NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
Department of the Army Madigan Army Medical Center ATTN: AFZH-MD-RP Tacoma, WA 98431	U. S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030-03368	46-02645-03	May 7-8, 1985

Licensee:

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

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

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

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

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REG5 LIC30
46-02645-03 PDR

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

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

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

[ ] D. Records of ______ were not properly maintained. 10 CFR ______ or License Condition Number ______.

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

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

[X] H. Contrary to License Conditions 12 and 19, the Radiation Control Committee granted authorization to 3 physicians for the use of Part 35 defined Group VI byproduct XXXXXXX material, who had not satisfied the required training and experience qualifications criteria.of Appendix A, USNRC Regulatory Guide 10.8.

[ ] I. ______

[X] J. Contrary to 10 CFR 20.201, a radiation survey was not made to evaluate the radiation hazard existing in the vicinity of the storage safe containing multi-millicurie quantities of Cesium 137 in sealed sources located in the Radiotherapy Depattment.

[X] K. Contrary to 10 CFR 20.105, radiation levels were measured by the licensee to be in excess of the limit of 2 mr/hr present in a womens latrine, an unrestricted area, resulting from the therapeutic use of licensed material on Ward 13 durigg Jan. 28 and February 19, 1985.

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
Larry H Powell	3 June 1985	David D Skov	5/24/85

NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

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

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

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

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

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

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

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

[ ] D. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____.

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

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

[X] H. Contrary to License Conditions 12 and 19, the Radiation Control Committee granted authorization to 3 physicians for the use of Part 35 defined Group VI byproduct ~~material~~ material, who had not satisfied the required training and experience qualifications criteria of Appendix A, USNRC Regulatory Guide 10.8.

[ ] I. _____

[X] J. Contrary to 10 CFR 20.201, a radiation survey was not made to evaluate the radiation hazard existing in the vicinity of the storage safe containing multi-millicurie quantities of Cesium 137 in sealed sources located in the Radiotherapy Department.

[X] K. Contrary to 10 CFR 20.105, radiation levels were measured by the licensee to be in excess of the limit of 2 mr/hr present in a womens latrine, an unrestricted area, resulting from the therapeutic use of licensed material on Ward 13 during Jan. 28 and February 19, 1985.

I hereby state that the corrective actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
Lt. Col. H. Lowell	3 June 1985	David D. Allen	5/24/85

ORIGINAL TO LICENSEE

DEPARTMENT OF THE ARMY
MADIGAN ARMY MEDICAL CENTER
TACOMA, WASHINGTON 98431-5000

REPLY TO
ATTENTION OF

HSHJ-RP

26 June 1985

SUBJECT: Report of the Radiation Control Committee

Commander
Madigan Army Medical Center
Tacoma, WA 98431-5000

1. IAW paragraph 4f(14), AR 40-37, 7 January 1977, the Madiagn Army Medical Center Radiation Control Committee (RCC) convened at 1300 hours on 24 June 1985.

Members Present:

LTC Robert F. Murphy, MSC	Representing the Deputy Commander for Clinical Services, Acting RCC Chairman
COL Stanton R. Brown, MC	C, Nuclear Medicine Clinic
COL Donald H. Kull, MC	C, Radiation Therapy Clinic
MAJ David W. Lee, MSC	Radiation Protection Officer, Recorder
CPT Loren M. Dehnert, MSC	Radiopharmacist, Department of Pharmacy
CPT Joseph P. Hellman, MSC	Clinical Radiological Physicist
CPT Danny Chang, MSC	Alternate Radiation Protection Officer

Members Absent:

COL Robert D. Karl, Jr., MC	C, Department of Radiology
MAJ Charles J. Hannan, MSC	Department of Clinical Investigations
CW3 Lawerence M. Ikari, MSC	C, Biomedical Equipment Maintenance Branch, Logistics Directorate

2. Old Business. The minutes of the Radiation Control Committee (RCC) meeting of 21 March 1985 were reviewed and approved as written.

3. New Business.

a. Nuclear Regulatory Commission (NRC) Compliance Inspection Results and Corrective Actions. MAMC underwent an unannounced compliance inspection of its NRC License No. 46-026-45-03 on 7--8 May 85. This inspection was conducted by Mr. David D. Skov, Radiation Specialist, of the Region V NRC Office, Walnut Creek, CA. A copy of his official inspection report is attached (Encl 1). Three deficiencies were found during this extremely thorough compliance inspection:

(1) The MAMC RCC had inadvertently granted three physicians, COL Robert D. Karl, MAJ Eileen K. Fill, and CPT Ben L. Sueoka, authorization to use Group VI radioactive materials. These individuals, all from the Department of Radiology, were not qualified IAW NRC Regulatory Guide 10.8 to use such materials. Title 10, Code of Federal Regulations (CFR), Part 35.100(f) defines Group VI radioactive materials as those sealed radioactive sources, such as Cesium-137 or Iridium-192, that are used for intercavitary or interstitial cancer treatment. An investigation by the Radiation Protection Office revealed that these three physicians were inadvertently authorized to use Group VI radioactive materials, for which they were not qualified by appropriate training and experience outlined in NRC Regulatory Guide 10.8, due to an administrative error on the part of the Radiation Protection Office. Specifically, a format was originally given to the secretary, Department of Radiology, which she used to type out COL Karl's application to the MAMC RCC to use selected radioactive materials. This format mistakenly included authorization to use Group VI radioactive materials. This format was also used to compile the applications of MAJ Fill and CPT Sueoka to use radioactive materials; hence, the error was compounded. Despite the fact that the MAMC RCC inadvertently authorized these three physicians to use Group VI-type radioactive materials, due to this administrative error by the Radiation Protection Office, none of the above three physicians have in fact ever used such materials. In order to correct these Group VI radioactive material authorizations, the MAMC RCC authorized the Radiation Protection Officer to in effect make a "line-item" deletion of the Group VI radioactive material authorizations for each of these physicians. This meant that on each physician's approved radioactive material authorization, that his/her previous authorization to use Group VI radioactive materials was simply lined through with an annotation referencing these RCC minutes of 26 June 1985. The file copies of each of these physician's radioactive material authorizations maintained in the Radiation Protection Office and in each physician's official credentials file were annotated accordingly. Finally, the format used by the secretary, Department of Radiology, was also corrected. In summary, the above "line-item" deletions for the above three physicians regarding the deletion of their previous inadvertent authorization to use Group VI radioactive materials coupled with increased vigilance in the future on the part of the Radiation Protection Office not only corrects this NRC compliance inspection finding, but hopefully will also obviate any future such occurrences.

(2) A second finding of the NRC compliance inspection dealt with the fact that no documentation existed at the time of the inspection either in the Radiation Protection Office files or in the Radiation Therapy Clinic files regarding the performance of an instrumented radiation protection survey of the unrestricted areas surrounding the lead storage safe that contains multimillicurie amounts of Cesium-137 sealed sources in the Radiation Therapy Clinic. Such a survey is required by 10 CFR 20.201 to verify that the radiation levels in areas surrounding this storage safe room are less than 2 mR/hr. At the time of the survey, the highest radiation exposure levels measured by the NRC inspector were 0.4 mR/hr at the wall in MAJ Patel's office and between 0.1 and 0.15 mR/hr 18 inches away from this point. MAJ Patel normally sat at her desk well beyond this 18-inch point. CPT Hellman, Nuclear Medical Science Officer, performed an instrumented radiation protection survey of all areas surrounding the Cesium-137 storage safe on 16 May 85 (Encl 2). As described in his report of 28 May 85, he was able to reduce the radiation exposure level at the new site of MAJ Patel's desk area to less than 0.01 mR/hr. It is not known precisely why such a radiation protection survey had not been performed and documented previously inasmuch as this Cesium-137 lead storage safe has been

present in the Radiation Therapy Clinic since circa 1977. CPT Hellman, who is CPT Judd's successor, assumed that such a survey had been performed by CPT Judd as did CPT Chang, the previous primary Radiation Protection Officer. At any rate, such a radiation protection survey required by 10 CFR 20.201 has now been performed and copies of this survey are on file both in the Radiation Protection Office and in the Radiation Therapy Clinic. This survey corrects this second NRC compliance inspection finding.

(3) The third and final NRC compliance inspection finding pertained to the fact that radiation levels in excess of the 2 mR/hr limit specified in 10 CFR 20.105 were measured in the unrestricted areas surrounding the Ward 13 sealed source brachytherapy room during Iridium-192 and Cesium-137 therapies conducted on 28 January and 19 February 1985. Specifically, in the Iridium-192 therapy conducted on 28 January 1985, a radiation level of 2.5 mR/hr was measured in the latrine directly adjacent to the brachytherapy room, and in the Cesium-137 therapy of 19 February 1985, a radiation level of 8 mR/hr was measured in the unrestricted private room latrine directly adjacent to the brachytherapy room on Ward 13. On both occasions, no patients actually occupied the private room adjacent to the Ward 13 brachytherapy room. Furthermore, the Radiation Protection Office mistakenly interpreted 10 CFR 20.105(b)(1) as permitting radiation levels in unrestricted areas higher than 2 mR/hr if the areas where such radiation levels were measured were not actually occupied by ward personnel. This turned out to be a wrong interpretation of this paragraph in the federal law. To date, no other brachytherapy treatments have been conducted that have resulted in radiation levels in unrestricted areas in excess of the 2 mR/hr limit. Title 10 CFR 20.105(b)(1), as pointed out by the NRC inspector, effectively assumes that an imaginary human being is continuously present in all unrestricted areas during the entire course of any brachytherapy treatment irrespective of whether or not any ward personnel or other patients are actually present in such areas. Given this reality, two additional mobile lead radiation shields have been procured by the Radiation Protection office on lateral transfer fro , the Troop Medical Clinic #1. These shields will be placed inside the brachytherapy room to reduce the radiation exposure levels to the unrestricted areas outside of the brachytherapy room to less than 2 mR/hr. Additionally, two large, mobile radiation shields containing one inch-thick lead have been placed on requisition. The use of these additional shields will allow the Radiation Protection Office to insure that radiation levels in adjacent unrestricted areas will not exceed 2 mR/hr. The above described problem of radiation levels in excess of 2 mR/hr in unrestricted areas stems from the fact that none of MAMC's brachytherapy treatment rooms have any lead shielding permanently installed in the room walls; hence, the need to use mobile lead shields. The Radiation Protection Office recommended in the report (HSHJ-RP), 1 June 1985, subject: Radiation Shielding Evaluation of 100% Design Plans RE: New Madigan Army Medical Center (MAMC), that three rooms in the new MAMC be fully shielded with integral wall sheet lead for brachytherapy purposes.

b. Posting of Response to NRC Inspection Findings. IAW 10 CFR 19.11(e), a copy of these MAMC RCC minutes describing the corrective actions to the above NRC inspection findings will be posted in the Nuclear Medicine Clinic, the Radiation Therapy Clinic, and on the main MAMC Radiation Protection bulletin board for a period of at least five working days.

c. Commendation of the Radiopharmacist. CPT Loren M. Dehnert, MSC, is the MAMC radiopharmacist presently assigned to the Pharmacy Service. All of his daily work, however, is performed within the Nuclear Medicine Clinic. Prior to CPT Dehnert's arrival, the previous records regarding Nuclear Medicine Clinic radioactive material accountability were in disarray. CPT Dehnert meticulously organized all of these documents. Current Army file directives outlined in AR 340-18 indicate that these documents may be transferred to the Records Holding Area after two years. CPT Dehnert astutely recognized, however, that these records must be maintained for inspection by the NRC indefinitely. CPT Dehnert not only organized and stored the above described records within the Nuclear Medicine Clinic, but also carefully trained the Nuclear Medicine Clinic technicians regarding the proper recordkeeping procedures of the various radioactive material dose calibrator quality assurance checks. Without CPT Dehnert's careful attention to radioactive material use and documentation, the outcome of MAMC's most recent NRC compliance inspection within the Nuclear Medicine Clinic would have been substantially more severe.

d. Application for an Amendment to MAMC NRC License No. 46-02645-05. Title 10 CFR Part 35.21(c) currently requires that teletherapy units, such as MAMC's Cobalt-60 radiation therapy unit, be calibrated according to a specific calibration protocol endorsed by the NRC. As indicated in enclosure 3, this protocol, written in 1971 by a committee of the American Association of Physicists in Medicine (AAPM), has since been superceded by an updated protocol published by the same organization. The apparent need for MAMC to apply for an amendment to its NRC License No. 46-02645-05 arises from the fact that the NRC, itself, has not updated 10 CFR 35.21(c) to reflect this newer, updated calibration protocol. Inasmuch as the NRC has not yet updated 10 CFR 35.21(c), a request for an amendment to MAMC's therapy license was submitted through channels on 20 June 1985. Hopefully, this amendment request will be approved after receipt of which MAMC will begin calibrating its teletherapy units under the new, updated calibration protocol.

e. Annual Radiation Protection Program Review/ALARA Evaluation. IAW the committment made by MAMC in its application for its current NRC License No. 46-02645-03, the annual review of the overall MAMC Radiation Protection Program was submitted to and approved by the MAMC RCC (Encl 4).

f. Quarterly Radiation Protection Program Audit. LTC Murphy, Administrative Coordinator to the DCCS, conducted the quarterly audit of the MAMC Radiation Protection Program on 24 June 1985 the report of which is attached as enclosure 5.

g. Decentralization of NRC Licensing Authority. The NRC, effective 1 April 1985, has decentralized its licensing authority for federal activities. As indicated in enclosure 6, this means that MAMC, instead of submitting NRC license applications or amendment requests thru HQ, HSC, thru OTSG, to the main Washington, DC NRC Office, will henceforth submit such applications and amendment requests thru HSC and OTSG to the Region V NRC Office, Walnut Creek, CA.

h. Upcoming Radiation Control Committee Changes. The MAMC Radiation Control Committee (RCC) will have two new members arising from the PCS of the RCC Chairman, COL Floyd L. Wergeland, MC, and the retirement of LTC Thomas R. Oberhofer, MSC, C,

HSHJ-RP

26 June 1985

SUBJECT: Report of the Radiation Control Committee

Microbiology, Department of Pathology in June 1985. COL Wergeland will be replaced as Chairman of the RCC by COL Leslie M. Burger, MC, due to arrive at MAMC on 14 July 1985, and LTC Oberhofer will be replaced by CPT John Schilhab, MSC, also due to arrive at MAMC in July 1985. An updated listing of the MAMC RCC membership will be published in August 1985 after receipt and evaluation of COL Burger's and CPT Schilhab's curriculum vitae. The CV's for these two new RCC members will be submitted to the MAMC RCC at the next RCC meeting scheduled for September 1985.

4. Continuing Business. None.

5. The meeting was adjourned at 1345 hours, 24 June 1985.

ALFRED S. BUCK, M.D., F.A.C.S.
Colonel, MC
Acting Deputy Commander for Clinical Services

6 Encl
as

DAVID W. LEE
MAJ, MSC
Radiation Protection Officer
RCC Recorder

APPROVED/~~DISAPPROVED~~

DARRYL H. POWELL, M.D.
Brigadier General, MC
Commanding

DISTRIBUTION:
1 ea RCC Member
8 Executive Committee