NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Milwaukee County Medical Complex
Milwaukee, Wisconsin

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

During an NRC inspection conducted on September 26 through 28, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee shall create in any unrestricted area radiation levels which, if an individual were continuously present, could result in the individual receiving a dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, radiation levels in an unrestricted area exceeded 2 millirems in any one hour or 100 millirems in any seven days on two occasions, and the exception did not apply. Specifically, on September 14 through 17, 1990, radiation levels of 19 millirems per hour were present in the southwest fourth floor stairwell of Froedtert Hospital, an unrestricted area, due to a brachytherapy implant procedure in an adjoining room. Similarly, on May 19 through 21, 1989, NRC evaluations determined that radiation levels in the range of 50 to 60 millirems per hour were present in the same stairwell, due to another brachytherapy implant treatment in the same room.

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of 10 CFR Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985. Item 20 of the application requires, in part, that radiation surveys of brachytherapy implant patient rooms and surrounding areas be conducted as soon as practicable after the

sources have been implanted. The survey is to include exposure rate measurements at the patient's bedside, 3 feet away from the bed, and at the entrance to the room.

Contrary to the above, On May 19, 1990, following an 800 millicurie Iridium 192 brachytherapy implant:

1. The licensee did not make surveys to assure compliance with 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, a survey, or other evaluation of radiation levels, was not performed in the unrestricted areas contiguous to the room of the brachytherapy patient.

2. The licensee failed to perform a survey of the brachytherapy implant patient room as soon as practicable following implantation of the brachytherapy sources. Specifically, Ir-192 was implanted on May 19, 1989 at 6:30 p.m. and no survey was performed until approximately 7:00 a.m. on May 20, 1989.

C. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 20 of the application requires, in part, that a person removing any brachytherapy sources document in a log book the number of sources removed, the number of sources of the same type remaining in the safe, the name of the person removing the sources, the patient's name, and the date for removal. Upon return of the sources, the same procedure is to be followed.

Contrary to the above, the brachytherapy source log book did not include all of the required information. Specifically:

1. The log book did not indicate the identity of the person removing or returning Ir-192 sources for a brachytherapy procedure which began on September 14, 1990. In addition, the log did not include the date that the sources were removed from the storage location.

2. The log book did not indicate the identity of the person removing or returning Ir-192 sources for a brachytherapy procedure which began on August 21, 1990. In addition, the log incorrectly indicated the number of Ir-192 sources remaining in the storage location as "0 millicuries" although there were approximately 33 millicuries of Ir-192 source material remaining.

3. The log book did not indicate when three 10 milligram - radium equivalent Cesium 137 sources removed from storage on September 10, 1990 were returned to storage.

4. The log book did not indicate the patient's name, the date removed from storage, or the identity of the person who removed two 25 milligram - Radium equivalent Cesium 137 sources that were returned to storage on August 8, 1988.

D. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 7 of the application requires, in part, that the Radiation Safety Committee (RSC) establish policies and approve or deny applications for the use of ionizing radiation within the Medical Complex.

The RSC's approval of an application for use of byproduct material includes, among other things, designated possession limits.

Contrary to the above, possession limits established in approved authorizations by the RSC have been exceeded by two researchers. Specifically, the licensee's September 26, 1990 inventory record disclosed that:

1. An approved individual possessed a total of 43 millicuries of Category B2 material (low energy beta emitters and low activity uses of gamma emitters) which exceeded his RSC approved possession limit of 20 millicuries.

2. An approved individual possessed 41 millicuries of H-3, a Category B2 material, which exceeded his RSC approved possession limit of 20 millicuries.

E. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated January 15, 1987.

Item 2 of the January 15, 1987 letter requires that the criteria for approving potential users of byproduct material for non-human use be, at a minimum, the criteria listed in 10 CFR 33.15(b).

10 CFR 33.15(b) requires, in part, 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 hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used.

Contrary to the above, the RSC has approved potential users for non-human use of byproduct material whose training and experience did not meet the minimum requirements described in 33.15(b). Specifically:

1. As of September 28, 1990, an individual was authorized to use byproduct materials; however, the individual's application for radioactive material use showed the only training in radiation protection or health physics to be attendance at the annual radiation safety inservices provided by the RSO, and these inservices were not of sufficient scope or duration to satisfy the requirements of 10 CFR 33.15(b).

2. As of September 28, 1990, an individual was authorized to use byproduct materials, including a special authorization for possession

of Tritium (H-3) for radiolabeling; and the individual's application showed no previous experience with H-3.

3. As of September 28, 1990, an individual was authorized to use byproduct materials, including Iodine 125; however, the individual's application showed no previous experience with that isotope, and documented only experience in handling up to 1 millicurie of H-3.

4. As of September 28, 1990, a principal investigator was authorized to use byproduct materials; however, the individual's application for radioactive material use showed that the individual's training was limited to four hours of basic radiation protection practices, measurements, and calculations. The application further specifically stated that the investigator had no training in biological effects of radiation.

F. 10 CFR 33.13(c) requires that the licensee establish administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations.

License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 7 of the application requires, in part, that the RSC establish policies and approve or deny applications for the use of ionizing radiation within the Medical Complex.

The RSC's approval of an application for use of byproduct material includes, among other things, a requirement that the individual authorized to use ionizing radiation train and instruct all personnel in his laboratory in the specific procedures to be followed concerning the use of ionizing radiation.

Contrary to the above, a graduate student working for an approved user in laboratory 325 MCW handled ionizing radiation sources in the form of P-32 from June 1990 through September 1990 and had received no training with regard to proper survey and monitoring requirements prior to working with the P-32.

G. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 17 of the application requires that:

1. Laboratories be surveyed by the individual user in a manner appropriate for the radioactive materials used in the laboratory. The frequency of such surveys shall be weekly when greater that 100 microcuries are used or when any process is performed involving less then 1 millicurie of Phosphorous 32 (P-32). If more than 1 millicurie of P-32 is used, then a survey will be made immediately after the use.

2. All elution, preparation, and injection areas in the Nuclear Medicine Department will be surveyed each day of use with an appropriate low-range survey meter or a series of wipe tests.

3. The RSO, or his designee, shall perform monthly radiation and contamination level surveys in all common radioactive waste holding or storage areas.

Contrary to the above, required surveys were not, in all cases, performed in that:

1. a. An individual in laboratory 325 MCW used greater than 100 microcuries of P-32 from May 1990 to September 1990 and failed to perform required surveys during that time.

b. An individual in laboratory 229 MCW used greater than 100 microcuries of P-32 on several occasions in June and July 1990 and failed to perform weekly surveys during the weeks of use.

c. An individual in laboratory 242 MCW used greater than 100 microcuries of Sulfur 35 (S-35) on several occasions between July 20, 1990 and September 27, 1990 and failed to perform any surveys.

2. The Medical Complex Nuclear Medicine Department failed to perform daily surveys of elution, preparation, and injection areas on numerous days of use between July 6 and August 16, 1990.

3. The RSO, or his designee, failed to perform monthly waste storage and holding area radiation surveys of any type between March 21, 1989 and February 1, 1990 and between June 29, 1990 and August 16, 1990. The RSO, or his designee, also failed to perform monthly waste storage area contamination surveys from January 1989 to September 1990.

H. 10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the purposes authorized in the license.

License Conditions 6.E, 7.E, 8.E, and 9.E authorize the possession and use of any byproduct material listed in Group VI of Schedule A, 10 CFR 35.100. Group VI limits the possession and use of Ir-192 to seeds encased in nylon ribbon for interstitial treatment of cancer.

Contrary to the above, the licensee purchased and, on several occasions from 1987 through mid-1990, used Ir-192 as sealed sources in a Nucletron Corporation Model 4000 remote afterloader brachytherapy device for intracavitary treatment of cancer.

I. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 23 of the application requires, in part, that thyroid counts be performed on employees working with or near the vicinity of one millicurie or more of volatile or dispersible I-125 in a fume hood within ten days of the use, as described in Regulatory Guide 8.20 for infrequent use.

Contrary to the above, thyroid counts were not performed on an employee following iodination in a fume hood which involved one millicurie of volatile I-125 in the form of sodium iodide. These iodinations occurred on December 29, 1989 and July 31, 1990.

J. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 10 of the application requires that dose calibrator constancy checks include a reference source check on the appropriate setting of all commonly used radionuclides at least weekly, or on the day of use.

Contrary to the above, as of September 28, 1990, dose calibrator reference source checks were not performed on certain commonly used radionuclide settings for the dose calibrator located in the Medical Complex Nuclear Medicine Department. Specifically, no checks were performed on the Technetium 99m, Molybdenum 99 or the Iodine 131 dose calibrator settings.

K. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 15 of the application prohibits, among other things, eating or drinking in any area where radioactive material is stored or used. Storage of food, drink or personal effects with radioactive materials is also prohibited.

Contrary to the above, on September 27, 1990, in laboratory 325 MCW, food was stored in a refrigerator which also contained radioactive materials. Further, evidence of beverage consumption was also observed by the NRC inspector in the same laboratory.

L. 10 CFR 20.401(b) requires, in part, that each licensee maintain records showing the results of surveys required by 10 CFR 20.201(b), and records of disposals made under 10 CFR 20.303.

Contrary the above:

1. As of September 28, 1990, the licensee did not maintain records of those surveys made to assure compliance with 10 CFR 20.101, which restricts the radiation dose of personnel working in restricted areas. Specifically, no record of whole body or extremity exposure evaluations were maintained for nuclear medicine personnel who failed to submit their assigned TLD dosimetry devices for April and/or May 1990.

2. As of September 28, 1990, the licensee did not maintain records of the disposal of licensed materials made to the sanitary sewerage system. Specifically, no record was maintained of P-32 disposal into the sink of laboratory 229 MCW during the 1990 calendar year.

M. License Condition No. 28 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated May 29, 1985.

Item 17 of the application requires, in part, that the Radiation Safety Officer (RSO), or his designee, perform radiation audits at least once each quarter in all laboratories using radioactive materials.

Contrary to the above, laboratory radiation audits were not conducted by the RSO, or his designee, from the first quarter of 1988 through September 28, 1990.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - $3,750 (assessed equally among the 12 violations).

Pursuant to the provisions of 10 CFR 2.201, Milwaukee County Medical Complex (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances,

(3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1990), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to a Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

Carl J. Paperiello for

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 23rd day of November 1990

Enter

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

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

Gentlemen:

This refers to the routine safety inspection conducted by Messrs. W. J. Slawinski and J. Cameron of this office on September 26-28, 1990, of activities at Milwaukee County Medical Complex, Milwaukee, Wisconsin authorized by NRC License No. 48-04193-01 and to the discussion of our findings with Ms. Janice Lato and Messrs. S. Tomkalski, C. Wilson, Ph.D. and R. Yoss at the conclusion of the site inspection.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements and interviews with personnel.

During this inspection, certain of your activities appeared to be in violation of NRC requirements. You will be notified by separate correspondence of our decision regarding enforcement action based on the findings of this inspection. No written response is required until you are notified of the proposed enforcement action.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosed inspection report will be placed in the NRC Public Document Room.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

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

Enclosure: Inspection Report
No. 030-03444/90001(DRSS)

cc w/enclosure:
DCD/DCB (RIDS)

bcc w/enclosure:
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS

RIII	RIII	RIII	RIII	RIII	RIII
Slawinski/da/mj	Cameron	Schultz	Grobe	Pederson	Norelius
10/25/90	10-25-90	10-25-90	10/25	10/25	10/25

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UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-03444/90001(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

Site Inspection Conducted: September 26 through 28, 1990

Inspection At: Milwaukee County Medical Complex
Milwaukee, WI

Inspectors: Wayne Slawinski 10-25-90
Wayne Slawinski, Senior Date
Radiation Specialist, Nuclear
Materials Safety Section 1

William H. Schultz/sor 10-25-90
James Cameron Date
Radiation Specialist, Nuclear
Materials Safety Section 1

Reviewed By: William H. Schultz 10-25-90
William Schultz, Chief Date
Nuclear Materials Safety
Section 1

Approved By: John G. Grobe 10-25-90
J. A. Grobe, Chief Date
Nuclear Materials Safety
Branch

Inspection Summary

Inspection on September 26-28, 1990 (Report No. 030-03444/90001(DRSS))
Areas Inspected: Routine, announced safety inspection to assess the adequacy of the licensee's NRC-licensed operations including: organization and management controls; qualifications, training and instruction to workers;

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audits and appraisals; inventory, material control and accountability; facilities and equipment; receipt and transfer of material; external and internal exposure controls and monitoring, radiological surveys; radwaste management; notifications and reports; and posting/labeling.

Results: Numerous apparent violations and concerns were identified which reflect a need for strengthening the NRC-licensed program and that collectively represent a significant lack of attention and management control over licensed activities. Fifteen apparent violations of NRC regulatory requirements were identified and consist of failure to: (1) maintain radiation levels in unrestricted areas within limits (Section 11); (2) establish proper administrative controls and provisions relating to management review and (3) perform laboratory audits at required frequencies (Section 7); (4) evaluate radiation levels in unrestricted areas (Section 11); (5) perform timely brachytherapy implant patient room and surrounding area surveys (Section 11); (6) maintain individual researchers' licensed material possession within internally established limits (Section 8); (7) properly evaluate proposed researchers training and experience and disapprove licensed material use by unqualified applicants (Section 5); (8) perform laboratory, nuclear medicine department and radioactive waste holding/storage area surveys as required (Section 13); (9) instruct all laboratory personnel in applicable survey and monitoring procedures (Section 5); (10) confine possession and use of byproduct material to the purposes authorized by the license (Section 2); (11) document brachytherapy source accountability and movement as required (Section 3); (12) perform thyroid bioassays (Section 12); (13) perform dose calibrator constancy checks as required (Section 9); (14) properly control beverage consumption and food storage in laboratories (Section 6); and (15) maintain records of disposal and personal exposure evaluations as required (Section 14 and 11, respectively).

DETAILS

1. Persons Contacted

*J. Lato, Assistant Hospital Administrator, Milwaukee County Medical Complex
B. Macmillan, Technician, Radiation Safety Office
*S. Tomkalski, Associate Hospital Administrator, Milwaukee County Medical Complex
*C. Wilson, Ph.D., Radiation Safety Officer
*R. Yoss, Radiation Safety Coordinator, Radiation Safety Office
D. Zellmer, Ph.D., Medical Physicist, Radiation Oncology Department

The inspectors also contacted several other licensee representatives including MCMC researchers, research assistants, technicians and graduate students, nuclear medicine department personnel and other medical physicists from the licensee's radiation oncology department.

*Denotes those present at the site exit interview on September 28, 1990.

2. Description and Scope of Licensed Program

The Milwaukee County Medical Complex (MCMC) is a type A broad scope medical and research program as defined by 10 CFR 33.11(a) and includes a Radiation Safety Committee (RSC) and Radiation Safety Officer as required by 10 CFR 33.13. Radiopharmaceuticals are used for medical diagnosis and therapy procedures at Froedtert and Milwaukee County Medical Complex Hospitals, while research involving radioactive materials is conducted by approximately 90 RSC approved researchers (principal investigators) using laboratory facilities located primarily in the Medical College of Wisconsin (MCW) Complex. Research activities utilize microcurie to millicurie quantities of radioactive material, primarily as tracer materials for biologic studies. The nuclear medicine program at Froedtert Hospital is the more limited of the the two nuclear medicine operations with two scanning cameras and a hot lab. The nuclear medicine program at the MCMC Hospital utilizes approximately eight scanning cameras, a hot lab facility and includes training programs for residents. Radiopharmaceutical therapy and brachytherapy are actively performed at both hospitals and the majority of the implant patients are hospitalized at Froedtert. The licensee performs about 15-30 brachytherapy implant therapies each year.

The MCMC license currently authorizes research activities utilizing any byproduct material between Atomic Nos. 3 and 83, inclusive, in any form up to 100 millicuries for most isotopes, with a total possession limit of 25 curies. Possession limits for certain other research use isotopes extend up to 3 curies. The license also authorizes the use of all radiopharmaceuticals approved by the FDA for diagnosis and therapy, as necessary, including up to 25 curies of sealed sources for brachytherapy.

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the purposes authorized by the license. License Condition 9E limits the use of sealed sources listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35, to any procedure listed in that schedule for Group VI material. Group VI of Schedule A, 10 CFR 35.100, limits use of Ir-192 to interstitial treatment of cancer. Contrary to this requirement, on several occasions from 1987 through mid-1990, the licensee used Ir-192 brachytherapy sources for intracavitary treatment of cancer, employing a Nucletron Corporation Model 4000 remote afterloading device. The use of byproduct material (Ir-92) for purposes not authorized by the license appears to constitute an apparent violation of 10 CFR 30.34(c).

One apparent violation was identified.

3. Purpose of the Inspection

This was a routine announced safety inspection to evaluate the licensee's radiation protection program and determine the licensee's compliance with commission rules, regulations and license conditions. The inspection focused on the licensed research program and overall management and RSC involvement and oversight. The nuclear medicine programs at MCMC and Froedtert Hospitals were cursorily reviewed during this inspection.

The previous inspection of the overall NRC-licensd program was conducted September 1986. Special inspections were conducted in 1987 and 1988 and focused exclusively on specific allegations concerning material use by unauthorized physicians.

4. Organization and Management Controls

The inspectors reviewed the licensee's organization and management controls for the radiation protection program, including radiation safety committee and radiation safety office management and oversight, organizational structure, staffing, and effectiveness of procedures and other management techniques used to implement the program.

a. Overview

Licenses of broad scope are issued only to those institutions that (1) have had previous experience operating under a specific institutional license and (2) have an established comprehensive radiation management program. A broad scope license is intended to accommodate those institutions involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. The radiation management program is required pursuant to 10 CFR 33.13 to consist of administrative controls relating to management review as necessary to assure safe operations including establishment of appropriate procedures to assure control and use of material and completion of internal safety evaluations of proposed uses and users. The Milwaukee County

Medical Complex (MCMC) broad scope NRC license authorizes use of byproduct material by anyone, in accordance with review and approval procedures developed and implemented by the Radiation Safety Committee (RSC). License Condition No. 11(a) requires that material be used by, or under the supervision of, individuals designated by the RSC.

Overall responsibility for the conduct of NRC-licensed activities at the medical complex is vested in the MCMC Hospital Administrator. NRC-licensed research activities are conducted primarily at the Medical College of Wisconsin (MCW) and licensed material for medical diagnosis and therapy at MCMC and Froedtert Memorial Hospitals. The Medical School Dean and the Froedtert Hospital Radiology Department Manager are responsible for their respective programs. These individuals report to the MCMC assistant and associate hospital administrators, who ultimately report to the MCMC hospital administrator. Direct program management and oversight is provided by a radiation safety committee (RSC) and a radiation safety office. The radiation safety officer (RSO) reports to the RSC Chairman who, in turn, reports to MCMC hospital administration.

As a result of the numerous violations and weaknesses identified during this inspection, it appears that the medical complex has not exercised the necessary management controls and oversight over its NRC-licensed program. The licensee's management control and oversight program are discussed further in the subsections below.

b. Radiation Safety Committee (RSC)

The University's RSC is composed of a chairman, a management representative, several members trained and experienced in the safe use of those radioactive materials authorized by the NRC license, and other members whose expertise complements the primary function of the committee to administer the institution's licensed program. The committee's current composition was reviewed by the inspectors and satisfies NRC requirements. The RSC meets quarterly to review proposed user applications, amendments and renewals and exposure summary reports for adherence to ALARA concepts, as required. However, the RSC's review and/or approval mechanism for proposed users appears insufficient since use approvals are granted to researchers without adequate consideration of the proposed users experience, training, and familiarity with the type and quantity of material requested. (Examples of this apparent weakness are described in Section 5.) The inspection also identified a concern with the RSC's routine blanket approval for possession and use of a variety of isotopes, regardless of a proposed users request or previous experience with the specific type, quantity or form of licensed material granted. This concern is described further in Section 8.

License application dated May 29, 1985, referenced in Licence Condition 28, requires that the RSC "review the actions of the RSO" ano "annually review the Medical Complex's efforts to maintain ALARA policies, including the efforts of the RSO, approved users, employees and management." Although the RSC reviews occupational exposure summary reports generated by the RSO during their quarterly meetings and performs similar "report" reviews on an annual basis, the committee does not audit the implementation of the radiation safety program as necessary to assure compliance with regulatory requirements. As a result of this apparent failure to adequately audit and oversee program implementation, the committee has been unaware of the programmatic weaknesses that exist including those problems identified during this inspection. Consequently, it appears necessary for the RSC to develop and implement more stringent protocol review and approval methods and an internal audit mechanism to better evaluate the RSO's performance and overall program implementation.

c. Radiation Safety Office

The radiation safety office is directly responsible for governing the day-to-day operations of the radiation protection program at the medical complex. The primary responsibility of the office is to ensure proper development and implementation of the radiation protection program approved by the RSC, through training and deployment of various audit and control mechanisms.

Other radiation safety office responsibilities include but are not limited to, the following:

- Provide general surveillance over all activities involving radioactive material through auditing, monitoring and performing radiation surveys.
- Determine compliance with regulatory requirements and conditions of project approvals (protocols) as specified by the RSC.
- Conduct training programs and instruct personnel in proper radiation protection procedures.
- Communicate with the RSC and university management and keep them informed of program issues, developments and problems.

The MCMC radiation safety office staff is comprised of an RSO, radiation safety coordinator (assistant RSO), a technician and a secretary. The RSO and assistant have each been employed by the radiation safety office for more than 8 years. This technical staff is smaller than that of most licensee's with similar size/scope programs. According to the RSO, the safety office's inability to meet laboratory audit requirements (Section 7) is directly attributable to the staffing shortage.

In addition to the research laboratory audit problem identified in Section 7, the inspection disclosed additional concerns regarding the radiation safety office's knowledge of license commitments and oversight of other (non-research related) program operations and compliance status. Specifically, the radiation safety office was unaware of certain radiation oncology department brachytherapy operations and the nuclear medicine department compliance status.

d. Summary

It appears that certain departments performing NRC-licensed activities at MCMC are operating autonomously and that licensee management is not adequately fulfilling its responsibility to oversee and govern licensed operations throughout the medical complex.

As evidenced by the numerous apparent violations and concerns identified during this inspection and described in this report, the licensee's overall management control and oversight program appears weak.

No violations were identified.

5. User Qualifications, Personnel Training and Worker Instruction

The inspectors reviewed selected aspects of approved researcher and ancillary staff qualifications and training for compliance with license requirements, commitments and 10 CFR 19.12 criteria.

License Condition No. 28, which references the application dated May 29, 1985 and the letter dated January 15, 1987, requires that the RSC review and approve/deny potential users of licensed materials based upon the training and experience requirements of 10 CFR 33.15(b). 10 CFR 33.15(b) requires that byproduct material be used only by, or under the direct supervision of, individuals who have received 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 hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used.

A review of randomly selected user applications and authorizations granted by the RSC revealed that nearly 50 percent of the approved users selected for inspector review did not appear to meet the minimum training and experience requirements specified above. Specifically:

a. An approved user (Dr. M. L. Haasch) lacked any formal training in 10 CFR 33.15(b) criteria, other than attendance at the annual inservices provided by the radiation safety office staff over the past 9 years. Their inservices are not of sufficient scope or duration to satisfy the 10 CFR 33.15(b) requirements. Dr. Haasch has been approved for use of 50 millicuries of high energy beta emitters and high activity uses of gamma emitters.

b. An approved user (Dr. H. Beinert) lacked recent training in radiation safety, his application for radioactive material use indicated only on-the-job training handling radioactive materials in the 1940's. Although Dr. Beinert has been approved by the RSC to use up to 150 millicuries of H-3, his application shows no previous experience with this isotope or similar quantities of low energy beta emitters.

c. An approved user (Dr. C. Lai) lacked any previous experience with the byproduct material for which he is approved. Although Dr. Lai is approved for use of I-125, his application shows no previous experience with gamma emitters.

d. An approved user (Dr. A. Haas) had been authorized for the use of all beta emitters, all unsealed uses of gamma emmiters, and radiolabeling with up to 10 millicuries of radioiodine and 150 millicuries of H-3. However, his application for radioactive material use shows that applicable training is limited to 4 hours of basic radiation protection practices, measurement and calculations and specifically states that he had received "no training in biological effects of radiation."

The Radiation Safety Officer stated that he was unaware of the 33.15(b) license commitment and that the requirements are overly restrictive. Failure to follow the specified criteria for approving potential users for non-human use of byproduct materials constitutes an apparent violation of License Condition No. 28.

10 CFR 33.13(c) requires that the licensee establish appropriate administrative procedures to assure control of procurement and use of byproduct material and safety evaluations of proposed uses of byproduct material, which take into consideration such matters as operating and handling procedures.

Research applications/protocols for the use of byproduct materials are reviewed and approved by the Radiation Safety Committee to ensure that licensed materials are used safely and with regard to regulatory and license requirements/commitments. RSC approved protocols include requirements that authorized users provide training and instruction to all personnel in their laboratories. Personnel are to be instructed in the specific procedures to be followed concerning the use of ionizing radiation in the laboratory including survey and monitoring requirements.

Contrary to the above, a graduate student working for Dr. Haas in laboratory 325 MCW has handled millicurie quantities of P-32 since June 1990 and reportedly received no training with regard to proper survey and monitoring procedures. The student had not been instructed that routine laboratory surveys were to include a survey for removable contamination in the areas where P-32 is used. As a result, the student failed to perform appropriate laboratory surveys as required. Laboratory surveys are discussed further in Section 13.

Failure to properly instruct laboratory personnel in the specific procedures to be followed concerning the use of licensed materials, including laboratory survey requirements, constitutes an apparent violation of 10 CFR 33.13(c).

Inspector review of inservice records indicated that the frequency and content of the training provided to ancillary personnel in housekeeping, nursing and to laboratory staff satisfied 10 CFR 19 and license requirements. The Radiation Safety Office provides instruction to ancillary staff initially upon employment and annually thereafter as required. No problems were noted in this area.

Two apparent violations were identified.

6. Radiation Protection Procedures

The Radiation Safety Office has developed a radiation safety manual, which is distributed to all approved users. This manual is not referenced in the license application; however, portions of the manual have been submitted in support of licensing actions. The manual was reviewed by the inspectors and appears adequate; no problems were noted with its content. License Condition No. 28, which references the application dated May 29, 1985, includes Item 15, entitled, "General Rules and Safe Use of Radioactive Material." This section is also included in the licensee's aforementioned radiation safety manual. Item 15 of the application prohibits eating, drinking or smoking in any area where radioactive material is used or stored and the storage of food, beverages or personal effects with radioactive materials.

During laboratory inspections on September 27, 1990, the inspectors observed food stored with radioactive materials in a refrigerator located in Dr. Haas' laboratory, 325 MCW and evidence of beverage consumption (half-filled coffee pot and empty soft drink cans). The storage of food with radioactive materials and beverage consumption in radioactive material use laboratories constitutes an apparent violation of License Condition No. 28

One apparent violation was identified.

7. Internal Audits and Appraisals

The inspectors reviewed the licensee's self audit and appraisal program for compliance with 10 CFR 33.13 and license commitments. Inspector findings are provided below.

Research activities are conducted using licensed material in approximately 80-100 labs located primarily in the medical college complex. These activities are required to be conducted pursuant to RSC approved protocols, which typically define the radiological controls necessary to ensure safety and compliance with regulatory requirements. Item 17 of license application dated May 29, 1985 and Item 7 of letter dated

January 26, 1987, both referenced in License Condition 28, respectively require that "radiation audits" be performed at least once each quarter by the RSO or his designee in all research laboratories using radioactive materials and that results of surveys performed by the radiation safety office during their "periodic audits" be maintained. Contrary to this requirement, the radiation safety office discontinued performance of research laboratory audits and surveys during the first quarter of 1988. The audits ceased reportedly because the number of labs continued to increase and safety office staff was insufficient to meet the audit requirements. The failure to perform radiation safety office audits and surveys in all research labs on at least a quarterly basis, appears to constitute a violation of regulatory requirements. The radiation safety office continues to routinely visit research labs to collect radwaste and distribute personal dosimetry devices; however, these visits do not constitute audits.

Inasmuch as neither the RSC nor MCMC administration were reportedly aware of the problems associated with implementation of its NRC-licensed program, including the discontinuance of radiation safety office lab audits in 1988, it appears that the licensee has not established proper administrative controls and provisions relating to management review pursuant to 10 CFR 33.13. The failure to establish administrative controls and previous relating to management review, necessary to assure safe operations, appears to constitute a violation of 10 CFR 33.13(c).

The overall lack of an adequate internal audit and inspection program has resulted in a significant program weakness. Two apparent violations were identified.

8. Inventory, Material Control/Accountability and Source Leak Testing

The inspectors reviewed the medical complex's licensed material inventory, material control and accountability systems and selected aspects of their sealed source leak test program. Inspector findings are discussed below.

a. Licensed Material Inventory, Control and Accountability

The medical complex broad scope license allows possession of a vast array of isotopes, in millicurie to curie quantities, for diagnostic and therapeutic medical applications, medical research and research and development. For example, the licensee is authorized to possess any radiopharmaceutical identified in 10 CFR 35.100-35.500 (medical use groups I-VI), in curie quantities or as needed for medical use, and millicurie to curie quantities of any byproduct material in any form with atomic numbers 3-83, for medical research and research and development. Several other specifically listed sealed sources are also authorized.

(1) Research Material Control and Accountability

The purchase of radioactive materials at the medical complex is dictated by guidelines established by the RSC. All purchase requests for radioactive materials are approved by the

radiation safety officer before the purchasing department issues a purchase order. Radiation safety office purchase order approval allows user authorization to be verified and thereby enhances inventory controls.

The licensee has developed a computerized user and material inventory control and tracking system for research activities. The tracking system is typically updated on a quarterly basis by the radiation safety office. Computer printouts list authorized users (principal investigators), and type and quantity (activity) of material possessed by each. Newly ordered material is added to the running inventory system by the radiation safety office upon order approval. Authorized users are required to submit material use and disposal information to the radiation safety office for quarterly inventory updates. No problems were noted with the development of the licensee's inventory and material control system for research related materials. However, problems were identified with the licensee's ability to maintain quantities of licensed material possessed by individual users within limits established by the RSC. Details of this problem and a related concern are provided below.

License Condition No. 28 requires the licensee to conduct its program in accordance with the statements, representations and procedures contained in an application dated May 29, 1985.

Item 7 of the application requires that the Radiation Safety Committee (RSC) establish policies and procedures and review/approve applications for the use of ionizing radiation within the Medical Complex.

Research applications/protocols for the use of byproduct materials are reviewed and approved by the Radiation Safety Committee and approved protocols include limitations on the possession of byproduct materials. Each authorized user approved application includes specific possession limits for various categories or groups of isotopes.

Contrary to the above, possession limits established in approved applications by the Radiation Safety Committee have been exceeded by certain researchers. Specifically, the licensee's September 26, 1990 inventory record disclosed that:

(a) Dr. H. Miziorko possessed a total of 43 millicuries of Category B2 materials (i.e., low energy beta emitters and low activity uses of gamma emitters) which exceeded his RSC approved possession limit of 20 millicuries.

(b) Dr. L. Ryan possessed 41 millicuries of H-3, a Category B2 material, which exceed his RSC approved possession limit of 20 millicuries.

Failure to maintain the quantity of licensed material possessed by individual researchers within internally established limits, appears to be a violation of License Condition 28.

In addition to the above, the inspectors expressed concern that the RSC routinely grants what appear to be unneccesarily liberal authorization to researchers for possession and use of various isotopes in one or more of four semi-broad categories, without verifying the proposed users previous training and experience with all materials and quantities approved. For example, a user was granted approval for "B2 category" material (i.e. any low energy beta emitter or low activity (less than 250 microcurie) uses of gamma emitters), although the proposed user has no experience with handling gamma emitters and had requested use of only one specific isotope. (Refer to Section 5 for related details). Licensed material "categories" and possession limits routinely granted by the RSC are as follows:

Categories	Possession Limits
B1: RIA kits	Less than 10 uCi/kit Total Possession less than 20 uCi
B2: Low energy beta emitters Low activity gamma emitters (_250 uCi in 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

Categories	Possession Limits
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 of H-3 less than 200 mCi and iodine less than 20 mCi

(2) Nuclear Medicine Material Control and Accountability

A sealed source inventory record and material use and accountability system is maintained by the nuclear medicine departments at MCMC and Froedtert hospitals. The inspectors selectively reviewed material use and accountability records for MCMC hospital for 1990 t[illegible]e date of this inspection; no problems were noted. Material purchase, receipt and patient disposition records appear to be prop[illegible]rly maintained as required.

(3) Radiation Oncology Material Control and Accountability

Brachytherapy sources used by the MCMC Radiation Oncology Department for therapeutic purposes are ordered, received and controlled by the oncology department medical physics staff. The radiation safety office does not normally control or oversee brachytherapy source inventory or movement. As of September 27, 1990, the radiation oncology department possessed 64 cesium-137 brachytherapy tube sources ranging in activity from 3-25 milligrams of radium equivalent. The licensee also routinely possesses varying amounts of iridium-192 brachytherapy seeds, which are ordered as needed and returned to the manufacturer after use.

License Condition No. 28 requires the licensee to conduct its program in accordance with the statements, representations and procedures contained in an application dated May 29, 1985.

Item 20 of the application requires that brachytherapy source movement be documented in a log book and include the number of sources removed, the number of sources of the same type

remaining in the safe or storage area, the name of the person removing/returning the sources, the patient's name, and the date of the removal/return.

Contrary to the above, the brachytherapy source accountability log did not always include all required information. Specifically:

(a) The accountability log did not indicate the identity of the person removing or returning Ir-192 sources for a brachytherapy procedure which began on September 14, 1990, nor include the date that the sources were removed from the storage location.

(b) The accountability log did not indicate the identity of the person removing or returning Ir-192 sources for the brachytherapy procedure which began on August 21, 1990. In addition, the log incorrectly indicated the number of Ir-192 sources remaining in the storage location as "0 millicuries" although there were approximately 33 millicuries remaining in storage during the implant procedure.

(c) The accountability log did not indicate if three 10 mg-RA-equivalent Cs-137 sources removed from storage on September 10, 1990 were returned to storage.

(d) The accountability log did not indicate the patient's name, the date removed from storage, or the identification of the person removing two 25 mg-RA-equivalent Cs-137 sources returned to storage on August 8, 1988.

Failure to properly document and account for all brachytherapy source movement appears to constitute a violation of License Condition 28.

In addition to the above, the inspectors identified concerns related to brachytherapy source storage and source accountability upon their explant from patients. Specifically, the brachytherapy source storage safe, used to store all cesium-137 sources when not in use, is not routinely locked, although hospital maintenance personnel have access to the room where the safe is located. Also, the licensee relies on user physicians to perform initial brachytherapy source accountability upon their explant from patients, and allows the physicians to return the explanted sources to the storage area where they remain until a medical physicist returns them to the storage safe and subsequently conducts an inventory. As a result of this practice, brachytherapy sources have remained in the source storage area within their transport cart for extended periods (7-10 days), before they were returned to the storage safe and complete inventories conducted.

b. Sealed Source Leak Testing and Accountability

The licensee conducts physical inventories to account for all sealed sources possessed under the license in accordance with License Condition 24 and source leak tests pursuant to License Condition 12. The radiation safety office tracks approximately 40 sealed sources for leak test purposes. Leak tests of sealed calibration and brachytherapy sources are performed by the radiation safety office. Inspector review of selected leak test records for 1989 to date in 1990 revealed no significant problems. The inspectors, however, alerted the licensee that a composite leak (wipe) test taken on numerous sources could spread contamination to other sources, if one or more sources was leaking or otherwise contaminated.

Two apparent violations were identified.

9. Facilities and Equipment

The licensee's medical and research facilities appear to be as described in their referenced May 29, 1985 application. Research laboratories appear to have adequate facilities for the safe use of radioactive materials, including fume hoods and/or glove box arrangements for use of volatile radionuclides. The inspectors visited a laboratory that contained a dedicated fume hood used for radiolabeling experiments with volatile H-3 and radioiodines. The fume hood housed a small glove box, designed by the licensee, for added contamination controls and worker protection from inhalation. The licensee reportedly possesses a couple of these mini glove boxes.

Nuclear Medicine facilities in the Medical Complex appeared adequate. Sufficient material and waste storage space were available for use. A properly operating fume hood for radioxenon and radioiodine storage and dose preparation was located in the hot lab. Radioxenon use areas were evaluated and found to be at negative pressure with respect to the surrounding areas as required. Exhaust ventilation is as stated in the licensee's referenced application.

License Condition No. 28, which references the application dated May 29, 1985, requires that certain dose calibrator checks be performed at specified intervals. Item 10 of that application requires that dose calibrator constancy checks include use of a relatively long-lived reference source, checked on all the commonly used radionuclide settings (i.e., Tc-99m, Mo-99, and I-131) at least weekly.

A selective review of records and interviews with the licensee personnel indicated that no weekly constancy checks of the dose calibrator located in the Medical Complex Nuclear Medicine department is performed. Failure to perform weekly dose calibrator constancy checks on all commonly used radionuclide settings constitutes an apparent violation of License Condition No. 28.

The licensee maintains an adequate supply of calibrated G-M and ionization type survey instruments. Instrument calibrations are performed in-house by the radiation safety office using brachytherapy sources that have been intercompared with a National Bureau of Standards traceable source. Survey instruments are calibrated to within 10 percent of the true or expected reading. However, the inspectors noted a potential ambiguity in calibration records which resulted in the licensee's inability to readily interpret calibration record information. In addition, the activity of the calibration sources were minimally acceptable to meet license commitments delineated in referenced letter dated January 15, 1987. The referenced letter requires that the licensee maintain at least one survey instrument calibrated on scales greater than 500 mR/hr; however, the limited activity of the calibration sources could introduce significant uncertainty in calibration precision.

One apparent violation was identified.

10. Receipt and Transfer of Material

The licensee utilizes two locations for radioactive material receipt, the MCMC Hospital and the Medical College of Wisconsin (MCW). After the receipt of materials at those locations, materials are transported to specific locations in the nuclear medicine radiopharmacy laboratory and room N-206-B at the Medical College. MCW packages are opened and monitored by radiation safety office staff and distributed to the individual researches. Nuclear Medicine packages are monitored and processed by the nuclear medicine technicians.

The inspectors reviewed receipt and survey records for radiopharmaceutical packages received at the MCMC nuclear medicine department from January 1990 to September 1990. No deficiencies were noted.

No violations were identified.

11. External Exposure Controls and Monitoring

The inspectors reviewed selected aspects of the licensee's external exposure control, monitoring and personnel dosimetry programs for research and medical therapeutic activities. Inspector findings are presented below.

a. Personnel External Exposure Monitoring

Personnel external whole body exposures are monitored by film badges supplied and processed by R.S. Landauer, Jr., and Company on a monthly basis, a vendor that meets 10 CFR 20.202(c) requirements. Landauer TLD ring badges are issued to researchers handling high energy beta or gamma emitters and to individuals in the departments of Radiation Oncology, Nuclear Medicine and Radiation Safety.

Currently, approximately 500 individuals are issued film badges for whole body exposure monitoring of NRC licensed and non-NRC licensed materials.

The inspectors selectively reviewed film and TLD badge processing results for researchers, MCMC nuclear medicine, radiation oncology and radiation safety office personnel for calendar year 1989 and 1990 through August. No exposures approaching 10 CFR 20.101 limits were noted. The highest extremity exposures were recorded for nuclear medicine student technicians.

10 CFR 20.210(b) requires that each licensee make such surveys (evaluations) as (1) may be necessary to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 10 CFR 20.401(b) requires that each licensee maintain records showing the results of surveys (evaluations) required by 10 CFR 20.201(b).

Contrary to the above requirement, records were not maintained of evaluations made to assure compliance with 10 CFR 20.101, radiation dose standards for individuals in restricted areas. Specifically, no record of exposure evaluations were maintained for five individuals working in the MCMC nuclear medicine department, who failed to submit their assigned whole body or extremity dosimetry devices for processing in April and May 1990. According to the licensee, exposure evaluations were performed by the radiation safety office and no significant exposures were deemed to have occurred. The licensee does not normally assign an exposure to personnel that lose or otherwise do not submit their dosimetry devices for processing, unless a significant exposure is determined to have been incurred.

b. Brachytherapy Implant Monitoring

The inspectors reviewed the licensee's exposure control program related to brachytherapy and radiopharmaceutical therapy procedures. The licensee typically performs several radiopharmaceutical and/or brachytherapy procedures requiring patient hospitalization per month. Brachytherapy procedures are controlled by the radiation oncology department and are routinely conducted during off-hours when radiation safety office personnel are not present at the medical complex. Consequently, initial radiation surveys of implant patients, their hospital rooms and surrounding areas are usually conducted by a medical physics or oncologist staff member and not radiation safety office personnel. As a result of this practice and the radiation safety office's subsequent failure to perform thorough surveys, radiological problems have occurred. These problems are described below.

Treatment records indicate that a patient was implanted with 800 millicuries of iridium-192 (a large loading) at about 6:30 p.m. on May 19, 1989, and patient room and surrounding unrestricted area surveys were not conducted until the radiation safety office staff returned to the facility at about 7:00 a.m. on May 20, 1989.

License Condition No. 28 requires that licensee to conduct its program in accordance with statements, representations and procedures contained in an application dated May 29, 1985.

Item 20 of the application requires that radiation surveys of brachytherapy implant rooms and surrounding areas be conducted as soon as practicable after the sources have been implanted. The survey is to include but not necessarily limited to exposure rate measurements at the patient's bedside, 3 feet away from the bed, and at the entrance to the room.

Contrary to the above, the licensee failed to perform implant patient room and surrounding area surveys in a timely (as soon as practicable) manner. As noted above, the licensee implanted 800 millicuries of Ir-192 on May 19, 1989 at 6:30 p.m. in room 4179 of Froedtert Hospital and did not perform any surveys until approximately 7:00 a.m. on May 20, 1989. The failure to perform timely surveys appears to constitute a violation of License Condition 28.

The surveys performed by the radiation safety office on May 20, 1989 for the above described procedure consisted solely of measurements at the patients bedside, one meter from the bed, and at the entrance to the patients room. Radiation levels at one meter from the patient were measured by the licensee at 300 mrem/hour. No survey or other evaluation was performed to determine radiation levels in the unrestricted area hallway and stairwell adjacent to the patient's room. As discussed below, the stairwell radiation level appeared to exceed regulatory limits.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, surveys were not made to assure compliance with 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, a survey or other evaluation of radiation levels in the unrestricted areas contiguous to room 4179 of Froedtert Hospital, was not performed following an 800 millicurie Ir-192 brachytherapy implant conducted on May 19, 1989.

Many brachytherapy implant patients are placed in room 4179 of Froedtert Hospital. The room is located at the end of a corridor and is specially constructed with lead lined walls and entrance door. However, the lead lining in one of the rooms four wall (adjacent to a stairwell) only extends up from the room floor about 4-5 feet. Lead lining in the remaining walls exte is up to the room's ceiling.

10 CFR 20.105(b) requires that radiation levels in unrestricted areas be limited so that if an individual were continuously present in the area, he could not receive a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, radiation levels in unrestricted areas exceeded 2 millirems in any one hour on at least two occasions since 1989. Specifically, from September 14-17, 1990, a patient was implanted with approximately 275 millicuries of iridium-192 and assigned room 4179, Froedtert Hospital. Licensee surveys performed on September 14, 1990 revealed a radiation level of 19 millirems per hour in the unrestricted area stairwell adjacent to the patient's room. Radiation levels at one meter from the patient were measured by the licensee at 90 mrem/hour.

Similarly, based on inspector calculations and evaluations, the previously discussed 800 millicurie iridium-192 implant procedure conducted between May 19-21, 1989 and employing the same room (4179) in Froedtert Hospital, appears to have produced radiation levels of about 60 millirems per hour in the stairwell adjacent to the room. The inspector's calculations and conclusions were extrapolated from licensee measurements made on May 20, 1989 and September 14, 1990. The stairwell is normally a relatively low traffic area and individuals do not usually loiter in the area for extended periods; therefore, no significant exposures are expected to have been incurred by individuals frequenting the stairwell area.

Four apparent violations were identified.

12. Internal Exposure Controls and Monitoring

The licensee has established administrative controls for the use of volatile radionuclides. Processes involving more than 10 millicuries of H-3 or 1 millicurie of radioiodine are required to be performed in a properly operating and approved fume hood. Fume hood approval must be obtained from the radiation safety office. Individuals using large quantities of H-3 in a single process must submit urine samples for bioassay. (H-3 bioassay was not specifically reviewed during this inspection.)

License Condition No. 28, which references the application dated May 29, 1985, requires in Item 23 that individuals who handle 1 millicurie or more of volatile I-125 or I-131 in a fume hood must submit to a thyroid

count within ten days as described in Regulatory Guide 8.20 for infrequent use. A review of I-131 radiopharmaceutical therapy and bioassay records indicated that nuclear medicine personnel had been properly monitored for thyroid uptake. However, a review of I-125 iodination records indicated that required bioassays had not always been performed for researchers conducting iodinations. Specifically, on December 29, 1989, Dr. M. Story handled 5 millicuries of volatile I-125 in a fume hood and did not have his thyroid monitored. Also, on July 31, 1990, Dr. Story performed an iodination in a fume hood using approximately 1 millicurie of volatile I-125 and did not have a thyroid count performed. Failure to perform thyroid bioassays within ten days of handling 1 millicurie or more of volatile radioiodine constitutes an apparent violation of License Condition No. 28. Bioassay records were reviewed for 1989 and 1990 through September 21; no significant uptakes were recorded. The inspectors' evaluation concluded that Dr. Story was not subjected to a significant uptake during his aforementioned iodinations.

One apparent violation was identified by the inspectors.

13. Radiological Surveys

The inspectors reviewed the licensee's radiological survey program for the research and MCMC nuclear medicine programs. Inspector findings are presented below.

License Condition No. 28, which references the application dated May 29, 1985 and the letter dated January 15, 1987, delineates the licensee's contamination and external radiation level survey and record keeping requirements. Item 17 of the application requires that labs be surveyed by the individual user (researcher) at frequencies dependent on the amount of material used within a given time period and in a manner appropriate for the materials used in the lab. Specifically, user laboratory surveys shall be conducted:

a. Monthly, when less than 100 microcuries are used.

b. Weekly, when more than 100 microcuries are used or when less than 1 millicurie of P-32 is used in any one process.

c. Immediately, following any process using more than 1 millicurie of P-32.

Contrary to the above, no laboratory surveys were performed in at least one example, and not performed at the required intervals in several other examples. Specifically:

a. Dr. Haas's laboratory 325 MCW, used P-32 on a near weekly basis in amounts exceeding 100 microcuries from May 1990 to September 1990, and failed to perform contamination surveys since April 1990.

b. Dr. Wilcox's laboratory 229 MCW, used greater than 100 microcuries of P-32 on several occasions in June and July 1990 and failed to perform weekly surveys (surveys were performed monthly).

c. Dr. Cashdollar's laboratory 242 MCW, used greater than 100 microcuries of S-35 on several occasions between July 20, 1990 and September 27, 1990 and failed to perform any surveys.

In most instances, laboratory personnel and/or the individual users were unaware of the institutional survey requirements. In one case, a researcher that failed to perform the required surveys claimed that the student he had assigned that task had graduated approximately 3 months prior to the inspection and remaining laboratory staff did not have the time to perform the surveys. Failure to perform laboratory surveys as required constitutes an apparent violation of License Condition No. 28.

Item 17 of the May 29, 1985 application requires all elution preparation and injection areas in the nuclear medicine department be surveyed each day that radiopharmaceuticals are used with an appropriate low-range survey meter or a series of wipe tests. Contrary to this requirement, the inspection disclosed that daily nuclear medicine department surveys had not been conducted between July 6-11, 14-16 and 18-29, 1990 and from August 4-16, 1990 when radiopharmaceuticals were used. Failure to perform nuclear medicine area surveys as required constitutes an apparent violation of License Condition No. 28.

Item 17 of the application further requires that the radiation safety office perform periodic surveys in all areas where radioactive materials are used and/or stored. Specifically, radiation safety office staff are required to survey:

a. Each research laboratory, at least quarterly, where radioactive materials are used.

b. Common waste handling and storage areas at least once each month for radiation and contamination levels.

Contrary to the above, the inspection disclosed that the radiation safety office failed to perform surveys as required. Specifically:

a. Laboratory areas where radioactive materials are used had not been surveyed since the first quarter of 1988. (This item is addressed in greater detail in Section 7).

b. The radiation safety office radioactive waste storage area had not been surveyed for contamination levels since at least January 1989. Also, no surveys of any type were performed in that area between March 21, 1989 and February 1, 1990 and during July 1990.

Failure of the Radiation Safety Office to perform contamination and radiation level surveys as required constitutes an apparent violation of License Condition No. 28.

researcher involved. On March 30, 1990, a research technician required tritiated thymidine for an experiment and noticed that the vial, which was supposed to be unopened at that time and contain 5 millicuries of the isotope, was open and empty. A label on the vial indicated that it had been opened on September 29, 1989. There was no record of the use or disposal of the material, either on the vial or in the laboratory's log book. Efforts to determine who had used the material or its ultimate disposition have been unsuccessful. An extensive contamination survey of the affected laboratory was performed on April 3, 1990, and indicated no significant problems. Bioassays conducted on laboratory personnel were negative. If the material was disposed in to the sanitary sewer as speculated, the research laboratory complex has significant water dilution to maintain effluent concentrations within regulatory limits. The matter was not pursued further during this inspection.

No violations were identified.

15. Posting, Labeling and Independent Measurements

The inspectors observed area postings, device/container labeling, and measured radiation levels in various research laboratories, nuclear medicine hot lab and scanning areas and the brachytherapy source and radiation safety office radwaste storage areas. No significant problems were noted. Posting and labeling appeared to satisfy applicable 10 CFR 20.203 requirements. Notice to workers was posted as required by 10 CFR 19.11. The inspectors toured approximately ten reserch laboratories located in the MCW complex.

(Inspector surveys were performed with an NRC ionization chamber, Eberline Model PIC-6A, SN 2302, last calibrated May 3, 1990 and a G-M meter with HP-260 probe, Ludlum Model 14C, SN 13160, last calibrated September 17, 1990.

17. Confirmatory Action Letter

As a result of the inspection findings, Region III concluded that: (1) licensee management, including the Radiation Safety Committee, does not provide adequate oversight of the licensed program, (2) the Radiation Safety Officer (RSO) is not effectively implementing the conditions of the license and applicable NRC requirements, and (3) licensed material is routinely use by individuals who do not meet the minimum training and experience requirements, as defined in the license. Due to the numerous violations and 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 CAL directed the licensee to:

a. Within 2 weeks of the telephone conversation:

(1) review the training and qualifications of current authorized users and immediately withdraw authorization for all individuals who do not meet the minimum training requirements, as specified in the 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, the 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 the facilities and licensed activities, the consultant will prepare and submit to the NRC a report of the audit findings.

The licensee's efforts at satisfying the commitments in Part a above will be discussed at the Enforcement Conference, scheduled for October 29, 1990. The licensee's overall efforts in satisfying the CAL commitments will be evaluated during future inspections.

18. Exit Meeting

The inspectors met with licensee representatives (denoted in Section 1) at the conclusion of the onsite inspection on September 28, 1990 and summarized the scope and findings of the inspection, the NRC Enforcement Policy, and the likely informational content of the inspection report with regard to documents and processes reviewed during the inspection. The licensee did not identify any such documents or processes as proprietary. The apparent violation and other concerns identified during the inspection and described in this report, were discussed with the licensee.

An additional apparent violation for failure to establish administrative controls and provisions relating to management review, pursuant to 10 CFR 33.13, was identified subsequent to the site inspection and not conveyed to the licensee at the exit meeting (Section 7).