900 TTY 257-5774

Memorandum

Date: October 15, 1990

To: All Authorized Users of Radioactive Material

From: Charles R. Wilson, Ph.D., Radiation Safety Officer
Medical Physics/MCMC

The NRC has requested that we verify that all individuals using radioactive material have the appropriate training and qualifications. Specifically, they wish us to demonstrate that all authorized users meet the requirements in Part 33.15 of Title 10 Code of Federal Regulations. I am, therefore, requesting that you confirm and verify you meet the following criteria. I must submit this information to the NRC by October 25th. I must have your response no later than October 19th. Please return response to:

MCMC
Radiation Safety/Box 193
or deliver to MCMC - 3M - Room 371

Please confirm your qualifications and document your answers completely on the attached sheet. If you have any questions or feel that you do not meet these qualifications, please let me know immediately.

Written response to this is mandatory. Failure to respond will jeopardize your authorization to use radioactive material.

Qualifications For Use of Radioactive Material

1. A college degree at the bachelor level, or equivalent training and experience in the physican or biological sciences or in engineering. Please list all degrees, majors, institutions and dates degrees were confirmed.

2. At least 40 hours of <u>training</u> and <u>experience</u> in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazard to exposure to radiation appropriate to the type and form of biproduct material to be used. Please list all training and experience, institution where training and experience was acquired, dates and times. Also list all radioactive material and activities previously used.

Name _____ Dept. _____

Signature _____ Phone _____ Date _____

Item #2-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue | Milwaukee, WI 53226 | 414-257-7900, TTY 257-5774

October 26, 1990

Margaret Wong-Riley, Ph.D.
Professor
Anatomy & Cellular Biology

Dear Dr. Wong-Riley:

We have been directed by the Nuclear Regulatory Commission to review all authorized user's training and experience. We are to revoke authorizations when the authorized user does not meet the minimum requirements. We are further directed to restrict authorizations to correspond with the training and experience of the authorized user.

Currently authorization is by the following categories:

B1: Commercial RIA kits
B2: Low *energy* beta emitters and low *activity* gamma emitters
B3: High *energy* beta emitters and high *activity* gamma emitters
B4: Radiolabeling with H-3, I-125 and I-113

You are currently authorized in category(s)B2 and B3. After reviewing your training and experience, your authorization has been restricted as follows:

restricted to beta emitter use only

If you feel this restriction is unwarranted or you wish to be reinstated for your previous use, please contact my office at 257-5381.

Cordially,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Associate Professor, Radiology
Radiation Safety Officer

Item #3-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Mary Haasch, Ph.D.
Research Asst. Professor
Pharmacology & Toxicology

Dear Dr. Haasch:

We have been directed by the Nuclear Regulatory Commission to review all authorized user's training and experience. We are to revoke authorizations when the authorized user does not meet the minimum requirements. We are further directed to restrict authorizations to correspond with the training and experience of the authorized user.

Currently authorization is by the following categories:

B1: Commercial RIA kits
B2: Low *energy* beta emitters and low *activity* gamma emitters
B3: High *energy* beta emitters and high *activity* gamma emitters
B4: Radiolabeling with H-3, I-125 and I-113

You are currently authorized in category(s)B1, B2 and B3. After reviewing your training and experience, your authorization has been restricted as follows:

restricted to beta emitter use only

If you feel this restriction is unwarranted or you wish to be reinstated for your previous use, please contact my office at 257-5381

Cordially,

Charles R. Wilson, Ph.D.
Associate Professor, Radiology
Radiation Safety Officer

HAASCH, MARY
B1,B2,B3

Item #4-LCA

or Use of Radioactive Material

1. A college degree at the bachelor level, or equivalent training and experience in the physican or biological sciences or in engineering. Please list all degrees, majors, institutions and dates degrees were confirmed.

Associate in Science	1974	Biological Sciences	University of Wisconsin Center - Manitowoc County
B.S.	1976	Microbiology & Public Health	University of Wisconsin - Oshkosh
Ph.D.	1989	Biological Sciences	University of Wisconsin - Milwaukee

2. At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazard to exposure to radiation appropriate to the type and form of biproduct material to be used. Please list all training and experience, institution where training and experience was acquired, dates and times. Also list all radioactive material and activities previously used.

1981-1983 Medical College of Wisconsin, Department of Medicine and Department of Biochemistry, Research Tech II and Sr. Research Technician. Introduction into the use of radioisotopes as on-the-job training. Weekly use of ^{3}H in µCi amounts, procedures of scintillation counting and proper waste disposal.

1983-1990 Medical College of Wisconsin, Department of Pharmacology and Toxicology, Sr. Research Technician, Research Technologist, Lab Manager. Primarily, use of ^{14}C and ^{35}S in µCi amounts on a periodic basis. I was responsible for the radioactive material inventory, generating quench curves and instructing others in the proper use of radioactive materials. During this time, I also became a graduate student at the University of Wisconsin-Milwaukee, where I used 50 to 100 µCi of ^{32}P on a weekly basis. The university required all users of radioactivity to read a manual, "Radiation Safety for Laboratory Technicians" and complete an open-book, 68 question, exam covering aspects of radiation and radioisotopes, radiation detectors, biological effects of radiation, reducing radiation exposure, current regulations and radiation safety procedures. I passed this exam.

August 1, 1990 Medical College of Wisconsin, Department of Pharmacology and Toxicology, Research Assistant Professor. Approved as an authorized user August 20, 1990.

Name Mary L. Haasch, Ph.D. Dept. Pharmacology

Signature Mary L. Haasch Phone 257-8612 Date 10/17/90

Item #5-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Helmut Beinert, Ph.D.
Professor
Biochemistry

Dear Dr. Beinert:

We have been directed by the Nuclear Regulatory Commission to review all authorized user's training and experience. We are to revoke authorizations when the authorized user does not meet the minimum requirements. We are further directed to restrict authorizations to correspond with the training and experience of the authorized user.

Currently authorization is by the following categories:

B1: Commercial RIA kits
B2: Low *energy* beta emitters and low *activity* gamma emitters
B3: High *energy* beta emitters and high *activity* gamma emitters
B4: Radiolabeling with H-3, I-125 and I-113

You are currently authorized in category(s)B2 and B4. After reviewing your training and experience, your authorization has been restricted as follows:

B4 is revoked

If you feel this restriction is unwarranted or you wish to be reinstated for your previous use, please contact my office at 257-5381.

Cordially,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Associate Professor, Radiology
Radiation Safety Officer

BEINERT, HELMUT
B2,B4
H3 LABELING ONLY IN B4

Item #6-LCA

For Use of Radioactive Material

1. A college degree at the bachelor level, or equivalent training and experience in the physican or biological sciences or in engineering. Please list all degrees, majors, institutions and dates degrees were confirmed.

Ph.D. University of Leipzig, Germany - 1943

2. At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazard to exposure to radiation appropriate to the type and form of biproduct material to be used. Please list all training and experience, institution where training and experience was acquired, dates and times. Also list all radioactive material and activities previously used.

I was introduced to work with radio-isotopes in 1947-49 personally by Professor H. Maier-Leibnitz, well known physicist (assistant to Walter Bothe at Kaiser-Wilhelm Institute Heidelberg, then chairman of Physics at Technical University Munich, later president of German National Science Foundation). He built Geiger tubes for me and instructed me in theory and practical use of isotopes. Books and manuals were barely available in 1947. The Air Force had an excellent manual by William Siri which I still use today. I have also profited from the presence at Madison of Charles HEidelberger (cf. his book on isotopes)

^{59}Fe	10 mCi	School of Aviation Medicine, Randolph	1947-50	in vivo labeling of cytochrome c in rats
^{55}Fe	5 mCi	Field Texas		
^{59}Fe	1 mCi	Enzyme Institute UW-Madison	1955	Studies of non-heme iron in mitochondria
^{14}C	10 mCi	Madison	1950-57	Studies of fatty acid oxidation in vitro
^{32}P	1 mCi	Madison	1956	
^{14}C	1 mCi	Madison	1983-84	
^{14}C, ^{3}H, ^{75}Se, ^{35}S, ^{65}Zn ^{54}Mn, ^{60}Co, ^{59}Fe, ^{55}Fe each $\leq$ 2mCi		MCW	1985-90	Studies on structure and function of iron-sulfur proteins

Name Helmut Beinert, Ph.D. Dept. Biochemistry

Signature Helmut Beinert Phone 266-4015 Date 10/16/90

Item #7-LCA

MILWAUKEE COUNTY
medical COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Ching-San Lai, Ph.D.
Assoc. Prof.
Biophysics

Dear Dr. Lai:

We have been directed by the Nuclear Regulatory Commission to review all authorized user's training and experience. We are to revoke authorizations when the authorized user does not meet the minimum requirements. We are further directed to restrict authorizations to correspond with the training and experience of the authorized user.

Currently authorization is by the following categories:

B1: Commercial RIA kits
B2: Low *energy* beta emitters and low *activity* gamma emitters
B3: High *energy* beta emitters and high *activity* gamma emitters
B4: Radiolabeling with H-3, I-125 and I-113

You are currently authorized in category(s)B2. After reviewing your training and experience, your authorization has been restricted as follows:

authorization to use radioactive materials is revoked

If you feel this restriction is unwarranted or you wish to be reinstated for your previous use, please contact my office at 257-5381.

Cordially,

Charles R Wilson

Charles R. Wilson, Ph.D.
Associate Professor, Radiology
Radiation Safety Officer

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Arthur Haas, Ph.D.
Assoc. Prof.
Biochemistry

Dear Dr. Haas:

We have been directed by the Nuclear Regulatory Commission to review all authorized user's training and experience. We are to revoke authorizations when the authorized user does not meet the minimum requirements. We are further directed to restrict authorizations to correspond with the training and experience of the authorized user.

Currently authorization is by the following categories:

B1: Commercial RIA kits
B2: Low *energy* beta emitters and low *activity* gamma emitters
B3: High *energy* beta emitters and high *activity* gamma emitters
B4: Radiolabeling with H-3, I-125 and I-113

You are currently authorized in category(s)B2, B3 and B4. After reviewing your training and experience, your authorization has been restricted as follows:

restricted from use of gamma emitters > 50 kev and B4 restricted to I-125 and I-131

If you feel this restriction is unwarranted or you wish to be reinstated for your previous use, please contact my office at 257-5381.

Cordially,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Associate Professor, Radiology
Radiation Safety Officer

Qualifications For Use of Radioactive Material

1. A college degree at the bachelor level, or equivalent training and experience in the physican or biological sciences or in engineering. Please list all degrees, majors, institutions and dates degrees were confirmed.

B.S. Biochemistry	1974	Texas Christian University
Ph.D. Biochemistry	1979	Northwestern University

Additional:

NIH Post-Doctoral Fellow 1979-1983 Fox Chase Cancer Center

2. At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazard to exposure to radiation appropriate to the type and form of biproduct material to be used. Please list all training and experience, institution where training and experience was acquired, dates and times. Also list all radioactive material and activities previously used.

See attached sheet

Name Arthur L. Haas Dept. Biochemistry

Signature Arthur L. Haas, Ph.D. Phone 257-8768 Date 10/29/90

Training and experience

Texas Christian University

Twelve (12) hours of course work in the principles and practices of radiation protection; radioactivity measurement, standardization, and monitoring methods; mathematics and calculations basic to the use and measurement of radioactivity.

Fox Chase Cancer Center

Four years of experience in the laboratory use of radioactive materials for enzyme assays and cell labeling. Isotopes used included ^{3}H, ^{14}C, ^{32}P, and ^{125}I. In addition, I was responsible for performing all protein radioiodinations for the research group in which I worked.

Medical College of Wisconsin

Since arriving at MCW, my research group has used ^{3}H, ^{14}C, ^{32}P, and ^{125}I in various enzyme assays and cell labeling studies. During this time there have been no instances of radioactive contaimination within the lab and no member of the group has had dosimeter readings significantly above background. We have refined out experimental protocols to require minimum levels of radioactive label so that no more than 10 μCi of any isotope is required in any procedure. To further prevent contamination, I personally perform all protein radioiodinations. Lab personnel are trained by me in the safe use of radioactive isotopes, proper shielding methods, and approved disposal procedures. In addition, I have been involved in training other laboratory personnel in the correct methods of protein radioiodination, contamination containment, and monitoring. Although I have had no formal course work in the biological effects of radiation, work toward my doctorate and subsequent professional experience has obviously allowed me to require a working knowledge of this topic.

Radioactive materials and maximum levels previously used

^{3}H	5 mCi
^{14}C	1 mCi
^{32}P	2 mCi
^{125}I	2 mCi

Item #10-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

William Cashdollar, Ph.D.
Assistant Professor, Department of Microbiology
Medical College of Wisconsin

Dear Bill,

This to acknowledge the removal of the hydrogen-3 compound (Inventory No. 90734, sodium borohydride, 25 mCi) from your laboratory because the activity on hand exceeds your individual vial possession limit. To resume work with this material you need to apply to the Radiation Safety Committee indicating your proposed use, the reason for using this much activity, your experience with handling this material and and special precautions that will be taken in using this material.

Sincerely,

Charles R. Wilson, Ph.D.
Radiation Safety Officer

Item #11-LCA

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Michael Gillin, Ph.D.
Associate Professor and Chief of Medical Physics
Department of Radiation Oncology
Medical College of Wisconsin

Dear Mike,

This to acknowledge the removal of the sulfur-35 compound (Inventory No. 90791, NaSO4, 36.8 mCi) from your laboratory because the activity on hand exceeds your indivi "al vial possession limit. To resume work with this material you need to apply to the Radiation Safety Committee indicating your proposed use, the reason for using this much activity, your experience with handling this material and and special precautions that will be taken in using this material.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer

Item #12-LCA

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 26, 1990

Allan Cowley, Ph.D.
Professor and Chairman, Department of Physiology
Medical College of Wisconsin

Dear Dr. Cowley,

This to acknowledge the removal of the hydrogen-3 compounds (Inventory No. 90517, Inulin, 0.8 mCi; Inventory No. 90644, Cat-A-Kit, 0.25 mCi) from your laboratory because the activities on hand exceeds your individual vial possession limits. Because of special storage condition the H-3 compound (Inventory No. 90762, 0.5 mCi) has been left in your laboratory but your use is restricted to activities less than 0.2 mCi in process at one time. To resume work with this material you need to apply to the Radiation Safety Committee indicating your proposed use, and your experience with this material.

Sincerely,

Charles R. Wilson, Ph.D.
Radiation Safety Officer

Item #13-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900 TTY 257-5774

October 1, 1990

Lawrence M. Ryan, M.D.
Chief, Rheumatology
Milwaukee County Medical Complex

Dear Dr. Ryan:

During the Nuclear Regulatory Commission inspection, September 26-28, 1990, it was noted that you have in your possession more activity of a single material than was authorized by the Radiation Safety Committee. You received 25 mCi of H-3 (sodium borohydride) on August 25, 1988. This is in direct violation of our license conditions and in order for us to be considered in compliance, you must immediately cease use of this material and transfer it to the Radiation Safety office until such time as your authorization has been amended to allow possession of this much activity. If you wish to resume use of this material, an amendment request should be filed with my office prior to October 31st to be in time for the next regularly scheduled meeting of the Radiation Safety Committee November 7, 1990. Your request should contain a brief statement justifying the increase in possession limits, a description of special handling procedures, storage and disposal requirement, if any, and a statement regarding the training you will provide for individuals using this amount of material, if necessary.

If you wish to resume use of this material before the next regularly scheduled Radiation Safety Committee meeting, an emergency amendment request can be made. Please contact my office regarding the procedure for such a request.

Sincerely,

Charles R Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

Item #14-LCA

MILWAUKEE COUNTY
MEDICAL COMPLEX

October 1, 1990

Henry Miziorko, Ph.D.
Acting Chairman
Department of Biochemistry
Medical College of Wisconsin

Dear Dr. Miziorko:

During the Nuclear Regulatory Commission inspection, September 26-28, 1990, it was noted that you have in your possession more activity of a single material than was authorized by the Radiation Safety Committee. You received 25 mCi of H-3 (sodium boronydride) on August 25, 1988. This is in direct violation of our license conditions and in order for us to be considered in compliance, you must immediately cease use of this material and transfer it to the Radiation Safety office until such time as your authorization has been amended to allow possession of this much activity. If you wish to resume use of this material, an amendment request should be filed with my office prior to October 31st to be in time for the next regularly scheduled meeting of the Radiation Safety Committee November 7, 1990. Your request should contain a brief statement justifying the increase in possession limits, a description of special handling procedures, storage and disposal requirement, if any, and a statement regarding the training you will provide for individuals using this amount of material, if necessary.

If you wish to resume use of this material before the next regularly scheduled Radiation Safety Committee meeting, an emergency amendment request can be made. Please contact my office regarding the procedure for such a request.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

Item #15-LCA

MEDICAL COLLEGE OF WISCONSIN

H.S. Cheung, Ph.D.
M.P. Cohen, M.D.
M.E. Cronin, M.D.
M.E. Csuka, M.D.
P.B. Halverson, M.D.
G.S. Mandel, Ph.D.
N.S. Mandel, Ph.D.
D.J. McCarty, M.D.
A.K. Rosenthal, M.D.
L.M. Ryan, M.D.
R.L. Wortmann, M.D.

Department of Medicine
Rheumatology Section

October 2, 1990

Chairman
Radiation Safety Committee
Medical College of Wisconsin

Dear Sir:

I
This letter is to explain our recent purchase of 25 mCi of ^{3}H acetic anhydride and to ask for a one time exception for the use of this labeled material. The ^{3}H acetic anhydride is to be used in our laboratory for the labeling of both casein and collagen. These labeled proteins are used as substrates for the detection of enzymatic activity in the media of cultured cells. A number of people will be using these assays in their work and sufficient material will be labeled to cover all their needs. Five mCi of ^{3}H acetic anhydride will be used for each labeling reaction and the work carried out under the guidelines established by the Radiation Safety Committee. Initially only 10 mCi will be used and it was planned to store the remainder for future use. The 25 mCi size was ordered since this was the lowest amount size available at the specific activity appropriate for our work. Additionally, this size was much more economical than purchasing a lower amount with a higher specific activity.

I would like to request that the 25 mCi be split into 5 mCi aliquots which will then be used as required. I thank you for your consideration of this matter.

Sincerely,

Lawrence M. Ryan, M.D.
Professor of Medicine
Chief, Division of Rheumatology

Milwaukee County Medical Complex
(MCMC Box 118)
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 257-6356

Item #16-LCA

MEDICAL COLLEGE OF WISCONSIN

Henry M. Miziorko, Ph.D
Professor

Department of Biochemistry

October 15, 1990

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section
MCMC

Dear Dr. Wilson:

I would like to request an amendment to the pending renewal of my authorization to use radioactive materials, increasing the allowed possession limits of tritium to 25 millicuries of a single substance. Such an amendment to my authorization was approved by the Radiation Safety Committee October 1982 (see attached copies of my October 1, 1982 request and your letter of October 19, 1982); I believed this approval to still be in effect.

We purchased 25 mCi of sodium [3H]-borohydride in August, 1988. This was the smallest quantity of this material of suitable specific activity commercially available. For a typical experiment, I prepare a stock solution by opening the sealed glass ampule in the hood, transferring a grain of the solid to a test tube, and dissolving this material in a suitable amount of 0.1 M sodium carbonate. The remainder of the [3H]-borohydride is resealed in the glass ampule, and stored in an appropriately labeled container in the radioactive materials box in our -20 C freezer. No other lab personnel besides myself are involved in handling the 25 mCi quantity. No single experiment involves more than 5 mCi of the [3H]-borohydride.

While I am happy to have you store the 25 mCi shipment until we need it for our experiments, I request reinstatement of approval to use this material as described.

Very truly yours,

Henry M. Miziorko

Henry M. Miziorko, Ph.D.
Professor and Interim Chairman

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8435 / 8257 / 8259
FAX (414) 257-2008

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

October 19, 1982

Henry M. Miziorko, Ph.D.
Department of Biochemistry
Medical College of Wisconsin
Milwaukee, WI 53226

Dear Henry:

Your request to increase your possession limit of tritium to 25 millicuries has been approved by the Radioisotope Committee. I have included for your information the institution's policy on bioassays of tritium users.

Sincerely,

Chuck

Charles R. Wilson, Ph.D.
Radiation Safety Officer

CRW/js
Enc.
cc: C. Casey

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

Item #17-LCA

Standard Nuclear Consultants, Ltd.

Nuclear Medicine • Radiology • Industrial Specialists

STAN BUHR
JIM MIKOWSKI
(~~312~~) 365-5858
708

P.O. Box 362, Manhattan, IL 60442 □ 15016 Donny Hill Road, Elburn, IL 60119

October 18, 1990

Janice Lato
Assistant Administrator
Milwaukee County Medical Complex
8700 W. Wisconsin Ave.
Milwaukee, WI 53226

Dear Ms. Lato:

This is in follow-up to our telephone conversation yesterday concerning the possibility of Standa.d Nuclear Consultants, Ltd. providing health physics consulting services to the Milwaukee County Medical Complex and affiliated facilities.

Standard Nuclear Consultants, Ltd. assists medical, research/academic, and industrial radioactive material users throughout the Midwest in initiating nuclear and radiology services and maintaining sound radiation safety practices to ensure compliance with regulatory agency license conditions and applicable regulations. Standard Nuclear Consultants, Ltd. is licensed by the Nuclear Regulatory Commission (license no. 12-20362-01) and Illinois Department of Nuclear Safety (license no. IL-01300-01) to provide these services, including transport of NBS (NIST) traceable sealed reference standards for perfoming on-site calibrations of survey meters and other instruments. Jim Mikowski is also included on lists of qualified individuals to perform the inspections of radiolographic and fluoroscopic equipment in those Midwestern states which maintain those lists.

Following is a sample of some of the other area clients for which we provide regular health physics consulting service:

Baxter Healthcare Corporation
Round Lake, IL 60073

Bellin Memorial Hospital
Green Bay, WI 54305

Beloit Memorial Hospital
Beloit, WI 53511

Highland Park Hospital
Highland Park, IL 60035

Holy Family Medical Center
Manitowoc, WI 54220

Cerac, Inc.
Milwaukee, WI 53201

Elmhurst Memorial Hospital
Elmhurst, IL 60126

G.D. Searle
Skokie, IL

St. Mary's Medical Center
Racine, WI 53405

St. Mary's Medical Center
Madison, WI 53715

Lunar Radiation Corp.
Madison, WI 53713

Medical Associates Health Center
Menomonee Falls, WI 53051

Memorial Hospital at Oconomowoc
Oconomowoc, WI 53066

Mercy Medical Center
Chicago, IL 60616

NutraSweet Company
Mt. Prospect, IL 60056

St. Therese Hospital
Waukegan, IL 60085

Victory Memorial Hospital
Waukegan, IL 60085

Waukesha Memorial Hospital
Waukesha, WI 53186

VA Medical Center
Danville, IL 61832

St. Luke's Hospital
Racine, WI 53403

The principal consultants who would perform this service would be one of the following:

- Robin Bauer B.S., University of Miami, 1983
  M.M.Sc., Radiological Science, Emory Univ. 1985

  1/86 - 11/89, Health Physicist for Illinois Department of Nuclear Safety

  11/89 - present, Health Physics Consultant for Standard Nuclear Consultants

- Stan Buhr B.A., Concordia College, Moorhead MN, 1970

  1/84 - present, Health Physics Consultant and Co-Owner, Standard Nuclear Consultants

  12/77 - 12/83, Health Physics Consultant for Stan A. Huber Consultants

- Jim Mikowski B.S., Illinois Benedictine College, 1974

  1/84 - present, Health Physics Consultant and Co-Owner, Standard Nuclear Consultants

  3/80 - 11/83, Health Physics Consultant for Stan A. Huber Consultants

As you requested, enclosed is a proposal for the service we can provide. If we can provide additional information about our company, or the enclosed proposal, please contact us at the letterhead telephone number. Thank you.

Sincerely,

Stan W. Buhr

Stan Buhr
SB/mjp

Standard Nuclear Consultants, Ltd.

Nuclear Medicine • Radiology • Industrial Specialists

STAN BUHR
JIM MIKOWSKI
(~~312~~) 365-5858
708

P.O. Box 362, Manhattan, IL 60442 □ 15016 Donny Hill Road, Elburn, IL 60119

October 18, 1990

Janice Lato
Assistant Administrator
Milwaukee County Medical Complex
8700 W. Wisconsin Ave.
Milwaukee, WI 53226

Dear Ms. Lato:

Following are components of professional health physics consulting services to be provided to the Milwaukee County Medical Complex and affiliated facilities by Standard Nuclear Consultants, Ltd.

Consulting and Technical Services

The purpose of these services is to provide a two day, comprehensive review of your nuclear operations, in follow up to a recent inspection by the Nuclear Regulatory Commission. At the conclusion, written recommendations will be made for correcting any identified violations and assisting in preparing a response to the NRC outlining corrective action and methods to avoid future non-compliance.

Licensing-Regulations

One of the main goals of this service is to assist the Radiation Safety Officer in maintaining compliance with the Nuclear Regulatory Commission license conditions and pertinent regulations for the safe use of radioactive materials.

Radiation Survey Program

Assist in maintaining a radiation survey program, consistent with license requirements/regulations, of areas where radioactive materials are used, stored or disposed.

Radioactive Waste Management

Assist in maintaining the radioactive waste program for materials decayed to background, shipped by commercial disposal or incinerated.

Personnel Monitoring

Film and/or TLD badge results will be evaluated for regulatory and ALARA radiation exposure limits.

Other services, such as instrument calibration, leak testing and inservice are also available. Quotes for these services will be provided on request.

COST

The total cost for these services may be determined from the following fee schedule:

Professional consulting services to be provided for two (2) days to the the Milwaukee County Medical Complex and affiliated facilities.....$400.00/day

Travel.....$ 45.00/visit

A written summary report of recommendations made by the consultant is provided for your records.

You may indicate acceptance of this proposal for quarterly services by signing below and returning it to the Elburn, IL office.

Sincerely,

Stan W. Buhr

Accepted by:_____

Stan Buhr
Health Physicist

Date: October 18, 1990

Date:_____

Preliminary Responses to Apparent Violation
Contained in Letter Dated October 17, 1990
from Charles E. Norelius

Volume II

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

OCT 17 1990

Milwaukee County Medical Complex
ATTN: Ms. Julie Hanser, FACHE
Hospital Administrator
8700 West Wisconsin Avenue
Milwaukee, WI 53226

License No.: 48-04193-01
Docket No.: 030-03444
EA 90-181

Gentlemen:

This refers to the telephone conversation between Ms. Janice Lato, Assistant Hospital Administrator, and Mr. W. H. Schultz of this office on October 16, 1990, regarding arrangements for an enforcement conference between members of our respective organizations. This meeting is scheduled for 1:00 p.m. (CDT), Monday, October 29, 1990 at the NRC Region III office at 799 Roosevelt Road, Building 4, Glen Ellyn, Illinois.

The purpose of this meeting is to discuss the findings of the inspection conducted at your facility on September 26-28, 1990. The inspection identified 14 apparent violations of NRC requirements and 4 areas of concern. An inspection report will be provided to you prior to our scheduled meeting and a summary of the apparent violations and concerns is enclosed for your review. Please be prepared to discuss the root causes and contributing factors for these violations and concerns and your corrective actions taken and/or planned to preclude recurrence of these violations.

If you have any questions related to this meeting, please contact Mr. W. H. Schultz of this office at (708) 790-5268.

Sincerely,

W. L. Axelson for

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

Enclosure: As stated

cc w/enclosure:
DCD/DCB (RIDS)

Enclosure

Milwaukee County Medical Complex
Milwaukee, Wisconsin

I. Apparent Violations

A. Radiation level in stairwell of Froedtert Hospital in excess of limits on May 19-21, 1989 and September 14-17, 1990. Occurred during brachytherapy treatment. [10 CFR 20.105(b)]

B. Radiation Safety Officer failed to perform quarterly audits in all laboratories using radioactive materials. Last performed during first quarter of 1988. [License Condition No. 28]

C. Survey not performed to evaluate radiation levels in unrestricted areas at Froedtert Hospital on May 19, 1989 after implant of a brachytherapy source. [10 CFR 20.201(b)]

D. Failure to survey patient room and surrounding area after implant of brachytherapy source on May 19, 1989 at Froedtert Hospital. [License Condition No. 28]

E. Individual users who have been approved by the Radiation Safety Committee exceeded their possession limits for licensed material. [10 CFR 33.13(c)]

F. Radiation Safety Committee approved users for licensed material although the individual's documented training and experience did not meet minimum requirements. [License Condition No. 28]

G. Radiation surveys required to be performed daily, weekly, and monthly depending on usage of facility. Numerous occasions where timely surveys were not conducted. [License Condition No. 28]

H. Authorized users approved by Radiation Safety Committee required to train all personnel in their laboratories. In June 1990, a graduate student with no training worked with licensed material. [10 CFR 33.13(c)]

I. A remote afterloader brachytherapy device was purchased and used without NRC approval. [10 CFR 30.32(g)]

J. Log describing use of the afterloader had deficient entries on several occasions. [License Condition No. 28]

K. Thyroid counts were not performed on several occasions after individuals worked with iodine-125. [License Condition No. 28]

L. Dose calibrator reference source constancy checks were not performed on commonly used radionuclide settings. [License Condition No. 28]

M. Food was stored in a refrigerator that also contained radioactive material. [License Condition No. 28]

N. In some cases, records were not maintained of personnel exposures and disposal of licensed material to the sewer. [10 CFR 20.401(b)]

II. Areas of Concern

A. (1) The Radiation Safety Committee reviews of proposed users appear to lack comprehensiveness with regard to education/training; experience; facilities; and knowledge of institutional license requirements governing non-human use.

(2) The Radiation Safety Committee grants "semi-broad scope" authorizations to users for various isotopes in five categories even if proposed user has little or no experience with other materials in the specific category.

B. Documentation of survey instrument calibrations is confusing and poorly maintained. Licensee personnel responsible for performing and documenting calibrations had difficulty interpreting the records.

C. The brachytherapy source storage safe is not routinely locked although maintenance personnel have access to room where safe is located. Door to elevator controls is located in storage room.

D. The licensee relies on the user physicians to perform the source accountability and initial patient/patient room surveys for brachytherapy implants. In addition, licensee personnel (radiation safety staff and user physicians) allow brachytherapy sources to remain in the transport cart for extended periods of time (7-10 days) before returning them to the storage safe. During those periods, the cart is located in the source storage room noted above.

Preliminary responses to apparent violations contained in letter of October 17, 1990 from Charles E. Norelius.

I. APPARENT VIOLATIONS

A. Radiation level in stairwell of Froedtert Hospital in excess of limits on May 19-21, 1989 and September 14-17, 1990. Occurred during brachytherapy treatment. [10 CFR 20.105(b)]

During a brachytherapy implant performed May 19-21, 1989, a radiation survey in the stairwell adjacent to Room 4179SW, FMLH was not performed. The activity of this implant would have resulted in a radiation level in excess of 2.0 mR/hr in this unrestricted area. During another implant, September 14-17, 1990 a level higher than allowed was noted, but no action was taken. The technician involved has been reprimanded (Item #1) and has revised our survey procedure to insure that all areas are surveyed and that complete information is obtained.(Item #2) This survey form is now in use. Prior to use of this form, surveys were recorded in a log book on a hand-drawn sketch of the room layout.

If an exposure level in a restricted area around this room exceeds the limits in Section 20.105(b), the following actions will be taken: See floor plan of room and adjacent areas given on Item #2.

a. Room 4181 SW, (Adjacent of Room 4179 SW)
Access to this room will be restricted. No patient will be housed in this room while the implant is in progress.

b. Corridor Outside Room 4179 SW
An ISO exposure line representing 2 mR/hr will be marked on the floor of the hallway and signs will be placed restricting access to the area behind this line to only radiation workers. Portable bedside shields (2 available) will be used to minimize the area of the hallways so restricted.

c. Interstitial Spaces (Above and Below Room 4197 SW)
These spaces are normally locked and access is limited to engineering personnel. When exposure rate exceeds limits in Section 20.105(b), engineering personnel will only be allowed access to these areas when accompanied by a member of the Radiation Safety staff. FMLH engineering staff will be notified of each implant during which this restriction applies

d. Stairwell (Adjacent to Room 4179 SW)
Because of this room's location in the hospital, the stairwell adjacent to room 4179 SW is used infrequently (at shift changes) and occupancy is essentially nil. In the event exposure levels exceeds applicable limits, signs will be placed in the stairwell on the fifth and fourth floors stating that the area between the fifth and third floor is a restricted area, and the signs will direct anyone to exit the stairwell on the fifth or fourth floor except in case of an emergency. It is unlikely, even in the event an individual ignores the warning signs, that an individual will be exposed to a significant exposure because of the limited time it takes to go between floors (estimated time less than 15 seconds).

Similar survey forms will be developed for the other rooms in the facility used for brachytherapies. Unrestricted areas will be surveyed and access will be restricted as required.

B. Radiation Safety Officer failed to perform quarterly audits in all laboratories using radioactive materials. Last performed during first quarter of 1988. [License Condition No. 28]

The purpose of these audits is to verify that proper laboratory procedures are being followed, laboratory records are being maintained, and to perform radiation surveys. There are approximately 80 laboratories located in MCMC, MCW, FMLH, Eye Institute and in MFRC. These laboratories are visited by the Radiation Safety staff to remove radioactive waste (twice a month), exchange personnel monitoring devices (once a month), distribute inventory forms (quarterly), exchange wipe test record logs (annually) and deliver packages whenever radioactive material is received. These routine visits to the laboratories were substituted for the formal audits, and surveys were not performed.

As of October 26, 1990 all laboratories have been audited. Laboratory audits will henceforth be performed quarterly and records of these audits will be maintained.(Item #3) The Radiation Safety officer will report the results of these audits to the Radiation Safety Committee quarterly to insure that these audits are performed as required.

C. Survey not performed to evaluate radiation levels in unrestricted areas at Froedtert Hospital on May 19, 1989 after implant of a brachytherapy source. [10 CFR 20.201(b)]

See response to Apparent Violation A.

D. Failure to survey patient room and surrounding area after implant of brachytherapy source on May 19, 1989 at Froedtert Hospital. [License Condition No. 28]

This particular implant was performed late (about 6:30 pm) on the afternoon of May 19, 1989. The radiation survey of the areas around patient's room, however, was not performed until the morning of the next working day. Radiation Safety staff will, in the future, monitor all brachytherapy as soon as they are performed. During normal working hours no change in procedure is needed. As is the current policy, Radiation Oncology will call the Radiation Safety office to notify it that an implant is in progress and a member of the Radiation Safety staff will perform a survey. For implants performed after 4:30 pm, Radiation Oncology will be requested to call the Radiation Safety beeper number. A member of the Radiation Safety office will be available to perform the survey whenever the implant is completed. Based on previous experience, the number of after-hour surveys will be less than one per month. (In the previous 22 months, January 1989 through August 1990, a total of 51 brachytherapies were performed of which 13 were performed after 4:30 pm).

E. Individual users who have been approved by the Radiation Safety Committee exceeded their possession limits for licensed material. [10 CFR 33.13(c)]

On two occasions, one in 1988 and the other in September 1990, two authorized users received 25 mCi of tritium in single vials. Although neither purchase exceeded the user's total possession limit, their individual vial possession limits (5 mCi) were exceeded. It is our current policy to review all orders of radioactive material prior to purchase. The health physics technician who normally reviews all purchase order requisitions incorrectly approved these purchase orders. A letter of reprimand has been placed in his file.(Item #4)

Both investigators were notified on October 1, 1990 and the vials in question were removed from their laboratories. Letters (Items #5 and #6) to this effect were sent to the authorized users. Dr. Ryan (Item #7) requested emergency consideration because he was in the middle of an experiment and his request was granted by the Radiation Safety Committee.(Item #8) Dr. Miziorko also requested his possession limit be increased.(Item #9)

To avoid a reoccurrence of this incident, we will more closely monitor purchase order requisitions for radioactive materials. To do so, we will prepare a daily inventory summary which will give the total activity of each radioactive material in the possession of each authorized users. A daily inventory will be used to verify that a given purchase order is in compliance with the authorized user's total authorized possession limit and the amount of material on hand.

F. Radiation Safety Committee approved users for licensed material although the individual's documented training and experience did not meet minimum requirements. [License Condition No. 28]

All authorized users have been reviewed by the committee and on a number of occasions, the Radiation Safety Committee has not approved a user's request for authorization, has restricted an individual's authorization, or tabled a request pending submission of additional information. Credentials have been re-reviewed to insure that all users met the minimum requirements. (Item #10)

G. Radiation surveys required to be performed daily, weekly, and monthly depending on usage of facility. Numerous occasions where timely surveys were not conducted. [License Condition No. 28]

Radiation surveys were not performed at the required frequency in Nuclear Medicine located in MCMC. Daily radiation surveys are required, and these were not performed in June and July of 1990. We were aware of this problem and had instituted a simpler survey procedure in early August to correct this deficiency. Since instituting the revised survey, there were several occasions when surveys were not performed. The survey form being used in Nuclear Medicine is attached as Item #11. To more closely monitor the performance of these surveys, the Radiation Safety office will audit the Nuclear Medicine Section monthly. The results of these audits will be contained in a quarterly report to the Radiation Safety Committee.

Surveys required in research labs were also not performed at the required frequency. In the future, the quarterly audits of all laboratories will insure compliance in the areas.

H. Authorized users approved by Radiation Safety Committee required to train all personnel in their laboratories. In June 1990, a graduate student with no training worked with licensed material. [10 CRF 33.13(c)]

In addition, an authorized user allowed 1) food to be stored in a refrigerator containing radioactive materials (Apparent Violation M), 2) cold zones (those areas where food and beverages can be consumed in a lab) were not properly labeled, and 3) records of GM surveys and sink disposals were not maintained or were missing (Apparent Violation G). The importance of compliance with the requirements of our license will be emphasized in future in-service lectures, and we have distributed a memo to all users reminding them of their responsibilities as authorized users.(Item #12) Coryce Haavik, Ph.D., Associate Dean of Research and Graduate Studies, has also asked the Basic Science Department Chairmen to remind their faculty members of the need to comply with condition of our license.(Item #13)

To insure that authorized users comply with their responsibilities to train their laboratory workers, the authorized user will be required to submit to the Radiation Safety office a signed and dated statement from any new employee, graduate student, visiting scientist or other collaborator working in the user's laboratory indicating that the new worker has received appropriate training. We will develop a minimum set topics which must be discussed in this lab orientation such as, the type of surveys and frequency required, waste disposal procedures, location of hot and cold zone, etc. Verification that this training has been given will be made at the quarterly audit.

I. A remote afterloader brachytherapy device was purchased and used without NRC approval. [10 CFR 30.32(g)]

The NRC requires specific license approval for the use of the Microselectron LDR remote afterloading brachytherapy unit which is used for interstitial and intercavitary treatment of cancer. Radiation Oncology was notified verbally during the inspection that no further treatments could be performed with this unit until an amendment authorizing its use was granted by the NRC.(Item #14) An amendment request was sent to the NRC October 4, 1990 (Item #15) but no reply has yet been received.

J. Log describing use of the afterloader had deficient entries on several occasions. [License condition No. 28]

Radiation Safety staff had reviewed the inventory records with the physics staff of Radiation Oncology several months ago and at that time it was requested that these records be maintained accurately.(Item #16) After the exit interview, another letter was sent to remind the physics staff of the importance of maintaining these records.(Item #17) A departmental policy will be developed for maintaining this records with the responsibility for compliance residing with the Radiation Oncology staff and management. To insure that these records are in compliance with our license conditions, these inventory records will be reviewed quarterly. The result of these audits will be reported to the Radiation Safety Committee.

K. Thyroid counts were not performed on several occasions after individuals worked with iodine-125. [License Condition No. 28]

During the inspection one investigator was identified as not having obtained the required bioassays. I have contacted the investigator informing him of the missed bioassays and will contact him in the future for an explanation when the dates of the missing bioassays are available.(Item #18) To insure that a required bioassay is performed, the I-125 to be used for radiolabeling will be kept by the Radiation Safety office until the radiolabeling is to be performed. The raw materials will then be given to the authorized user and a pre-labeling bioassay will be performed. An appointment for the post-labeling bioassay will be scheduled. If the user fails to keep this appointment, he/she will be contacted. If the post-labeling bioassay is not performed within 72 hours, the incident will be reported to the Radiation Safety Committee for action.

L. Dose calibrator reference source constancy checks were not performed on commonly used radionuclide settings. [License Condition No. 28]

It was noted that the weekly verification of the operation of all commonly used radioisotope settings of the Nuclear Medicine dose calibrator were not being performed weekly. These constancy checks have now been instituted and are being performed as required.(Items #19 and #20) A departmental policy will be developed for maintaining this records with the responsibility for compliance residing with the Nuclear Medicine staff and management. Compliance with this requirement will be verified during the monthly audit of Nuclear Medicine by the Radiation Safety office and the results of these audits will be reported to the Radiation Safety Committee.

M. Food was stored in a refrigerator that also contained radioactive material. [License condition No. 28]

See response to Apparent Violation H.

N. In some cases, records were not maintained of personnel exposures and disposal of licensed material to the sewer. [10 CFR 20.401(b)]

See response to Apparent Violation H. Personnel exposures will be reviewed monthly. In cases of the loss of the dosimeter, an estimate of the exposure that the individual might have received will be made. This estimate will be based on the average monthly exposure to the individual or other individuals working in the same area. If the estimated exposure is less than or equal 10 mrem for the whole body and less the 30 mrem for the extremities, no adjustment in the individual's personnel dosimetry record will be made. If the estimated exposure is greater than the levels indicated, the dosimetry record will be modified.

II. AREAS OF CONCERNS

A. (1) The Radiation Safety committee reviews of proposed users appear to lack comprehensiveness with regard to education/training; experience; facilities; and knowledge of institutional license requirements governing non-human use.

The training and experience credentials of all authorized users will have been reviewed by October 26, 1990.

(2) The Radiation Safety Committee grants "semi-broad scope" authorizations to users for various isotopes in five categories even if proposed user has little or no experience with other materials in the specific category.

Our procedures will be re-evaluated. Categories of use will be made less generous and the possession limits will likely be reduced.

B. Documentation of survey instrument calibrations is confusing and poorly maintained. Licensee personnel responsible for performing and documenting calibrations had difficulty interpreting the records.

A standard operating procedure will be prepared which will clearly state the procedural steps to be followed for the calibration of survey instruments. All constants used in the calculation and assumptions regarding the relationship between exposure rate and distance, and verification of source strength will be included.

C. The brachytherapy source storage safe is not routinely locked although maintenance personnel have access to room where safe is located. Door to elevator controls is located in storage room.

After the inspection, a letter was sent to Tim Longden, Administrator of Radiation Oncology, regarding this area of concern.(Item #21) His action is contained in his response.(Item #22)

D. The licensee relies on the user physicians to perform the source accountability and initial patient/patient room surveys for brachytherapy implants. In addition, licensee personnel (radiation safety staff and user physicians) allow brachytherapy sources to remain in the transport cart for extended periods of time (7-10 days) before returning them to the storage safe. During those periods, the cart is located in the source storage room noted above.

Henceforth, the initial brachytherapy survey of the patient and room will be performed by the Radiation Safety staff (See Apparent Violation C). Currently, the survey performed at the completion of the brachytherapy is made by the oncologist. This survey is intended to verify that all sources have been removed, and the important feature of this survey is not he magnitude of the radiation level, but that no radiation is to be present. If there is a measurable level, the oncologist knows that withdrawal of all sources has not been accomplished and will take the necessary action.

We will adopt the policy that brachytherapy sources must be returned to storage safe or transport containers and the inventory entries be completed within 24 hours of the completion of the brachytherapy. The responsibility for compliance of this policy will reside with the Radiation Oncology staff and management. Compliance with this policy will be audited by the Radiation staff during the quarterly audits of Radiation Oncology.

Item #1

MILWAUKEE COUNTY
medical complex

October 1, 1990

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

Robert Yoss
Radiation Safety Coordinator
Medical Physics/Box 193
Milwaukee County Medical Complex

Dear Bob:

As you know, at the exit interview the NRC inspectors indicated a two violations resulting from your failure to perform surveys and evaluate the radiation levels in unrestricted areas adjacent to the room of a patient implanted with 800 mCi of iridium 192. The extraordinary large amount of radioactive material should have alerted you of the need to handle this case with extra care, and this is a letter of reprimand regarding the poor judgement you exercised in this instance.

We also were cited for your failure to promptly perform a survey after the implantation. However, what constitutes promptness is not clearly spelled out in the regulations or our license. Your survey was performed on the next working day after the implant and so in my opinion was performed in a timely fashion. The timing of post-implant surveys is a issue which I plan to bring before the Radiation Safety Committee.

To avoid a reoccurrence of this incident, I would like you to prepare, 1) a policy and procedure to handle surveys of patients receiving large activities implants that may cause exposure levels to exceed the allowable limits in unrestricted areas, and 2) survey forms showing the floor plan of the room and adjacent areas of all rooms routinely used for brachytherapy and I-131 therapy. These survey forms are to be used to record the results of all patient room surveys and are to have spaces for recording among other information, date, time, patient name, medical record number, radioactive material used, activity of the implant, survey instrument used, surveyor's initials, exposure levels at all appropriate locations, etc.

Sincerely,

Charles R Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer

CRW:mb

Radiation Safety Office Survey Form Item #2

BRACHYTHERAPY ROOM SURVEY FORM

Date:_____

Patient Name:_____ Room 4179 SW

RAM:_____ mg. Ra. Eq. mCi :_____ Type of Implant:_____

Date of implant:_____ Time of implant:_____

Check List

_____ 1. Sign on door.
_____ 2. Lead pig and forceps in room.
_____ 3. Survey meter in room.
_____ 4. Brachytherapy Patient Source Count and Survey Verification form in room and completed.
_____ 5. Lead shield in position
_____ 6. Nursing Instructions in patient chart

Room Survey

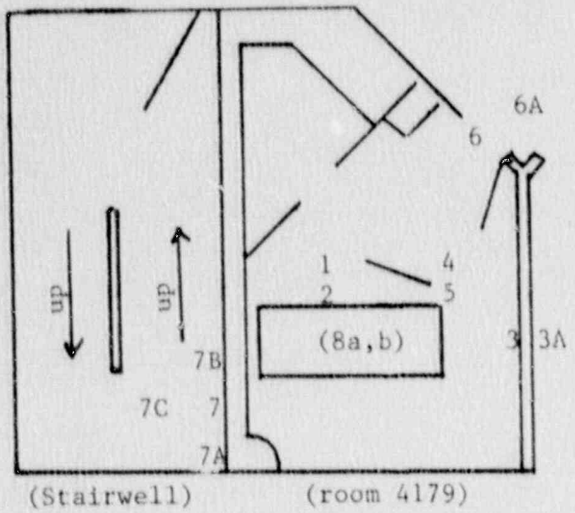
Survey the room with an ionization chamber. Prior to use verify the battery check and document check source. Check Source _____mR/hr.

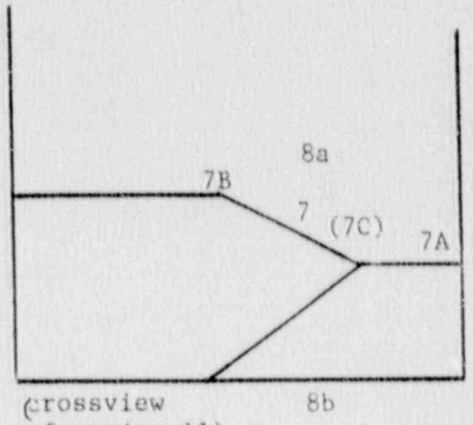
Location	Reading mR/hr		Reading mR/hr
1. 1 meter from patient	_____	6. Doorway-door closed	_____
2. Bedside	_____	7. Stairwell	_____
3. At wall in room	_____	8. Interstitial space:	
4. Above bedside shield	_____	a. above room	_____
5. Behind bedside shield	_____	b. below room	_____

Measurements are to be taken at the following locations if adjacent areas are greater than 2.0 mR/hr (e.g. if station 3. is 3.4mR/hr then station 3A. would be monitored).

3A. At wall in 4181	_____	7B. Stairwell	_____
6A. Hallway	_____	7C. Stairwell	_____
7A. Stairwell	_____		

Each of the above unrestricted areas with a radiation measurement greater than 2 mR/hr the area shall be restricted. Radiation caution signs shall posted. If radiation levels are greater than 2 mR/hr in the adjacent room, no patient will be allowed to use the room.





Item #3

Laboratory Audit 1991

Lab Room No.:

Auth. User: Categories:

Lab Manager:

Authorization Expiration: 31-Dec-92

		Calendar Quarter 1	2	3	4
1. Date					
Surveyor					
2. Active Use	Yes				
	No				
3. Lab Surveys Performed					
a. as required/on time	Wipe				
	G-M				
b. recorded properly	Wipe				
	G-M				
b. contaminated areas cleaned and retested					
c. floor plan current					
4. Postings					
a. NRC Form 3 & Notice to Employees					
b. radiation signs-doors					
c. radiation signs-sinks					
d. radiation signs-work areas					
e. radiation signs-containers					
f. "cold zones"					
5. Sink disposal log current					
6. Radiation Safety Violations					
a. food and drink in area					
b. quarterly inventory returned					
c. dosimeters returned					
7. Radiation Safety Survey	G-M				
vial number(s)					

8. Comments

Item #4

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

October 1, 1990

Bernard MacMillan
Health Physicist
Radiation Safety
Medical College of Wisconsin

Dear Mac:

This is a letter of reprimand for your approval of a purchase order of radioactive material in a quantity greater than that allowed as a single purchase by an authorized user. The order approved for Lawrence Ryan, M.D. September 25, 1990 resulted in a violation of one of our license conditions and must not happen in the future. All orders for radioactive material are to be verified against the list of authorized users and possession limits to determine; 1) that the individual initiating the order is, in fact, an authorized user, 2) that the activity ordered is within the individual's possession limit, 3) that the activity per vial does not exceed 5 mCi unless previously approved in writing, and 4) that the activity plus the amount of material on hand in the user's possession does not exceed his/her total possession limit.

In addition, if there are any questions regarding a specific order, you are not to process the order without my approval.

Sincerely,

Charles R Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

Item #5

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 1, 1990

Lawrence M. Ryan, M.D.
Chief, Rheumatology
Milwaukee County Medical Complex

Dear Dr. Ryan:

During the Nuclear Regulatory Commission inspection, September 26-28, 1990, it was noted that you have in your possession more activity of a single material than was authorized by the Radiation Safety Committee. You received 25 mCi of H-3 (sodium borohydride) on August 25, 1988. This is in direct violation of our license conditions and in order for us to be considered in compliance, you must immediately cease use of this material and transfer it to the Radiation Safety office until such time as your authorization has been amended to allow possession of this much activity. If you wish to resume use of this material, an amendment request should be filed with my office prior to October 31st to be in time for the next regularly scheduled meeting of the Radiation Safety Committee November 7, 1990. Your request should contain a brief statement justifying the increase in possession limits, a description of special handling procedures, storage and disposal requirement, if any, and a statement regarding the training you will provide for individuals using this amount of material, if necessary.

If you wish to resume use of this material before the next regularly scheduled Radiation Safety Committee meeting, an emergency amendment request can be made. Please contact my office regarding the procedure for such a request.

Sincerely,

Charles R Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

Item #6

MILWAUKEE COUNTY
MEDICAL COMPLEX

October 1, 1990

Henry Miziorko, Ph.D.
Acting Chairman
Department of Biochemistry
Medical College of Wisconsin

Dear Dr. Miziorko:

During the Nuclear Regulatory Commission inspection, September 26-28, 1990, it was noted that you have in your possession more activity of a single material than was authorized by the Radiation Safety Committee. You received 25 mCi of H-3 (sodium borohydride) on August 25, 1988. This is in direct violation of our license conditions and in order for us to be considered in compliance, you must immediately cease use of this material and transfer it to the Radiation Safety office until such time as your authorization has been amended to allow possession of this much activity. If you wish to resume use of this material, an amendment request should be filed with my office prior to October 31st to be in time for the next regularly scheduled meeting of the Radiation Safety Committee November 7, 1990. Your request should contain a brief statement justifying the increase in possession limits, a description of special handling procedures, storage and disposal requirement, if any, and a statement regarding the training you will provide for individuals using this amount of material, if necessary.

If you wish to resume use of this material before the next regularly scheduled Radiation Safety Committee meeting, an emergency amendment request can be made. Please contact my office regarding the procedure for such a request.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

Item #7

MEDICAL COLLEGE OF WISCONSIN

H.S. Cheung, Ph.D.
M.R. Cohen, M.D.
M.E. Cronin, M.D.
M.E. Csuka, M.D.
P.B. Halverson, M.D.
G.S. Mandel, Ph.D.
N.S. Mandel, Ph.D.
D.J. McCarty, M.D.
A.K. Rosenthal, M.D.
L.M. Ryan, M.D.
R.L. Wortmann, M.D.

Department of Medicine
Rheumatology Section

October 2, 1990

Chairman
Radiation Safety Committee
Medical College of Wisconsin

Dear Sir:

I
This letter is to explain our recent purchase of 25 mCi of ^{3}H acetic anhydride and to ask for a one time exception for the use of this labeled material. The ^{3}H acetic anhydride is to be used in our laboratory for the labeling of both casein and collagen. These labeled proteins are used as substrates for the detection of enzymatic activity in the media of cultured cells. A number of people will be using these assays in their work and sufficient material will be labeled to cover all their needs. Five mCi of ^{3}H acetic anhydride will be used for each labeling reaction and the work carried out under the guidelines established by the Radiation Safety Committee. Initially only 10 mCi will be used and it was planned to store the remainder for future use. The 25 mCi size was ordered since this was the lowest amount size available at the specific activity appropriate for our work. Additionally, this size was much more economical than purchasing a lower amount with a higher specific activity.

I would like to request that the 25 mCi be split into 5 mCi aliquots which will then be used as required. I thank you for your consideration of this matter.

Sincerely,

L Ryan

Lawrence M. Ryan, M.D.
Professor of Medicine
Chief, Division of Rheumatology

Milwaukee County Medical Complex
(MCMC Box 118)
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 257-6356

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 17, 1990

Dear Dr. Ryan:

The Radiation Safety Committee has authorized you to use ionizing radiation in categories B2 and B3 in accordance with the statements made in you application dated November 17, 1986 and letter dated October 2, 1990. This authorization expires December 31, 1990. If any conditions of your use change, it is your obligation to contact the Radiation Safety Committee.

CONDITIONS

Possession Limits

Under this authorization you are allowed to possess radioactive materials up to the following activities:

Categories	Possession Limits
B1: RIA kits	Less than 10 uCi/kit **Total Possession** less than 200 uCi
B2: Low energy beta emitters Low activity gamma emitters (< 250 uCi in process at one time)	5 mCi each beta emitter 2 mCi each gamma emitter **Total Possession** less than 20 mCi
B3: High energy beta emitters High activity gamma emitters	5 mCi each beta emitter 10 mCi each gamma emitter **Total Possession** less than 50 mCi
B4: Radiolabeling H-3, I-125 or I-131	H-3 150 mCi each use I-125 10 mCi each use I-131 10 mCi each use **Total Possession** H-3 less than 200 mCi **Total Possession** Iodine less than 20 mCi

Training

You are responsible for the training and instruction of all the personnel in your laboratory. Personnel are to be instructed in the specific procedures to be followed concerning the use of ionizing radiation in your laboratory and are to be informed of conditions of your authorization.

Special Conditions

One time permission to purchase H3 acetic anhydride in 25 mCi quantity for labeling.

Sincerely,

B. David Collier, M.D.
Associate Professor of Radiology
Chairman, Radiation Safety Committee

MEDICAL COLLEGE OF WISCONSIN

Henry M. Miziorko, Ph.D.
Professor

Department of Biochemistry

October 15, 1990

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section
MCMC

Dear Dr. Wilson:

I would like to request an amendment to the pending renewal of my authorization to use radioactive materials, increasing the allowed possession limits of tritium to 25 millicuries of a single substance. Such an amendment to my authorization was approved by the Radiation Safety Committee October 1982 (see attached copies of my October 1, 1982 request and your letter of October 19, 1982); I believed this approval to still be in effect.

We purchased 25 mCi of sodium [3H]-borohydride in August, 1988. This was the smallest quantity of this material of suitable specific activity commercially available. For a typical experiment, I prepare a stock solution by opening the sealed glass ampule in the hood, transferring a grain of the solid to a test tube, and dissolving this material in a suitable amount of 0.1 M sodium carbonate. The remainder of the [3H]-borohydride is resealed in the glass ampule, and stored in an appropriately labeled container in the radioactive materials box in our -20 C freezer. No other lab personnel besides myself are involved in handling the 25 mCi quantity. No single experiment involves more than 5 mCi of the [3H]-borohydride.

While I am happy to have you store the 25 mCi shipment until we need it for our experiments, I request reinstatement of approval to use this material as described.

Very truly yours,

Henry M. Miziorko

Henry M. Miziorko, Ph.D.
Professor and Interim Chairman

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8435 / 8257 / 8259
FAX (414) 257-2008

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

October 19, 1982

Henry M. Miziorko, Ph.D.
Department of Biochemistry
Medical College of Wisconsin
Milwaukee, WI 53226

Dear Henry:

Your request to increase your possession limit of tritium to 25 millicuries has been approved by the Radioisotope Committee. I have included for your information the institution's policy on bioassays of tritium users.

Sincerely,

Chuck

Charles R. Wilson, Ph.D.
Radiation Safety Officer

CRW/js
Enc.
cc: C. Casey

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

Memorandum

Date: October 15, 1990

To: All Authorized Users of Radioactive Material

From: Charles R. Wilson, Ph.D., Radiation Safety Officer
Medical Physics/MCMC

The NRC has requested that we verify that all individuals using radioactive material have the appropriate training and qualifications. Specifically, they wish us to demonstrate that all authorized users meet the requirements in Part 33.15 of Title 10 Code of Federal Regulations. I am, therefore, requesting that you confirm and verify you meet the following criteria. I must submit this information to the NRC by October 25th. I must have your response no later than October 19th. Please return response to:

MCMC
Radiation Safety/Box 193
or deliver to MCMC - 3M - Room 371

Please confirm your qualifications and document your answers completely on the attached sheet. If you have any questions or feel that you do not meet these qualifications, please let me know immediately.

Written response to this is mandatory. Failure to respond will jeopardize your authorization to use radioactive material.

Qualifications For Use of Radioactive Material

1. A college degree at the bachelor level, or equivalent training and experience in the physican or biological sciences or in engineering. Please list all degrees, majors, institutions and dates degrees were confirmed.

2. At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazard to exposure to radiation appropriate to the type and form of bipproduct material to be used. Please list all training and experience, institution where training and experience was acquired, dates and times. Also list all radioactive material and activities previously used.

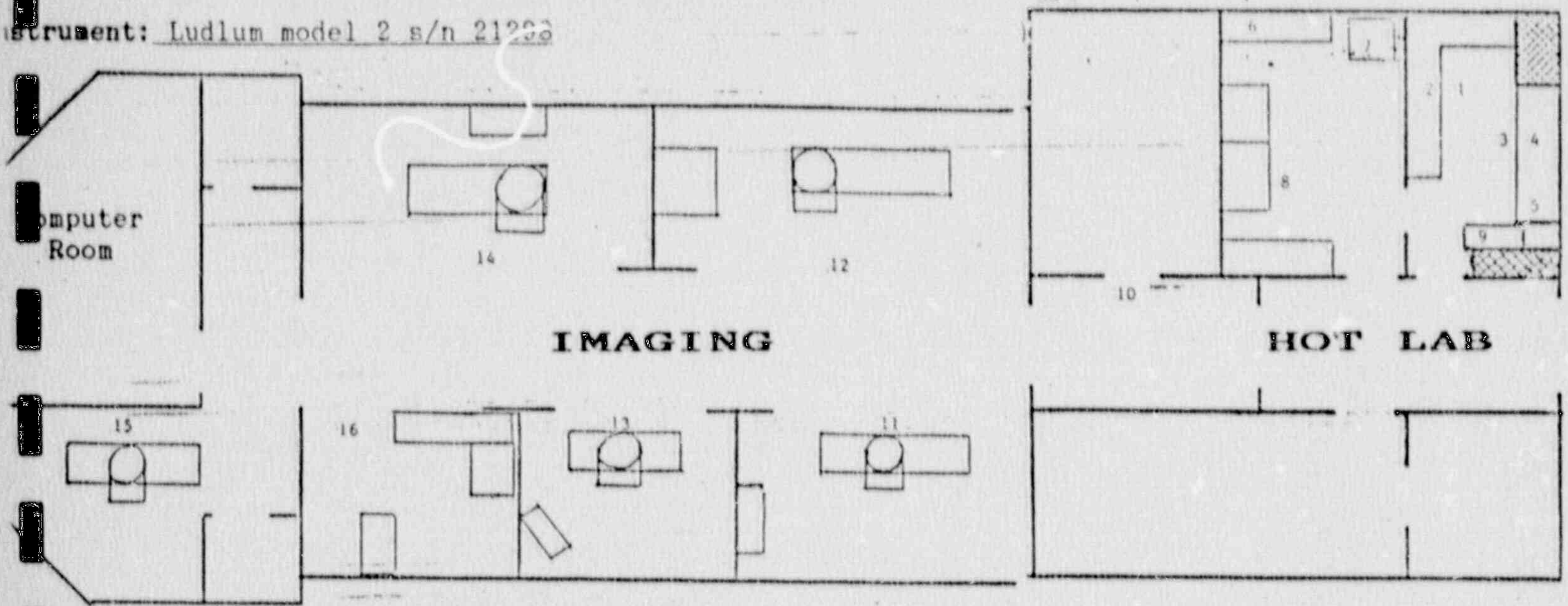
Name _____ Dept. _____

Signature _____ Phone _____ Date _____

RADIATION SURVEY
Item #11

for the month of__________

strument: Ludlum model 2 s/n 21293



mR/hr at location

gger vel	0.1	0.07	0.07	0.1	0.07	0.05	0.1	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05		
te	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Init
2																		
3																		
5																		
6																		
9																		
2																		
3																		
6																		
9																		

IF TRIGGER LEVELS ARE EXCEEDED, IMMEDIATELY NOTIFY THE RADIATION SAFETY OFFICER

extension 5381

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

Memorandum

Date: October 3, 1990

To: All Authorized Users of Radioactive Material

From: Charles R. Wilson, Ph.D. Charles R. Wilson
Radiation Safety Officer

During the recent NRC inspection, a number of violations of conditions of our license were noted. This letter is to request that you review your responsibilities as authorized users of radioactive material as outlined in the radiation safety manual (copy of responsibilities attached) and the specific commitments you made when applying for authorization to use radioactive material.

I would also like to remind you that:

1. No food or beverages are to be stored with radioactive material.

2. Cold and hot zones are to be clearly marked in your laboratory.

3. All individuals working in your laboratory are to have been instructed in the proper use of radioactive material and all conditions pertinent to your authorization.

4. Laboratory surveys are to be performed as required and all results recorded.

Your cooperation is essential in maintaining the institution in compliance with all of the regulations we operate under.

CRW:mb
Encl.

From: Radiation Safety - Policy and Procedure Manual

D. Authorized Users

Users are required to submit an Application For Use of Radionuclides (Appendix IV) to the RSC at the time of original application, for renewal or amendment of the original application. The application will be reviewed by the Radiation Safety Committee with attention to the qualifications of the applicant regarding the types, quantities and uses of the materials

requested on the application, and to a demonstrated ability of the applicant to ensure ALARA policies are followed through appropriate procedures and special protective equipment.

After the RSC has approved the application, authorized users will be responsible for obtaining, storing, using and disposing of all radioactive materials purchased under their authorization. and with respect to radiation safety, are responsible for the employees under their supervision. Attendance at inservice education sessions and relevant history of ALARA compliance will be considered during the process for reapplication for use of radionuclides.

Authorized users sharing laboratory facilities with other staff or facility members shall inform each colleague of storage and use areas of radioactive materials, type and quantity of radioactive materials in the laboratory, and precautions or restrictions involved.

Authorized users will comply with the policies and procedures described in the Radiation Safety Manual, state and federal regulations, standards of good practice, and in addition authorized users shall:

1. Maintain the purchase and use of radionuclides within approved limits; maintain records of the receipt, use, transfer and disposal of radioactive materials; and submit an inventory report to the RSO on forms provided within specified time limits.

2. Evaluate all procedures before using radioactive materials to ensure that exposures will be kept as low as reasonably achievable, using trial runs where possible.

3. Inform the RSO of proposed changes in operating procedures, techniques, facilities, alteration within facilities and employees.

4. Consult with and receive the approval of the RSC during the planning stage prior to using radioactive materials for a new procedure.

5. Ensure that employee are qualified to use radioactive materials safety and use appropriate safety devices. Provide an initial radiation safety intruction as part of laboratory orientation for new personnel.

6. Monitor radiation levels and/or contamination of area under their control in accordance with the Medical Complex's NRC license.

7. Permit the Radiation Safety Officer to inspect and evaluate their areas at any reasonable time.

8. Inform the RSO regarding the termination of the authorized user's employment so that work areas may be surveyed and quantities of radionuclides may be audited.

9. On an annual basis attend a minimum of one inservice education session presented by the Radiation Safety Officer.

10. Ensure individuals in your laboratory attend annual radiation safety inservices.

Item #13

MEDICAL COLLEGE OF WISCONSIN

Division of Research and Graduate Studies
Office of Associate Dean

October 10, 1990

Charles R. Wilson, Ph.D.
Chief, Medical Physics & Imaging Science
Department of Radiology
MCW

Dear Dr. Wilson,

Please be advised that following our conversation I discussed with the Basic Science Chairmen the problems recently identified regarding the correct use of radioisotopes by MCW faculty, staff and students. Dean Cooper, who chaired the meeting, also has been appraised of the situation.

They were concerned about the nature and extent of the problem and asked for details, which I provided. They expressed an intent to emphasize to their faculty the importance of adhering to the standards established in the MCW Radiation Safety manual. I have every reason to believe that in the future you will find that the proper procedures are being adhered to.

Sincerely,

Coryce O Haavik

Coryce O. Haavik, Ph.D.
Associate Dean for Research
and Graduate Studies

8701 Watertown Plank Road
Milwaukee, Wisconsin 53226
(414) 257-8218
FAX (414) 257-8215

Item #14

MEDICAL COLLEGE OF WISCONSIN

October 1, 1990

Department of Radiology
Section of Diagnostic Radiology

Michael T. Gillin, Ph.D.
Chief, Medical Radiation Physics
Radiation Oncology Dept.
Milwaukee County Medical Complex

Dear Mike:

During the Nuclear Regulatory Commission inspection of our license, September 26-28, 1990, we were told that specific NRC approval was required for the use of the Selectron (remote afterloading system) and that we were not to use this device until an amendment authorizing its use has been approved. Attached are the guidelines for licensing this device and I have indicated those items I would like you to complete. Dr. Janjan has tentatively scheduled a treatment using this device for October 10th and William Adam, Acting Head of Licensing for the NRC Region III, has agreed to process our request on an emergency basis so that this treatment can be made. I would appreciate your prompt attention in providing this information so that we can FAX the application to Dr. Adam as soon as possible.

We have apparently been in violation of the NRC licensing requirement since the installation of this unit. I have reviewed my file regarding its installation and find no indication that such approval was required. Also, I do not recall seeing anything about licensing requirement for this unit in either the HPS or AAPM newsletters. Would you review your correspondence, technical information, etc. regarding this unit to determine if we missed the requirement accidentally or if the company simply did not inform us of the need to license this unit at the time we purchased it.

Please inform all radiation oncology staff that until the amendment to our license is granted, this unit cannot be used.

Sincerely,

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb
Encl.
cc: Frank Wilson, M.D.
bcc: Tim Longden

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

October 1, 1990

William J. Adam, Ph.D.
Acting Chief of Licensing
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Bill:

I appreciate your prompt response in sending me the information required for licensing a remote afterloading device. Attached is the information requested. As I indicated in our telephone conversation of Sept. 28th, there is a patient who is tentatively scheduled for therapy with this device on October 10th and if our amendment request can be processed in time for this therapy, I would appreciate it. If additional information or clarifications are needed, please call me at (414) 257-5381 or Michael Gillin, Ph.D., Chief of Medical Physics, Radiation Oncology (414) 257-5636.

No license fee is required as the Milwaukee County Medical Complex is a branch of the Milwaukee County Government.

Sincerely,

Charles R. Wilson, Ph.D.
Associate Professor of Radiology
Radiation Safety Officer

CRW:mb
Encl.

Low Dose Rate Remote Afterloading System
At MCMC and FMLH

I. Description of Sources

A. Source Description

1. Ir-192
2. Ir-192 seeds in ribbon form from Best Industries or Nuclear Products, Inc. or Ir-192 wire from Amersham or CISUS
3. Maximum activity is 185 GBq (5 Ci)
4. Maximum number of sources is 15

B. Device Description

1. Manufacturer: Nucletron
2. Model name: Microselectron LDR

II. Intended Use:

To be used for interstitial and intracavitary treatment of cancer to augment the existing program in brachytherapy. This is the low dose rate unit and does not represent a significant change in the normal practice of brachytherapy.

III. Proposed Users:

Radiation Oncology clinical faculty, who are all board certified physicians in Radiation Oncology or the equivalent. These physicians will be supported by the Physics and Dosimetry staff of the Department of Radiation Oncology.

IV. Training for Individuals

A. Device operators are the physician and physics staff of the Department of Radiation Oncology.

B. The sources are exchanged with each use. Sources are prepared and tested by the Physics and Dosimetry staff of the department. Since the sources are the normal strength for radiation brachytherapy, no special skills are required.

C. Michael T. Gillin, Ph.D.
Associate Professor
Radiation Oncology
Medical College of Wisconsin

D. This device is used for 24 hours per day for the duration of the implant which may last up to one week. No other individual is on-site during this entire time. Support staff is available for telephone consultations.

E. The device is tested prior to each use to insure proper source transfer, proper time measurement, and proper unit functioning. There are no emergency procedures required for this low dose rate unit. No documentation of this is made.

V. Facilities

A. Attached is a floor plan of the room 4C96 and adjacent areas (Fig. 1). The room above 5C96 and below 3C96 are of identical layout. The distance from functional floor to functional floor is 18 feet (4.6 m) and the floors are composed of 6" of concrete. There is an interstitial space containing heating and cooling ducts and other utilities located between the functional floor. This space is occupied only during inspections and maintenance work. The distance between the functional floor and the floor of the interstitial walk platform is 10 feet (3 m). This walk platform is concrete 2.5" thick. (See attached diagrammatic section (Fig. 2) of interior partition and ceiling)

The following is a summary of the main materials in the walls, floor and ceiling:

South wall: No shielding required, outside area is above grade.

East wall: Gypsum wall board, 1 1/4" total thickness on metal studs and lead shielding 1/4" (6.3 mm) to a height of 7 feet (2.1 m). Adjacent area is a patient room and is unrestricted.

North wall: Lead shield, 1/4" (6.3 mm) to a height of 7 feet (2.1 m). Adjacent area is hospital hallway and is unrestricted.

West wall: Gypsum wall board, 2 1/2" total thickness on metal studs and lead shielding 1/4" (6.3 mm) to a height of 4.5 feet (1.37 m). Adjacent area is emergency stairwell and is unrestricted.

Floor: 6" concrete in floor plus 2 1/2" concrete in interstitial walk platform, adjacent area below is a patient room, distance between floors is 18 feet.

Ceiling: Same as floor.

Distance from center of bed, room 4C96 to following areas:

Room 3C96 and 5C96	:	18 feet (5.5 m)
Fourth floor interstitial space	:	10 feet (3.0 m)
Third floor interstitial space	:	8 feet (2.4 m)
Room 4C98	:	10 feet (3.0 m)
Hallway	:	12 feet (3.7 m)
Stairwell	:	6 feet (1.8 m)

B. 1. The primary treatment room has closed circuit TV and a separate audio system. Since this is a low dose rate unit, failure of any component of the visual or audio system will not prevent the system from being used, as there are no special patient monitoring requirements for normal brachytherapy.

C. 1. The normal treatment room has a door interlock. The institution reserves the right to use this device in locations other than the normal treatment room if it is decided that there is a compelling reason to do so.

2. All rooms containing patients who are undergoing a brachytherapy treatment are appropriately labeled.

3. There might be a possibility of using this device in one of the Radiation Oncology treatment rooms. Thinking is the means of assuring that other devices are not turned on to make radiation while using the remote afterloader.

4. A radiation measuring device is present for each brachytherapy patient, independent of the use of the afterloading system.

5. To the best of our understanding of this device, once the sources have been withdrawn, a separate action must be taken to redrive the sources out to the treatment position.

D. Shielding Evaluation

1. The maximum "on-time" is on the order of 1 week treatment.

2. The activities of implants to be performed in Room 4C96 will vary but adjacent unrestricted areas on the fourth floor will be surveyed to insure compliance with Section 20.105(b). If exposures in any area exceeds the limits in Section 20.105(b), the rooms 5C96 and 3C96 will be surveyed. If exposures in the following areas exceeds the limits in Section 20.105(b), the actions indicated will be taken.

a. Room 4C98, distance, 12 feet (3.7 m)
Access to this room will be restricted. No patient will be housed in this room while the implant is in progress.

b. Hallway
An ISO exposure line representing 2 mR/hr will be marked on the floor of the hallway and signs will be placed restricting access to the area behind this line to only radiation workers. Portable bedside shields (2 available) will be used to minimize the area of the hallways so restricted.

c. Interstitial Spaces (above and below room 4C96)
These spaces are normally locked and access is limited to engineering personnel. When exposure rate exceeds limits in Section 20.105(b), engineering personnel will only be allowed access to these areas when accompanied by a member of the Radiation Safety staff. Engineering will be notified of each implant for which this restriction applies.

d. Stairwell

Because of its location, this stairwell is infrequently used and occupancy is essentially nil. In the event exposure levels exceed limits, signs will be placed in the stairwell on the fifth floor and third floors stating that the area between the fifth and third floor is a restricted area, and directing anyone to exit the stairwell on the fifth or third floor except in case of an emergency. It is unlikely even in the event an individual ignores the warning signs that the individual will be exposed to a significant fraction of the recommended maximum annual dose of 0.5 rem for a member of the general public because of the limited time it would take to go between floors (estimated time less than 15 seconds).

3. For restricted areas, the normal controls will be used.

VI. Operating Procedures

1. Written standard operating procedures have been developed.

2. Copies have been distributed to the Physics and Dosimetry staff.

3. When not in use, the remote afterloading system is kept in the Brachytherapy Room within the Department of Radiation Oncology, Milwaukee County Medical Complex. The treatment room is a normal hospital room and is used for normal patient care when the unit is not in this room.

4. When the device is used, the patient who is to be treated with it is the only patient in the room.

5. Since the device is used very infrequently, daily checks are not made.

B. Calibration of Device

It is not necessary to calibrate this device nor is it possible to do so. All sources used in brachytherapy are calibrated following the recommendations in AAPM Report 13.

VII. Emergency Procedures

Emergency procedures are not required for this device.

VIII. Waste Disposal

Sources are disposed of by returning them to their manufacturer.

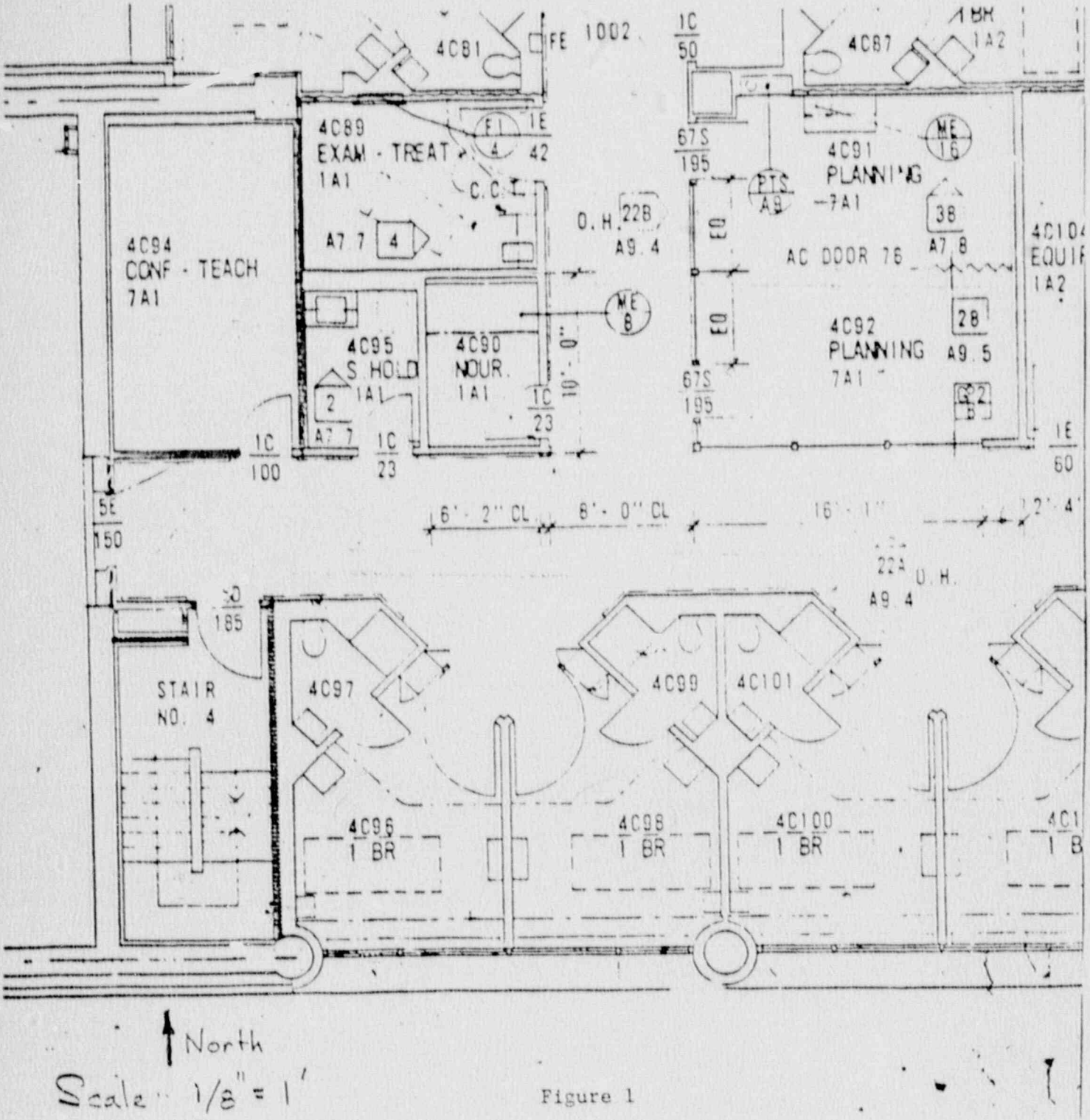


Figure 1

Froedtert Memorial Lutheran Hospital
9200 W. Wisconsin Ave., Milw., WI 53226
Southwest corner of the building showing
the room in which the Selectron is used, 4C96.

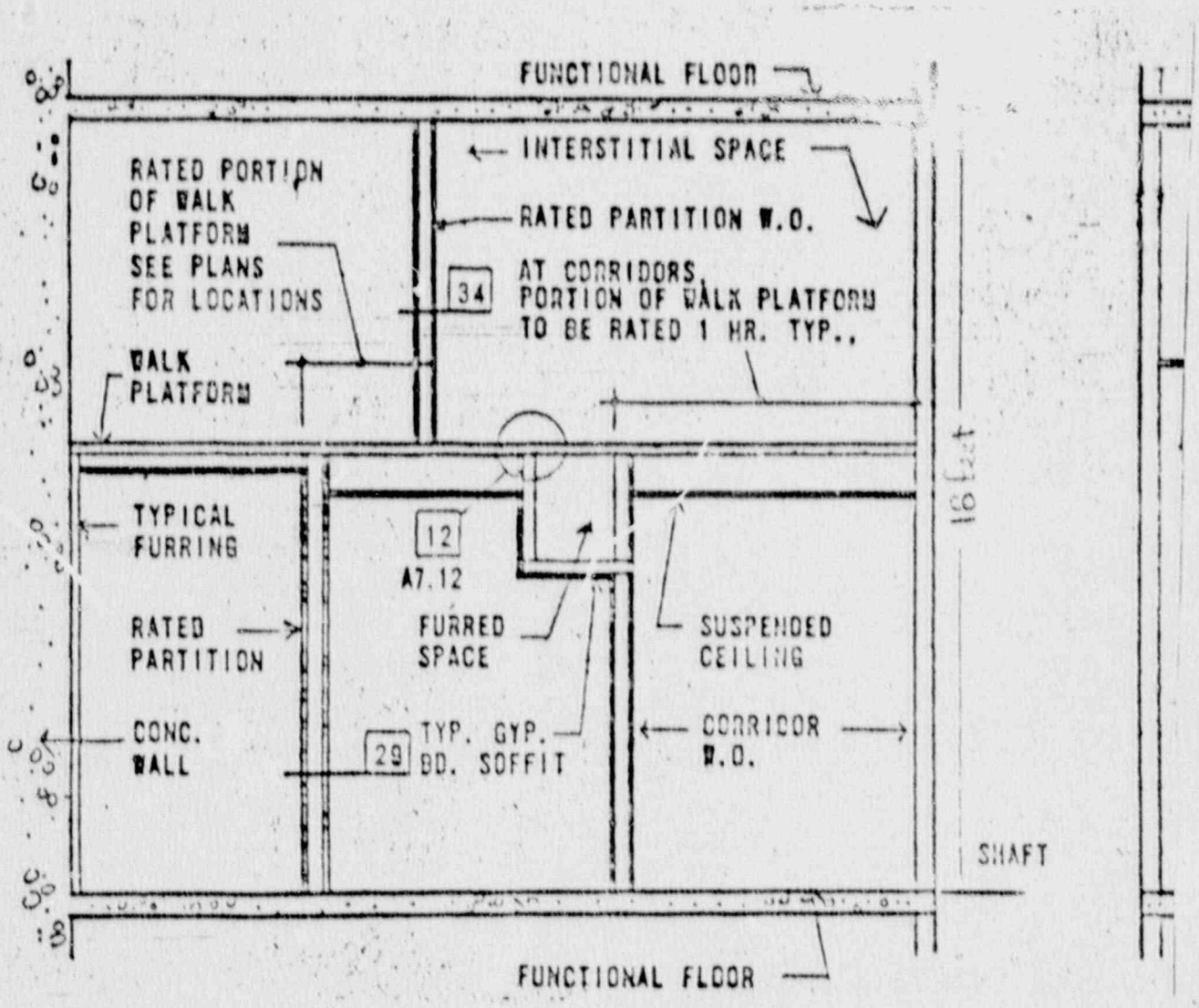


Figure 2

Diagrammatic section of interior partition and ceiling illustrating functional floors and interstitial space between floors.

Scale: 1/8" = 1'

Item #16

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

MEMORANDUM

July 26, 1990

Mike Gillen
Radiation Oncology
Milwaukee County Medical Complex

Dear Mike:

I recently reviewed branchytherapy radiation safety records with Dan Grimm. I noted that the source removal verification forms for patients receiving I-125 eye plaques were not completed and that some inventory entries regarding return of these sources to storage or decay pigs were incomplete. Dan explained that the I-125 plaques are removed under general anesthetic in the Eye Institute and after removal the sources are picked up by Radiation Oncology personnel and returned to your department. Surveys to verify source removal are difficult to perform because the patient is generally unavailble being either in the OR or recovery room. Although, because of the nature of the plaque used, it is unlikely for a source to be left in the patient, it is nevertheless required by the NRC to survey the patient to verify source removal. To insure this survey is done, radiation safety staff will perform this survey in the future, and I am requesting that when your staff is notified to pick up source, you will in turn notify the radiation safety office that the plaque has been removed. If no one is in my office, or one of the radiation safety staff cannot be reached by telephone page, please leave the message on the answering machine.

I would also like to request you to urge your staff to complete the necessary inventory entries regarding these sources as soon as possible after their removal.

Charles R. Wilson, Ph.D.
Radiation Safety Officer

CRW:mb
cc: R. Yoss
Dan Grimm

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Section of Diagnostic Radiology

October 1, 1990

Michael Gillin, Ph.D.
Chief, Medical Radiation Physics
Radiation Oncology Department
Milwaukee County Medical Complex

Dear Mike:

During the Nuclear Regulatory Commission inspection September 26-28, 1990 it was noted that there were a number of incomplete entries in the radioactive source inventory logs. These missing data were considered a violation of conditions of our license. This letter is to request that you impress upon your staff the importance of maintaining these records as completely as possible and if they encounter an incomplete record in the log, to either contact the individual responsible or my office.

Bob and I met with Dan Grimm several months ago and plan to review these records on a quarterly basis. It is anticipated that this quarterly review will allow us to avoid a similar deficiency in the future.

Sincerely,

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb
cc: Dan Grimm
D. Zellmer, Ph.D.
K. Sherwood

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-6774

October 1, 1990

Michael Story, Ph.D.
Urology Department
Froedtert Memorial Lutheran Hospital

Dear Mike:

During the Nuclear Regulatory Commission inspection September 26-28, 1990 in a review of our bioassay records and your use records, the inspectors found that on three occasions during the last 12 months you failed to obtain pre- or post-iodination bioassays for I-125. I am disappointed that I have to remind you that in your request to use radioactive materials you agreed to perform these bioassays. It is essential for all investigators to abide by all conditions of their authorizations in order for the institution to maintain its compliance to the NRC license and regulations.

I do not, at this time, know the dates of the missing bioassays, but I will send them to you for your comments when I receive them from the NRC. In the meantime, I urge you to make sure that whenever performing a labeling procedure that the required pre- and post-iodination bioassays are obtained.

Sincerely,

Charles R Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb
cc: M. Story User File

Item #19

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 1, 1990

Frank G. Steffel, NMT, RT
Supervisor, Nuclear Medicine
Milwaukee County Medical Complex

Dear Frank:

During the Nuclear Regulatory Commission inspection September 26-28, 1990 it was noted that the weekly or day-of-use test using Cobalt 57 for all frequently used isotope settings of the dose calibrator were not being performed. This QC test is a license condition and must be performed weekly. Please initiate these constancy check immediately.

Please instruct all Nuclear Medicine staff to perform this test and of the importance of maintaining records of this test.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb
Encl.
cc: D. Palmer, Ph.D.
Kutlan Ozker, Ph.D.

MULTI-ISOTOPE CONSTANCY VERIFICATION FOR MCMC RADIONUCLIDE DOSE CALIBRATOR

DIRECTIONS: PLACE THE CO-57 REFERENCE SOURCE IN THE DOSE CALIBRATOR AND RECORD THE READING FOR EACH OF THE PREASSIGNED RADIONUCLIDE KEYS

TUESDAY	Tc99m	Xe133	I-131	I-123	Ga-67	Tl201	In111	Mo-99	Initials
10/09/90									
10/16/90									
10/23/90									
10/30/90									
11/06/90									
11/13/90									
11/20/90									
11/27/90									
12/04/90									
12/11/90									
12/18/90									
12/25/90									
1/01/91									
1/08/91									
1/15/91									
1/22/91									
1/29/91									
2/05/91									
2/12/91									
2/19/91									
2/26/91									
3/05/91									
3/12/91									
3/19/91									
3/26/91									

DWP File: manyisot

Item #21

MILWAUKEE COUNTY
MEDICAL COMPLEX

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 1, 1990

Tim Longden
Administrator
Radiation Oncology
Milwaukee County Medical Complex

Re: The Nuclear Regulatory inspection Sept. 26-28, 1990

Dear Tim:

At the exit interview, the NRC inspectors expressed concern regarding unauthorized access to the sealed source storage area in Radiation Oncology. They observed that the entrance to the elevator equipment room is inside the source storage room and requested we insure that access to the radioactive materials storage room is limited to only Radiation Oncology and Radiation Safety Staff.

Would you please make whatever changes you and Mike think are needed to answer the NRC's concerns and let me know what you have decided to do.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer
Medical Physics Section

CRW:mb

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

October 12, 1990

To: Charles R. Wilson, Ph.D. Radiation Safety Officer

From: Timothy Longden, Administrator Radiation Oncology

Subject: Nuclear Regulatory Inspection

Please be advised that both Dr. Gillin and I have reviewed the documentation submitted by Nucletron Corporation with regard to the Selectron remote afterloading systems.

It appears that from the documentation that the licensing of the machine itself to be an oversight. We were one of the first Radiation Therapy practices to obtain this type of equipment. In reviewing the documentation recently provided by Nucletron the manual appears to have had a number of revisions that evolved to require the actual licensing of the machine.

The issue of our sealed source storage area will be resolved as follows:

1. Mike Zylka, Hospital Engineer will require that anyone entering the elevator equipment room must advise our physics director or the radiation safety officer.

2. Mike Zylka also agreed to place a sign on the door so that the fire department and others are aware of what is stored in the room. Our emergency telephone numbers for both the physics director and radiation safety officer will be included. (see attachment)

I am hopeful that this will answer the NRC's concerns.

cc: M. Gillin, Ph.D.
J. F. Wilson, M.D.
J. Lato
M. Zylka

CAUTION RADIOACTIVE MATERIAL

EMERGENCY CALL:
Michael Gillin, Ph.D.
Radiation Oncology Physics Dir.
257-5656 Ans. Service 274-8052
or
Charles Wilson, Ph.D.
Radiation Safety Officer
257-1991 or 257-5381

Isotope	Max Activity Ci
I-125	0.5
Cs-137	1.0
Ir-192	1.0