APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Inspection Report: 030-02389/94-01

License: 25-01051-01

Licensee: Deaconess Medical Center
P.O. Box 37000
Billings, Montana 59107

Facility Name: Deaconess Medical Center

Inspection At: Deaconess Medical Center (DMC)
Billings, Montana

Northern Rockies Cancer Center
Billings, Montana

Inspection Conducted: March 28 through April 29, 1994

Inspector: Linda L. Kasner
Senior Radiation Specialist

Approved: Charles L. Cain 6/10/94
Charles L. Cain, Acting Chief, Nuclear Materials Safety and Safeguards Inspection Branch — Date

Inspection Summary

Areas Inspected: This was a special, announced inspection conducted in response to the licensee's telephonic notification of two misadministrations involving brachytherapy procedures. The inspection was focused on the misadministrations, the root causes and contributing factors; the licensee's Quality Management (QM) program and its implementation; and the licensee's oversight of its brachytherapy program.

Results:

- Two misadministrations were identified by the licensee's radiation safety officer (RSO) and a consulting medical physicist. The misadministrations involved tumor doses that were 21-24 percent greater than the prescribed tumor dose. An independent medical consultant reviewed both cases and determined that the radiation dose received by each patient was within a range of doses commonly prescribed for such treatments and that no long-term adverse health effects would be expected for the patients (Sections 1 and 2).

- The root cause of the misadministrations was determined to be a failure to adequately verify the accuracy of computer-generated dose tables used as the basis for developing treatment plans for brachytherapy procedures. Contributing factors to the misadministrations included problems involving the clarity of information provided in the Theratronics users' manual for the Theraplan treatment planning system, as well as a lack of clarity in the prompts and data presented to the treatment planning system users in printed format and at the treatment planning console (Section 3).

- Although the misadministrations were associated with only one of three treatment planning systems used by the licensee's authorized user physicians, the inspection disclosed that generally, all individuals participating in brachytherapy treatments either failed to perform a verification check of computer-generated treatment plans for each patient case, or failed to perform checks that were adequate to detect errors in final treatment plans and related calculations (Section 4).

- Several apparent violations were identified involving the licensee's failure to implement a QM program when NRC's QM Rule first became effective. In addition, the QM program which DMC later established failed to meet each of the objectives of 10 CFR 35.32 (Section 4).

- Apparent violations were identified involving the licensee's failure to train individuals working under the supervision of authorized users in the provisions of its QM program and a failure to provide required training to all nursing personnel (Section 4).

- Concerns were identified regarding weaknesses in communications between the RSO, authorized users, and other personnel involved in brachytherapy procedures. In addition, a concern was identified regarding the level of oversight provided by licensee management and the RSO for DMC's brachytherapy program (Sections 4 and 5).

Summary of Inspection Findings:

- Apparent violation 030-02389/9401-01 was opened: Failure to establish a QM program in January 1992 for administration of sodium iodide I-131 and for brachytherapy procedures (Section 4.2).

- Apparent violation 030-02389/9401-02 was opened: Failure of the licensee to ensure that the staff complied with license requirements to provide training to nurses caring for patients undergoing brachytherapy treatments (Section 4.2).

- Apparent violation 030-02389/9401-03 was opened: Failure to train individuals working under the supervision of authorized users in the provisions of the licensee's QM program (Section 4.2).

- Apparent violation 030-02389/9401-04 was opened: Failure to establish a QM program that met the objective that written directives were prepared

in accordance with NRC requirements prior to brachytherapy treatments (Section 4.2).

- Apparent violation 030-02389/9401-05 was opened: Failure to establish a QM program that met the objective that final plans of treatment and related calculations were in accordance with the respective written directive (Section 4.2).

- Apparent violation 030-02389/9401-06 was opened: Failure to establish a QM program that met the objective that each administration of radiation from brachytherapy was in accordance with the applicable written directive (Section 4.2).

- Apparent violation 030-02389/9401-07 was opened: Failure to conduct a review of the QM program at 12-month intervals (Section 4.2).

- Apparent violation 030-02389/9401-08 was opened: Failure to include all required information in records of surveys conducted in areas surrounding the patient's room following implantation of brachytherapy sources (Section 5).

- Apparent violation 030-02389/9401-09 was opened: Failure to include all required information in records of patient release surveys and in two instances, failure to retain a record of patient release surveys (Section 5).

- Apparent violation 030-02389/9401-10 was opened: Failure to include all required information in brachytherapy source inventory and use records and in one instance, failure to make a record of brachytherapy source use (Section 5).

Attachments:

- Attachment 1 - Persons Contacted and Exit Meeting
- Attachment 2 - Quality Management Program

DETAILS

1 BACKGROUND (87100)

1.1 Initial Notification of Misadministrations

On March 22, 1994, representatives from Deaconess Medical Center (DMC) and one of its consulting physics groups contacted the NRC Region IV office to provide telephonic notification of a misadministration. The misadministration involved a gynecological brachytherapy treatment, using cesium-137 sources, which was performed in September 1993. A second local medical facility also participated in the telephone call to the NRC Region IV office because a contributing factor to the misadministration appeared to be a discrepancy in software parameters used by a computerized treatment planning system which had been used to develop treatment plans at both DMC and the other facility. (A similar call was made to the NRC Operations Center on March 22, 1994.)

The misadministration was not identified by consulting physicists (for both licensees) until March 1994, during the course of a detailed review of brachytherapy treatment plans developed using a Theratronics Theraplan treatment planning system. The review was initiated by DMC's consulting physicists after an error was identified in a treatment plan on March 16, 1994. The consulting physicists initially reported that a new staff member (also the new radiation safety officer for DMC) had identified errors in a dose table generated by the treatment planning system during a routine treatment setup.

Following considerable review of treatment plans and data generated using the treatment planning system, the physics staff, with assistance from Theratronics, concluded that the source capsule attenuation coefficient for linear cesium-137 sources was in error for all treatment plans developed on the Theraplan treatment planning system after September 1992. Specifically, the consulting physicists reported that the source capsule attenuation coefficient used for cesium-137 after that date appeared to correspond to that of a platinum-iridium source capsule rather than the steel capsule used for cesium-137 sources owned by DMC and the other medical facility. By review of historical treatment data, the physicists were able to confirm that dose tables generated on the Theraplan treatment planning system prior to July 1992 appeared to be correct for treatment plans developed for use of cesium-137 sources. (There were no treatment plans developed on this system between July and October 1992.)

The licensee and its representatives noted that they had identified 11 patients who had received brachytherapy treatments in accordance with treatment plans developed using the Theraplan system, and that each of these treatments was being reviewed in detail. (Only 9 of the 11 patients were treated between October 1992 and November 1993, the period in which the software parameters were found to be erroneous.)

At the time of the initial notification, the consulting physicists were unable to determine the exact circumstances which resulted in a change in the above noted software parameters. However, sufficient investigation had been done by

the consulting physicists to determine that there were some data entry formats and conventions that users of the treatment planning system were previously unaware of.

On March 23, 1994, DMC and the other medical facility again contacted the NRC Region IV office and the NRC Operations Center separately to provide updates to their initial telephone notifications. DMC reported that based upon reviews completed after the notification provided on March 22 and subsequent discussions with NRC Region IV personnel, DMC identified two cases in which it appeared that the calculated tumor dose for brachytherapy treatments performed in accordance with treatment plans developed using the Theraplan system differed by more than 20 percent of the prescribed tumor dose. According to the radiation safety officer (RSO), based upon calculations performed using the correct data, the dose delivered to the prescribed treatment sites in these two cases was 21 and 24 percent greater than what the authorized users had intended. The second medical facility reported that six misadministrations had been identified involving treatments provided during the previous 18 months.

Due to the potential for generic problems with software parameters used by the Theraplan system and the fact that software errors went undetected and resulted in several misadministrations at more than one facility, the NRC Region IV office elected to promptly conduct a special inspection to review these events, determine the root causes, and assess the potential for generic problems in other Theratronics systems.

1.2 Background Information Regarding DMC's Brachytherapy Program

DMC is staffed by two separate groups of authorized users. One group has maintained cesium-137 sources at DMC for several years and has used DMC as its principle location for providing brachytherapy services in the past. At one time this group of physicians used a medical physicist and treatment planning facilities located in Billings, Montana. More recently, this group of physicians has utilized the services of a medical physics staff and treatment planning facilities located in Casper, Wyoming, and Bozeman, Montana. Although the physician users in this group claim ownership of the cesium-137 sources located at DMC, DMC has provided the facilities and staffing required to house and secure the sources, as well as to monitor their use. This group of physicians (referred to hereafter as physician Group 1) has also used other sources for both temporary and permanent brachytherapy implants, including iridium-192 and iodine-125. Although various members of physician Group 1 have practiced at DMC in the past, the individual members have expanded their practices and are currently providing care in several facilities spread over a broad geographic area. At the time of the inspection, only two physicians of the group were authorized to perform brachytherapy under DMC's license, and a third member had initiated the process of receiving approval to perform brachytherapy procedures at DMC. With exception of just a few cases, all brachytherapy treatments performed during the previous 2 years had been done under the direction of a single member of this group of physicians.

In 1992 and 1993, two new authorized users were added to the medical staff of DMC and to DMC's NRC license. These two physicians formed a partnership and

had primarily focused on developing their practices in the Billings area (these physicians are referred to as physician Group 2 hereafter).

The support staffs for the two groups of physicians are independent in that physician Group 1 uses a physics staff based in Casper, Wyoming, and Bozeman, Montana, for treatment planning; and physician Group 2 uses a physics staff based in Billings, Montana, for treatment planning. In both cases, the supporting physicists were not closely involved with the radiation safety program at DMC. However, one of the physicists working with physician Group 2 had regularly participated in radiation safety committee meetings and in periodic training at DMC. (This is discussed in further detail in Sections 4 and 5.)

The supporting physics staff for physician Group 1 had not accompanied authorized users from Group 1 during treatments at any time during the past 2 years, primarily because physician Group 1 and its supporting physics staff have used A.R.S. and C.M.S. computerized treatment planning systems which are located some distance from Billings. (The physicists are stationed in Casper and Bozeman.) Simulation radiographs for brachytherapy treatments performed by physician Group 1 had been done using portable x-ray units at DMC. Because of the geographic separation between DMC and the treatment planning systems used by physician Group 1, information needed to perform computerized treatment planning had been transmitted via facsimile to the physics staff in Casper, Wyoming. (Additional discussion regarding this practice is provided in Section 4.)

The supporting physics staff for physician Group 2 had accompanied the authorized users during the few brachytherapy treatments that physician Group 2 performed at DMC. Physician Group 2 and its supporting physics staff have used a Theratronics Theraplan treatment planning system and a simulation system located near DMC (within 2 city blocks) for treatment planning.

2 MISADMINISTRATIONS AND RECORDABLE EVENT: CASE REVIEW (87100)

The errors in treatment which prompted the inspection involved two misadministrations associated with brachytherapy treatments administered in accordance with treatment plans developed using a Theraplan treatment planning system. Based upon recalculation of radiation doses administered to prescribed tissue volumes (tumor site) and other critical organs, DMC's authorized users and consulting medical physicists determined that the tumor doses for the two patients were 21 and 24 percent greater than the prescribed doses, as documented in the applicable written directives and original treatment plans.

Both cases were reviewed by the authorized users as well as by an independent radiation oncologist to determine whether any adverse health effects were likely to occur as a result of the radiation doses received by the patients. Both the authorized users and the independent physician reviewer determined that it was unlikely that the doses received by these patients would result in any adverse health effects beyond those which may normally be expected for this form of treatment. It should also be noted that the misadministrations were associated with gynecological treatments which involved treatment by

external beam as well as by brachytherapy implants. Thus, the increased tumor doses resulting from the treatment errors were only a small percentage of the total radiation dose intended for each patient. The external beam component of these treatment combinations was delivered via use of a linear accelerator, a device which NRC does not regulate. Therefore, discussion of the radiation dose received by each patient will be limited to the brachytherapy component of each treatment.

In addition, the independent oncologist who reviewed these cases noted that overall, the authorized users associated with these cases had prescribed their treatments using radiation doses that in his view were conservative. As a result, the total radiation dose administered to the patients was within a range which is generally found acceptable according to standard medical practice.

The specific details of the above noted cases and the physicians' reviews are discussed below. Specific details regarding the root cause(s) of and factors which contributed to the misadministrations are discussed in Section 3.

2.1 Review of Treatment Parameters and Radiation Dose Received by Patients

As noted above, the errors in software parameters used by a Theratronics Theraplan treatment planning system were initially discovered on March 16, 1994, during the course of a brachytherapy treatment. Brachytherapy sources had been implanted in a patient, and the physicists were performing final checks of the treatment plan when the discrepancies in computer-generated dose tables were identified. The individual who initially identified the discrepancy between the computer-generated dose tables and a manual calculation of the radiation dose for specific points (a difference of approximately 20 percent) was a relatively new employee, also DMC's newly appointed RSO, and had not used the Theratronics treatment planning system before. In addition, this physicist used a method for performing manual checks of computer-generated dose tables and treatment plans that differed from the method that had been used by DMC's consultants in the past. The fact that the treatment plan was verified by a method other than that which was previously used was the principle factor which led to the identification of the software errors.

Once the errors were identified and corrected, with assistance from Theratronics, the RSO and consulting physicist determined that since there was only one data file for cesium-137 sources resident in the treatment planning system at the time, there was a high probability that other treatment plans completed for use of cesium-137 sources may have been subject to the same errors. The physicists subsequently conducted a thorough review of all brachytherapy treatments performed at DMC and a second hospital which had also performed brachytherapy treatments in accordance with treatment plans developed on the Theraplan treatment planning system. A total of 12 cases were identified, dating from June 1992 to March 1994, which were associated with treatment plans developed on the Theraplan system. Only three of these treatments were performed at DMC. One of the 12 was the treatment which was started on March 16, and because a corrected treatment plan was promptly

completed and the written directive modified accordingly, this treatment did not involve any overdose of radiation.

The remaining 11 cases were reviewed in depth, including retrieval of simulation films and original computer data, and tumor doses were recalculated using the correct source parameters. (In addition, a new method was used to verify the accuracy of the computer-generated dose tables as discussed elsewhere in this report.) Cesium-137 source data files which had been archived were examined, and through comparison of the source parameter data files, it was determined that a change in the source parameters had occurred after July 1992. (The cesium-137 source strength was specified in millicurie units in June and July 1992, and in milligram-radium-equivalent units after July 1992.) Although it appeared that the change which resulted in the use of erroneous source data occurred after July 1992, the RSO and consulting physicist recalculated the tumor dose, as well as the radiation dose for critical organs, for all 11 patients.

The table below shows the prescribed tumor dose* for each patient treated at DMC, the recalculated tumor dose and the ratio of the two.

Patient No.	Prescribed Dose	Recalculated Dose	Ratio*
1	3,500 cGy	4,357 cGy	1.24
2	1,486 cGy	1,792 cGy	1.21
3	3,053 cGy	3,222 cGy	1.06

*For the purposes of this table, the licensee defined the prescribed tumor dose as the initial calculated dose given the parameters specified in the written directive and treatment plan. The calculated tumor doses were approved by each authorized user prior to the completion of treatment, along with the full treatment plan (including isodose plot).

* The ratio is defined as recalculated dose/prescribed dose.

The authorized user physicians involved in these cases (physician Group 2) reviewed all revised dose data (both the revised brachytherapy component and revised combined total dose calculations) in order to evaluate whether any adverse consequences could be expected as a result of the actual doses received by the patients. These evaluations included review of the recalculated tumor doses as well as revised calculations of the doses received by critical organs (bladder, rectum, and bowel). Both authorized users determined that the corrected radiation doses were within the range of radiation doses commonly prescribed for such treatments and that no adverse consequences beyond those normally expected for this form of treatment were anticipated.

The physicians also contacted the patients to arrange for followup examination. During their subsequent contact with the patients, no symptoms or complaints were noted that were attributable to the radiation doses received by the patients.

On March 28, 1994, an independent physician with expertise in radiation oncology reviewed both cases. This review was requested by physician Group 2 in order to provide an independent assessment of any medical consequences that might be expected for the patients as a result of the treatment errors. The reviewer provided a written report of his conclusions to the authorized user physicians as well as to the inspector for review. In his report, the physician stated that "it is my opinion that the excess doses due to the incorrect calculations involve very modest [tissue] volumes in the patients, and are in all cases, well within the doses usual and customary to treatment of patients with the specific tumor types cared for. Thus far, no adverse acute or late reactions have been observed and I predict none will occur."

2.2 Notification Provided to the NRC, Patients, and Referring Physicians

As discussed above, the software errors were initially discovered on March 16, 1994. Following this discovery, DMC's consulting medical physicist and RSO spent 2-3 days identifying which patients had been treated in accordance with treatment plans developed using the Therapian treatment planning system and recalculating radiation doses received by the patients. DMC management representatives were first notified of the errors on March 21, 1994. At that time, only one misadministration had been identified. DMC provided telephonic notification of the misadministration to the NRC Region IV office and the NRC Operations Center on March 22, 1994. Following further discussions with NRC Region IV staff, the RSO continued his review of the three treatments performed at DMC and identified a second case which fit the criteria for a misadministration. Notification of this finding was provided to the NRC Region IV office and the NRC Operations Center on March 23, 1994.

The authorized user physicians who prescribed the treatments notified the referring physicians by telephone of the misadministrations within 24 hours of the above noted notifications to the NRC. Subsequent to their telephone discussions with the referring physicians, the authorized users forwarded copies of their revised chart notes (which included details of the radiation dose received by each patient) to the referring physicians. Both authorized users contacted their respective patients within 24 hours of the discovery of the misadministrations and informed them of the treatment errors. In addition, following discussion with the RSO, the authorized users elected to provide written reports of the misadministrations to the patients under their signature. These reports were mailed to the patients on April 4, 1994, and copies were enclosed with the licensee's written report of the misadministrations provided to the NRC. In their reports, the authorized users informed the patients of the percentage error and actual radiation dose received from the internal component of their treatment, the total radiation dose received from both the external and internal treatment components, and notified the patients that a written report was being forwarded to the NRC and that the report would be made available to the patients upon their request.

Based upon information gathered through interviews with the authorized users and DMC staff, it appeared that coordination between the hospital staff, the consulting physicist, the RSO, and authorized users was well organized. Because the RSO had actively participated in the investigation of the misadministrations and maintained good communication with licensee management,

the authorized users, hospital staff, and the consulting physicist, each party was apprised of the causes of the misadministrations and the status of various reports provided to referring physicians and the NRC. In addition, under the RSO's guidance, consensus was reached regarding the initial proposed corrective actions.

A written report documenting the misadministrations, the apparent causes, and the corrective actions taken to date was submitted by DMC to the NRC on April 6, 1994. The report provided discussion of the licensee's determination of the root cause of the misadministrations, various weaknesses in the licensee's QM program which contributed to the misadministrations, and included copies of the written reports provided to both patients as well as a copy of the licensee's modified QM program. Based upon the inspector's review, the report was found to contain all information required by 10 CFR 35.33.

In summary, two cases were identified through an investigation conducted by the licensee's RSO, consulting physicist and authorized users which appear to meet the criteria for misadministrations in that the tumor dose received by the patients exceeded the dose intended by the prescribing authorized user by 21 and 24 percent. However, based upon reviews conducted by the authorized users and an independent radiation oncologist, it does not appear that the misadministrations will result in any adverse health effects beyond those which may normally be expected for this form of treatment. The licensee reported the events to NRC as required and promptly notified the patients and referring physicians. Written reports of the misadministrations were provided to both the NRC and affected patients as required by 10 CFR 35.33.

In addition to providing required reports to the NRC, patients, and referring physicians, the licensee's consulting physicist and RSO submitted a report regarding the apparent software problems to the Food and Drug Administration (FDA) in accordance with FDA's MEDWATCH program.

The licensee and its representatives were informed during the inspection that NRC plans to have a medical consultant review each of the misadministrations and provide an assessment of any potential consequences, both short- and long-term, resulting from the radiation doses received by the patients.

3 ROOT CAUSES AND CONTRIBUTING FACTORS (87100)

The inspector's review of the misadministrations included: (1) detailed examination of the Theraplan system formats for data entry and the procedures used for independent verification of treatment plans and dose calculations by the consulting physicists working with physician Group 2, (2) interviews with representatives of the manufacturer of the treatment planning system, and (3) review of supporting documentation provided by the manufacturer for system users. In addition, the inspector conducted a review of safety bulletins issued by the manufacturer in accordance with requirements of the FDA in order to assess whether any incidents related to factors associated with the misadministrations had been previously identified to system users. No user safety bulletins were identified involving the specific issues associated with the misadministrations.

The root cause of the misadministrations was determined to be the method used to perform independent (manual) checks of computer-generated treatment plans and dose tables. Specifically, the published dose tables used by individuals performing treatment plan verification checks were inappropriate for use with the cesium-137 sources used for brachytherapy treatments at DMC. The contributing factors identified during the inspector's review included a lack of clarity in instructions related to data input provided in the Theraplan users' manual and in prompts and data presented to system users in printed format and at the treatment planning console. In addition, another contributing factor was the users' failure to implement a rigorous system of controls for data entry and system use. These issues are discussed in detail in the following paragraphs.

3.1 Root Cause of the Misadministrations

The initial discovery of the errors in the cesium-137 source data file occurred during an independent (manual) verification of a treatment plan on March 16, 1994. It should be noted that although DMC's QM program does not require this specific type of verification, the consulting physics group working with physician Group 2 had routinely performed manual dose calculations (using "along and away" tables) for one or more points for each patient case. On March 16, the individual performing the independent check (DMC's RSO) used a different set of along and away tables than those which had been used in the past. The manual dose calculations differed from the computer-generated dose calculations by approximately 20 percent, which prompted further investigation by the consulting physicists.

The independent verification check performed on March 16 was conducted using along and away tables developed by E. H. Quimby, et. al., which were published in Physical Foundations of Radiology, Fourth Edition. (The Quimby tables are a system of dose tables which allow a user to determine an expected dose rate value at a certain distance from a radium-226 source of given strength or other source specified in milligram-radium-equivalent. The tables contain dose rate data for radium-226 encapsulated in both 0.5 mm and 1.0 mm of platinum.) The physicist who performed the check on March 16 used the Quimby table corresponding to a source encapsulated in 0.5 mm of platinum.

After the initial discrepancy was identified, the physicist who performed the verification check conducted a second check to verify the accuracy of the computer-generated dose tables. This was done by entering data for a single source with known coordinates and generating a dose table which was then compared to a second published dose table. The published dose table used for comparison during this check was a dose rate table developed for cesium-137 sources encapsulated in 1.0 mm of stainless steel. The data was developed by V. Krishnaswamy, as published in Radiology, Vol. 105:181-184, 1972 and later reproduced in other textbooks. The second comparison also revealed a significant difference (greater than 20 percent) between the computer-generated dose tables and the manual dose calculations.

Following the second check, technical representatives from Theratronics were consulted for assistance. Theratronics representatives were able to provide the consulting physicists with a set of cesium-137 source parameters which had

been used at other medical facilities so that the resident source data file could be replaced with appropriate data. The new parameters were entered and a check was run using the Krishnaswamy tables in order to verify the accuracy of dose calculations performed using the new parameters. The computer-generated dose tables from this check corresponded well with independent checks performed using the Krishnaswamy tables (values were within 1.5 percent). The new source data parameters were used to develop a revised treatment plan for the brachytherapy treatment which was ongoing at that time. Dose tables for the particular combination of sources used on March 16 were recalculated and the implantation period was modified accordingly in order to deliver the authorized user's intended tumor dose.

Once acceptable source data parameters were established and entered in the appropriate software files, the consulting physicists sought to identify the root causes of the errors. Their initial investigation identified several facts which were later confirmed and supplemented during the inspector's review. The physicists' first finding was an obvious difference between the cesium-137 source data files resident in the treatment planning system and those provided by Theratronics. The source data parameters resident in the system and those provided by Theratronics are shown below. (These parameters are entered in a data file which is accessed by programs used to calculate dose tables for any given source combination.)

Source Parameter	Resident Data	Data Provided by Theratronics
*Source Type:	137-Cs	137-Cs
*Total Length:	2.00 cm	2.00 cm
*Active Length:	1.5 cm	1.5 cm
Gamma Constant:	8.25 R/mgm•hr	8.39 R/mgm•hr
Rad/Roentgen:	0.940	0.957
*Wall Filtration:	0.930 mm	0.930 mm
Filter Atten. Coeff:	0.000	0.221
*Half Life:	262980 hrs	262980 hrs
*Active Diameter:	0.124	0.1
Source Atten. Coeff:	0.081	0.081

* No changes were recommended for these items because they are physical characteristics defined by the manufacturer.

Based upon comparison of the two sets of data, the consulting physicists determined that the filter attenuation coefficient value was the major contributor to the differences in the calculated dose values. The physicists attempted to investigate this issue further and in doing so, retrieved some archieved source data parameter tables that had been used with earlier versions of the software system. In reviewing the older data files, the physicists noted that the filter attenuation coefficient used prior to September 1992 did not appear as 0.000 in records of the data tables. Licensee representatives initially identified the discrepancy in the filter attenuation coefficient value as the primary cause of the misadministrations.

Although the discrepancy in the filter attenuation coefficient entered in the source data file was identified by the inspector as a contributing factor which led to the misadministrations, it was not determined to be the root cause of the misadministrations. As discussed in Section 3.2, several other factors were identified which also appeared to have contributed to these events.

The inspector identified an error associated with the treatment planning verification process as the root cause of the misadministrations. This error involved the use of inappropriate along and away tables in performing independent checks of computer-generated dose tables. Had the independent (manual) treatment plan verification checks been performed correctly, the errors in the computer-generated dose tables should have been discovered. The basis for determining that the use of inappropriate dose tables in performing verification checks of treatment plans was the root cause of the misadministrations is explained below.

The algorithms used by the Theraplan treatment planning system calculate the radiation dose rate at any number of points based upon information entered from simulation radiographs and data which describes the characteristics of the specific sources used for any given treatment. The process used to complete these calculations is based upon optimizing the data input at the computer terminal, which is limited in many cases to two dimensions, to represent a three dimensional model of the dose distribution in a patient. The process requires that certain values be adjusted, in an iterative fashion, in order to approximate the actual dose distribution in a three dimensional figure. In order to verify the accuracy of the computer-generated treatment plans, the calculated dose rates are compared to measured data. Generally, this is accomplished by comparing computer-generated dose tables to a set of measured data and adjusting for source strength and geometry. There are several dose tables that have been published in various journals and textbooks which may be used to verify computer-generated dose tables. In addition, there are several methods used to perform such comparisons.

In this particular case, the routine practice involved the use of dose tables developed by Quimby (referenced above). As noted above, this verification check was typically done for each treatment plan. This practice involved some error because the user was required to perform the comparison using clinical data involving combinations of sources rather than comparing the calculated dose rate for a single source to the Quimby tables. (The error involved the users' ability to accurately localize the sources in simulation radiographs in order to manually calculate the dose rate at a given point using the Quimby table.) In addition, the source localization process also involved some error in digitization (the process used to transfer information from a radiograph to a computer file). DMC's consulting physicists were aware of the potential for errors in this method and attempted to take them into account in comparing the calculated and measured dose tables. However, the users failed to recognize an error involving the selection and use of the wrong Quimby table when they performed the verification checks.
Specifically, the treatment planning system users had entered data to characterize the sources in terms of milligram-radium-equivalent and accordingly, they entered a gamma constant that corresponded to the radium

equivalent as filtered by 0.5 mm of platinum. (Data entered in the source data file corresponded to information provided by the source manufacturer.) However, when the independent source checks were performed, the dose tables used to conduct the checks corresponded to dose rates for a radium-226 source as filtered by 1.0 mm of platinum. Thus, the dose rates used for comparison were approximately 10 percent lower than what would have been expected for the cesium-137 sources used for treatments. This error resulted in a failure to detect the fact that the computer-generated dose table values were approximately 20 percent lower than they should have been for the specific sources used because an erroneous value had been entered for the filter attenuation coefficient. This problem was further compounded by the fact that manual checks were performed using clinical data which consisted of a combination of sources rather than with a single source for which precise source coordinates were known. The individual who routinely performed verification checks stated that the variance between the computer-generated dose tables and the Quimby table values was generally on the order of 5 percent and in the majority of cases, was less than 10 percent. Thus, the user had assumed that the computer-generated dose tables were correct and had attributed the variance to errors in digitizing information from radiographs and other factors related to determining the source location from simulation films.

In discussions focused on determining why the wrong dose tables were selected and why the error was not identified earlier, the system users explained that the error in selecting the wrong dose table for comparison was primarily linked to the former experience of the individual who had performed the majority of the verification checks. The individual explained that his former experience in brachytherapy had involved the use of radium-226 "tubes" which were encapsulated in 1.0 mm of platinum. Thus, he had naturally selected the tables corresponding to a 1.0 mm platinum filter. The error was not identified earlier because only one individual typically reviewed and approved the treatment plans due to a lack of other staff experienced in this task.

In summary, had an appropriate set of measured data been used for comparison with the computer-generated dose tables, the errors in the computer-generated dose tables should have been identified. In addition, the fact that the calculated dose tables were erroneous was of lesser significance because it is expected that some variance will exist between the calculated dose tables and the measured dose tables, and that the source parameters will have to be adjusted in an iterative fashion in order to optimize the calculated dose tables such that they match measured data. Thus, the use of appropriate dose tables was fundamental to ensuring that (1) the algorithm used to generate calculated dose tables provided accurate data and (2) errors which may have occurred in data entry were identified.

3.2 Contributing Factors

As noted in Section 3.1, several factors were identified which appeared to have contributed to the misadministrations. Some of these factors were more significant than others; therefore, only those that merit further consideration as DMC develops corrective actions or considers modifications to its QM program are discussed in the following subsections.

3.2.1 Clarity of Information Provided to Theraplan System Users Regarding Data Entry Formats

Based upon discussions with the system users and Theratronics representatives, as well as the inspector's review of system prompts and data displayed at the system console and in printed format, concerns were identified regarding a lack of clarity in instructions found in the user's manual and in system prompts provided at the treatment planning console. In addition, some of the data appeared misleading to both the users and the inspector.

First, as noted in Section 2, when the errors were initially identified, the users examined the cesium-137 source data table and found that the value for the filter attenuation coefficient was displayed as "0.000". As they reviewed this data to determine the source of the errors, one of the physicists noted that a message, "RETURN for radium," was displayed as the system prompted the users for entry of a filter attenuation coefficient value. The users assumed that some default value was used if the user hit the "return" key in response to the prompt, and that the unknown default value probably corresponded to a platinum-iridium filter (material commonly used for radium-226 source capsules). However, the physicists noted that the only value that was displayed if they hit the "return" key was "0.000". Likewise, if the physicists entered the value "0" in response to the prompt, "0.000" was displayed at the terminal. In order to test their suspicion that perhaps the "return" key resulted in use of the same value as a "0" entry, dose tables were generated using both values and were found to be the same. After some review, the physicist who originally entered the source data parameters determined that he had entered a value of "0" and had assumed that this value was used as a valid entry based upon information displayed to him at the system console and in printed format.

The system users stated that they were not previously aware of any default value for the filter attenuation coefficient. Based upon discussions regarding practices related to loading software updates and data entry, it appeared that this was likely the case since the users had relied upon use of a utility file for updating the source data files when new versions of software were loaded on the system rather than entering the source data manually. Thus, the system users had not observed the note displayed at the treatment planning console for some period of time (possibly for years) nor had they noted it in the users' manual.

The findings noted above were reviewed further during the course of the inspection. This included a thorough review of instructions provided in the system users' manual, discussions with Theratronics representatives, review of information subsequently provided by the manufacturer which was not available in the users' manual, and investigation of data entry and screen prompts using the treatment planning system. The inspector's findings are discussed below.

Discussion of general data entry formats for both the external beam software and the brachytherapy software is provided in Section 3.5 of the users' manual. This section describes system conventions for entering numeric data as single integer values and fractional values, as well as for string data.

In addition, the section describes formats for default values and states, in part, that default options are "usually enclosed in square brackets" and that "default options are obtained by pressing RETURN only." Further, the text goes on to state: "in some cases, zero is a legal entry, but we wish to offer a default; in these cases, the default is obtained by pressing RETURN, and the value 0 is obtained by entering any character (the program generally will request 'Z', but any character will do) followed by RETURN."

Section 5.2.2, "Input/Edit of Linear Source Data," describes the conventions and formats for entering data to characterize linear sources. This section displays a table which briefly describes each parameter required for characterizing a linear source. The manual does contain a note under the description of the filter attenuation coefficient parameter. The note states "as radium has a complex emission spectrum of gamma rays, its transmission does not vary exponentially with filter thickness. The coefficient is a function of filter thickness, and this function may be selected in the program by pressing the return key." Based upon discussions with Theratronics representatives, it appears that the default consists of a string of data used by a polynomial function to calculate, in an iterative fashion, attenuation of the various gamma energies emitted from a radium-226 source.

Section 5.2.2, "Input/Edit of Linear Source Data," also provides some instruction regarding the fact that source characterization information for cesium-137 sources may be entered by more than one method and that in some cases adjustment of the source data parameters will be necessary in order to optimize calculated dose tables so that they match measured data. Specifically, a note under the section which describes data input for cesium-137 sources states: "a cesium linear source can be entered in one of two different ways. First, it can be entered in a manner equivalent to a radium source of specific filtration (i.e., 0.5 mm platinum). This assumes that the dose rate distribution for the source is identical to that of a radium source. This is an assumption, and the gamma constant (or exposure rate constant) will have to be adjusted to make the dose rate value at a point 1 cm from the source bisector to be the same as that for radium." The text continues with "if you wish to enter the cesium source as (a) radium equivalent, but using the actual wall filtration and attenuation coefficient, then you will also have to adjust the exposure rate constant. This will have to be adjusted so that the dose rate at 1 cm, (as) calculated by the program, agrees with the manufacturers' specifications."

One discrepancy was identified in instructions provided to the users for entering data for the gamma constant. The instructions in Section 5.2.2 focus the user on the fact that the gamma constant will have to be adjusted under certain circumstances. This would appear to indicate to the user that the specific value used for the gamma constant is of lesser concern because it will be modified in order to obtain a calculated dose rate that matches measured data. However, a note in the source parameter data entry section clearly states that the gamma constant should be entered for an "unscreened" source. Theratronics representatives noted that the software algorithm assumes that this parameter must be defined for an unfiltered source and that the filter attenuation coefficient must be entered as a value other than "0". This rationale is not explained to the user and appears to be confusing given

the fact that users are specifically instructed to modify the gamma constant value in order to optimize the calculated dose tables. The fact that "0" will not be accepted as a valid entry for the filter attenuation coefficient is also not explained in the users' manual. (The system users in this case elected to enter a screened gamma constant value, because that is the value supplied by the manufacturer and accordingly, elected to use a filter attenuation coefficient value of 0.)

Theratronics representatives also stated that the note under the description of the filter attenuation coefficient provided in Section 5.2.2 of the users' manual was sufficient to instruct users that a default function existed for this parameter. However, the text did not specifically state that a default function will be invoked if a keyboard entry other than "return", such as "0", is used. A review of the users' manual failed to identify any clear instruction in either Sections 3.5 or 5.2.2 which explained that a keyboard entry of "0" would invoke use of a default value. In Section 3.5, the users' manual states "in many cases, a zero (0) or a one (1) response is required. To speed up the process, the option which is felt to be the most common response has been assigned the value zero (0), so that a (return) will suffice." This was the only indication identified in the above noted sections that a relationship between the keyboard entry of "0" or "return" existed.

In fact, the software does handle both entries in a similar fashion in that the entry of either "0" or "return" will result in use of a default value in those instances where a default value exists. Although users are not specifically alerted to this in the user's manual, recognition of both keyboard entries in a similar manner is due to the fact that the software is written in the Fortran language. Because of the manner in which Fortran handles data entry, if a default value exists in the Theraplan system, entry of either a "0" or "return" will result in use of the default value.

In addition to the items discussed above, another concern regarding clarity of instruction provided to system users was identified. Instructions provided in the users' manual, as noted above and elsewhere in the manual, appeared to indicate that in cases where a default value exists, entry of the numeric value "0" should be done using the character "z" or any other alpha character. Through several attempts, the inspector and users discovered that no character would actually result in use of the numeric value "0" for the filter attenuation coefficient. This appeared to indicate that the software programmers apparently did not consider this to be a valid entry. This was discussed with Theratronics representatives who noted that the use of a zero value for the filter attenuation coefficient was inappropriate. However, based upon the type of source used for a given treatment and the users' preference for adjusting source data parameters to obtain optimized dose tables, there may be some disagreement among users regarding this issue. In fact, one of the users involved in this case stated that he had intended to use the value "0" for the filter attenuation coefficient because the gamma constant entered in the source data table accounted for an equivalent attenuation of 0.5 mm of platinum. This user also noted that given the data displayed at the system console and in printed format, he thought that the system had accepted his entry of "0".

Based on the findings discussed above, three issues involving clarity of information provided in the system users' manual and in prompts provided at the treatment planning console were noted as contributing factors to the errors which resulted in the six misadministrations. The first issue involved the fact that a default value exists which is not identified to the user on the system console in the same manner as described in the users' manual (e.g., in brackets) and the users' manual does not clearly explain that entering "0" for the filter attenuation coefficient will invoke use of the default value for radium-226. Notwithstanding the statements provided in Section 3.5 of the manual, there is no clear indication to system users that in cases where a default value exists, entering a "0" will invoke use of the default value. The second issue involved the fact that the system displayed the value "0.000" which may mislead a user who intends to enter the numeric value "0" for this specific parameter. Based upon the information displayed to him/her, the user could naturally assume that the "0" has been accepted as a valid numeric entry. The third issue involved the fact that the users' manual does not inform the users that the numeric value of zero is not a valid entry for the filter attenuation coefficient parameter.

3.2.2 Data Entry and Software System Controls

In addition to the issues discussed above, other factors related to controls established for system software maintenance and usage were also identified as contributing factors. In reviewing the management of computer systems at DMC's consultants' facilities, the inspector identified several weaknesses and areas which warrant additional attention. Specifically, routine backup of data and re-entry of data files needs to be formalized. One example of problems associated with software management appeared to have contributed to the misadministrations as discussed below.

Although users of the Theraplan system had updated the system on several occasions and had experienced few problems in the past, the users had not developed a formal process or procedures for updating software files or for re-entering data files when required. Potential effects of this oversight were somewhat limited because software updates were primarily done by one individual. However, several individuals had performed software update tasks on various occasions. Because several individuals use the system, the inspector noted that the users may need to develop procedures or guidance for the various individuals using the system in order to ensure that standard data formats are adhered to and that the integrity of data used by various software programs is maintained.

Generally, the Theraplan users had followed the manufacturer's recommendations for loading new versions of the software system when they became available. This included the use of utility files to upload older versions of source data files into the new software in order to maintain consistency and to relieve the users of the requirement to re-enter data manually. In addition, the users had followed good practice by maintaining backup files of older versions of software, as well as each new version received from the manufacturer. However, there was no apparent formal method for cataloging the software and some information could not be retrieved from older data files during the inspection. Notwithstanding the fact that some standard practices had been

developed and implemented to control data input, efforts to adhere to good software system management practices failed on at least one occasion and contributed to the misadministrations. This failure is described below. In addition, there were other instances identified in which data formats had been modified for no apparent reason (according to the system users).

According to the Theraplan users, as they were preparing for a brachytherapy treatment in September 1992, they noted that the cesium-137 data file had been deleted from the system. The users were unable to determine how the file was deleted, although some of the users did recall that they had had several problems with the system during that period. The users speculated that perhaps the system problems may have required them to reload the software system in its entirety. If that was the case, it is possible that the users simply uploaded a backup version of the software and failed to use the utility file to upload backup copies of the linear source data files. This would have had the same effect as deleting the cesium-137 source data file. (The data for cesium-137 sources is not provided by the manufacturer with each software update and must instead be reloaded from backup files or entered manually.)

Once the source data file was identified as missing, a user elected to manually enter the data and failed to review data used for the cesium-137 source parameters in previous versions of the software. Had the user consulted data files which had been archived from earlier versions of the software, either from backup tapes or printed format, he might have identified the fact that the filter attenuation coefficient did not appear as "0.000" and could have caught the error before it affected any patient treatment plans. In addition, as noted above, the users had routinely used a utility file to reload the source data files in recent system updates and had not manually entered the data for some period of time. The fact that data for this specific file was entered infrequently increased the potential for errors in manual data entry. The inspector also noted that had the manufacturer included cesium-137 source data in the group of resident source data files provided with the software, the potential for errors in data entry would have been sharply reduced. Although Theratronics provided source data files for nine different linear sources, data for cesium-137 sources was not included in the system software.

In addition to the error in re-entering data for the cesium-137 source parameters, other factors related to software system management were also identified as weaknesses, although they were not specifically related to the misadministrations. These included the fact that the users had partitioned the system to run on two workstations and had copied files from one workstation to the other without requirements to verify that files which were transferred in this method were current or accurate. In addition, although a log was maintained to document problems with the system, there was no formal requirement to do so and entries in the log were sporadic. As a result, it was impossible to determine why the cesium-137 source files were found missing in September 1992.

The inspector noted that the issues discussed above should be reviewed further by system users in order to develop controls and procedures over software system maintenance.

The inspector also noted other errors in data entry for the cesium-137 source parameters which indicate that checks for correct data entry may be warranted. Specifically, the active length of the sources was entered as 1.5 cm rather than 1.38 cm as indicated in the source description sheets provided by the manufacturer. Also, the gamma constant for the cesium-137 sources was entered as 8.25 R/mgm•hr, which corresponds to the exposure rate expected for a radium-226 source with 0.5 mm of platinum filtration, rather than for an unfiltered source as noted in the manual. The user entered this value for the gamma constant because he intended to enter data for cesium-137 in radium-226 equivalent values as specified by the manufacturer; however, this contributed to his entry of "0" as the filter attenuation coefficient.

3.2.3 Corrective Actions Taken for Computer Computerized Treatment Planning Systems

During the course of the inspection, the physicists working with physician Group 2 proposed and implemented corrective actions for future brachytherapy treatment planning activities with the Theraplan treatment planning system. As noted in Section 4, other issues were also identified involving treatment planning processes observed in all treatment planning systems used by DMC; however, at the conclusion of the inspection, the RSO had not yet completed his review of these issues. The actions described below are those proposed by the RSO and consulting physicist.

As discussed in Section 3, the Theraplan users corrected the erroneous source parameter data promptly after their discovery of errors in computer-generated dose tables. In addition, the physicists reviewed the methods previously used to verify computer-generated dose tables and have proposed modifications to the existing practices. Specifically, the users indicated that they plan to generate a dose table for a single source of known coordinates and perform a comparison of the calculated dose rates with Krishnaswamy tables prior to generating the patient-specific treatment plan for each brachytherapy case in the future. This check will essentially allow the users to verify the accuracy of calculated dose tables while eliminating the uncertainties that existed in the former method. The users also noted that they plan to implement checks to detect data input errors because errors were discovered in few cases during the course of their review of all brachytherapy cases performed during the previous 2 years. (It should be noted that the latter errors did not result in misadministrations.) Finally, the review of final treatment plans will be given greater attention so that users may improve their ability to identify errors in treatment plans and ensure that records of treatments are maintained as required by internal procedures. The fact that the staff available to perform such reviews has been increased should assist the consulting staff in achieving these goals.

The inspector noted that based upon the inspection findings, the actions described above will address several concerns regarding the treatment planning process used by one of DMC's consulting physics groups. However, as discussed in Section 4, several other concerns were identified relative to treatment planning activities conducted by DMC's other consulting physicists. Throughout the inspection, the licensee's RSO was apprised of the inspector's

concerns but the RSO had not yet had an opportunity to conduct a full review of activities conducted at other treatment planning facilities used by DMC's authorized users.

4 QUALITY MANAGEMENT PROGRAM (87100)

4.1 Scope of DMC's Brachytherapy Program

As noted in Section 1, DMC has two independent groups of authorized user physicians who perform brachytherapy treatments at its facility. Physician Group 1 uses two computerized treatment planning systems, one located in Casper, Wyoming, and a second located in Bozeman, Montana. Physician Group 1 is supported by a staff of two board certified medical physicists and an unknown number of dosimetrists. Physician Group 2 uses a computerized treatment planning system located in Billings, Montana, and a support staff which includes two board certified medical physicists and several dosimetrists.

Since NRC's Quality Management Rule became effective (January 1992), DMC has performed approximately 30 brachytherapy treatments involving temporary implants of either iridium-192 or cesium-137 sealed sources. In addition, DMC's authorized users have also performed treatments using permanent brachytherapy implants of iodine-125 seeds. The majority of the brachytherapy procedures completed at DMC were performed by a single physician from physician Group 1.

4.2 DMC's Quality Management (QM) Program

By letter dated January 27, 1992, DMC submitted a QM program to NRC in accordance with 10 CFR 35.32. The letter transmitting the program stated that the program was a "draft" which had been tentatively approved but had not yet undergone final approval by the radiation safety committee (RSC). The program submitted by DMC in January 1992 was limited to brachytherapy applications and did not include any provisions for administration of radiopharmaceuticals subject to NRC's QM Rule despite the fact that DMC routinely used sodium iodide I-131 in quantities in excess of 30 microcuries for both diagnostic and therapeutic applications.

The draft QM program submitted by DMC for brachytherapy procedures contained sufficient detail to address patient identification, use of written directives and their required content, verification of the treatment planning process and source localization and implantation, acceptance testing of systems associated with brachytherapy treatment planning, and various reviews of treatment documentation and implementation of the program.

On April 27, 1992, DMC submitted a "final draft" of its QM program to the NRC. The letter which transmitted the program stated that this version had been reviewed and approved by the RSC and would be implemented on May 1, 1992. This program contained provisions for administration of radiopharmaceuticals subject to NRC's QM Rule, as well as for brachytherapy treatments. However, the brachytherapy portion of the program had been changed significantly.

In discussions focused on determining why a second program was submitted and what provisions the licensee had implemented between January and May 1992, DMC staff and the former RSO stated that the original program submitted to NRC had been developed by one of DMC's consulting medical physicists who serves as a member of the RSC. This individual was the same medical physicist who worked with physician Group 2 in planning and administering brachytherapy treatments. Thus, the original program contained sufficient detail to address all aspects of brachytherapy. The second QM program submitted by DMC was developed by a consulting physicist who had only visited DMC and reviewed certain activities infrequently in the past.

According to DMC staff and the former RSO, the staff had been uncertain as to what policies and procedures should be included in a QM program and they had relied upon the advice of a consultant with an established reputation in the area to develop a program for them. The RSO admitted that he had largely relied upon the chief technologist of the nuclear medicine department to obtain the services of a consultant to develop the program. Both the RSO and staff stated that they had been aware of the need to submit a QM program to NRC in January 1992, but were unable to obtain assistance from the selected consultant until after January 1992. As a result, they submitted the program developed by an RSC member and hoped that the consultant would be able to assist them without much delay. However, as noted above, there was a delay in obtaining the consultant's assistance and as a result, DMC failed to establish a QM program for radiopharmaceutical usage until May 1992. In addition, the original program, dated January 27, 1992, was still considered a draft until the final program was submitted to NRC. According to information provided by licensee representatives during the inspection, neither the staff nor the RSO had identified the failure to establish a QM program for radiopharmaceutical usage or to follow the "draft" program provisions for brachytherapy as a violation during the first quarter of 1992 or subsequently thereafter.

The inspector examined DMC's usage of sodium iodide I-131 between February 1 and May 1, 1992, and found that six administrations of sodium iodide I-131 in quantities exceeding 30 microcuries had occurred prior to DMC establishing a QM program for this type of radiopharmaceutical use. The table below identifies the dates and quantities of sodium iodide I-131 administered to patients.

Date of Administration	Quantity Administered
February 17, 1992	2.93 millicuries (mCi)
February 26, 1992	28.5 mCi
March 3, 1992	3.0 mCi
March 11, 1992	148.2 mCi
March 16, 1992	10.0 mCi
April 24, 1992	12.1 mCi

In addition to having failed to establish a QM program to address the use of certain radiopharmaceuticals, the inspector noted that two brachytherapy procedures were performed prior to May 1, 1992, the date that DMC stated it would implement its QM program. These two treatments involved gynecological implants using cesium-137 and were performed on February 4 and April 10, 1992. In both cases, the authorized user had failed to prepare a written directive. Based upon interviews of the authorized users, the RSO, and the staff, the inspector determined that DMC had not required the authorized users or the staff to follow the draft QM program during this period.

The failure to establish a QM program for the use of sodium iodide I-131 in quantities in excess of 30 microcuries or for brachytherapy during the period from January to May 1992, was identified as an apparent violation of 10 CFR 35.32(a) which requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user (Apparent Violation 030-02389/9401-01).

Based upon a review of records associated with radiopharmaceutical administrations, the inspector determined that after May 1, 1992, authorized users had complied with the requirement to complete written directives prior to administering radiopharmaceuticals subject to the QM Rule.

The QM program developed by DMC's consulting physicist was presented to the members of the RSC; however, the authorized users who perform brachytherapy treatments at DMC and their consulting physicists stated that they had not been afforded an opportunity to provide comments on the program or to assist in its development. In fact, some of the physicists who had routinely performed treatment planning for treatments completed at DMC stated that they had never seen a copy of the program.

The inspector noted the contrast between the portions of the QM program applicable to radiopharmaceutical use, which included many details, and those applicable to brachytherapy. The staff noted that the consultant who developed the program did not routinely review brachytherapy procedures although he had performed audits at DMC on various occasions. Further, the consultant had not reviewed nor observed brachytherapy procedures or related activities at DMC or its consulting physicists' facilities. The inspector noted that the program applicable to brachytherapy failed to include procedures or instruction regarding: (1) how the patient's identity was to be verified, (2) treatment planning, (3) verification that the treatment plan was in accordance with the written directive, (4) verification that each administration of radiation was in accordance with the applicable written

directive, and (5) how deviations from written directives were to be evaluated. In summary, the program contained only a statement of each of the objectives defined in 10 CFR 35.32 and failed to include any instruction or procedures as to how those objectives were to be met. However, the program did contain a policy which addressed the need to perform an annual review of activities governed by the QM program and included an outline of information to be examined during each annual review.

Following DMC's implementation of the QM program, the chief nuclear medicine technologist provided training in the provisions of the program to his staff, and both the chief technologist and the medical physicist who served as an RSC member provided some level of instruction to members of the nursing staff who routinely cared for patients undergoing brachytherapy treatments. The latter training was provided concurrently with annual refresher training on radiation safety and was primarily focused on the subjects specified in 10 CFR 35.410.

Based upon discussions with nursing personnel, it appeared that the scope of instruction provided to the nursing staff was generally sufficient for the duties assigned to them. However, some concerns regarding verbal and written instructions provided to the nursing staff were identified to licensee representatives as discussed below.

Through review of patient charts, the inspector noted that several forms had been used to document instructions for nursing staff members caring for patients undergoing brachytherapy implants. In some cases, authorized users had not used any standard form and had instead written nursing instructions in the patient's chart. In general, the inspector found that sufficient information was provided for the staff regarding individuals to contact in the event that a source became dislodged or other complications were encountered during a brachytherapy treatment.

However, in some instances the inspector found that a form had been used which provided nursing instructions that appeared inappropriate given the level of training provided to the nursing staff. Specifically, the inspector noted that one physician from physician Group 1 had used a form for a period of time that required that the nursing staff call the responsible authorized user 1 hour prior to the scheduled termination of a brachytherapy treatment to remind the user of the need to be present to remove the applicator and sources. This was noted as a concern because based upon a review of patient charts, the inspector determined that there often was not enough information documented in the chart for the nursing staff to accurately determine when brachytherapy sources should be removed. A second issue involving this form was also identified. The form included specific instructions for the (nursing) staff to retrieve brachytherapy sources and place them in a portable lead safe if sources became dislodged during treatment. Although the nursing and technical staffs confirmed that this had never occurred, the inspector noted that the nursing staff had not been given sufficient instruction in proper methods for handling brachytherapy sources and were ill prepared to complete this task.

The nursing staff and the RSC had also identified concerns regarding the instructions provided to the nursing staff for brachytherapy treatments and

had discussed this issue in December 1992. The RSC's discussion of this issue led to the development of a new form which was placed into use during the second quarter of 1993. The new form did not contain instructions as noted above and instead required that the physician identify the date and time when the sources were to be removed. The form did not contain information regarding who should be contacted in the event that sources or an applicator became dislodged; however, based upon interviews of the nursing staff, it appeared that the staff understood that the nuclear medicine staff was to be contacted promptly under such circumstances.

The inspector also noted that the licensee had developed a procedure for radiation safety precautions during brachytherapy and had submitted the procedure, identified as Appendix S, to NRC by letter dated December 8, 1988, which is referenced in License Condition 16.B. The procedure, "Radiation Safety During Implant Therapy," contained instructions for conducting radiation surveys, brachytherapy source inventories, instructions to be provided to patients and the nursing staff, and other tasks associated with the use of brachytherapy sources. Item 3 of the procedure required that the nursing staff be briefed on radiation safety precautions, including a question and answer session, with each brachytherapy treatment.

The inspector interviewed nursing staff representatives and was informed that this type of instruction was not always provided to them. Based upon interviews conducted during the inspection, it appeared that instructions provided to the nursing staff varied depending on the authorized user who implanted brachytherapy sources and whether the technical staff had been notified of the treatment and was available when sources were implanted. In particular, one physician was noted as having provided very little, if any, instruction to the nursing staff. Both technical and nursing staff representatives noted that this physician had often scheduled his patients for implants during the evening hours and had infrequently notified the technical staff in advance that a brachytherapy case was scheduled. Because the technical staff was often not present for the aforementioned reasons and the authorized user did not provide instructions, nursing staff representatives did not always receive radiation safety instructions prior to caring for his patients as required under the license. The failure to provide radiation safety instructions to nursing staff members caring for a patient undergoing brachytherapy treatment was identified as an apparent violation of 10 CFR 35.21(a) which specifies, in part, that a licensee, through the RSO, must ensure that radiation safety activities are being performed in accordance with applicable procedures and regulatory requirements (Apparent Violation 030-02389/9401-02).

Two authorized users stated that they had not been provided with a copy of DMC's QM program and a third who performed brachytherapy procedures at DMC stated that he thought he had received a copy. Collectively, the authorized users stated that they had received no training in the program themselves. Likewise, the consulting physicists working for both groups of physicians stated that they had not received any training in the QM program. In fact, the licensee's consulting physicists were either uncertain as to whether they had received a copy of the QM program or explicitly stated that they had never seen the program prior to the recent investigations. As noted elsewhere in

this report, these physicists were responsible for treatment planning and assisting in source loading. Although one of the consulting physicists had developed the first draft of the QM program, each of the consulting physicists involved in DMC's brachytherapy program stated that they had not participated in the development of the final version of the QMP.

The failure to train the physicists responsible for treatment planning and handling brachytherapy sources in the provisions of the QM program was identified as an apparent violation of 10 CFR 35.25(a)(1) which specifies, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user must instruct the supervised individual in the licensee's written quality management program (Apparent Violation 030-02389/9401-03).

The issues involving participation of individuals responsible for performing brachytherapy treatments in the development of the QM program and the lack of training provided to physicists who were chiefly responsible for developing treatment plans were identified as significant concerns to licensee management. In addition, the inspector also reviewed with licensee representatives concerns that the current version of DMC's QM program failed to provide any instruction as to how the objectives of 10 CFR 35.32 were to be met by the staff and authorized users and also failed to address the process of treatment planning and verification of dosimetry calculations altogether. Further, the inspector noted that both groups of physicians and consulting physicists had very different methods for planning brachytherapy treatments and that the program failed to take into consideration some unique aspects of treatment planning and information handling associated with one group of physicians. The latter issue involves physician Group 1 which because of the geographic location of treatment planning systems used by this group, had employed the use of fax machines to transmit data from simulation radiographs as well as treatment plan information.

Based upon a review of 31 of 33 brachytherapy treatments performed at DMC since January 1992, a number of concerns and several apparent violations were identified. The apparent violations involved areas in which the licensee's QM program had failed to meet the objectives of 10 CFR 35.32, NRC's QM Rule. These issues are described below.

The first issue involved the authorized users' adherence to the requirement to complete a written directive prior to the completion of a brachytherapy treatment. As discussed above, DMC submitted a draft QM program to NRC in January 1992 but did not fully implement a QM program for brachytherapy until May 1992. Two cases were identified in which a written directive was not prepared by the responsible authorized user. These treatments were performed in February and April 1992. In addition, a number of cases were identified in which the written directive prepared by the authorized user failed to include all required information. These problems are summarized below:

- Failure to sign a written directive: Nine cases were identified in which the authorized user failed to sign the written directive. The treatments were performed in July, September, October and

November 1992; March, May, July and September 1993; and February and March 1994.

- Failure to specify the total dose: Five cases were identified in which the authorized user failed to specify the total dose in the written directive. These treatments were performed in July, September, October and November 1992; and August 1993. In addition, in several cases the source strength specified in the written directive did not match the sources in the licensee's possession at the time. In one case the authorized user did not specify the total dose or the exposure period and in a second, the authorized user failed to specify the total dose and source strength. In some cases, the authorized user specified a dose range (with ranges spanning over 1,000-1,200 centigray) rather than a total dose.

- Failure to specify the treatment site: Two cases were identified in which the authorized user failed to specify the treatment site in the written directive. These treatments were performed in July and November 1992.

The above noted examples were identified as an apparent violation of 10 CFR 35.32(a)(1) which specifies, in part, that a licensee must establish and maintain a written QM program which meets the objective that prior to administration, a written directive is prepared for any brachytherapy radiation dose. 10 CFR 35.2 defines a written directive for brachytherapy as an order in writing which prior to implantation includes the radioisotope, number of sources, and source strengths; and after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose) (Apparent Violation 030-02389/9401-04).

The majority of the above noted cases were associated with one authorized user physician. In discussing the reasons for the oversights and failures to prepare a complete written directive, the authorized user indicated that he did not consider a written directive to constitute a record of his intended treatment dose. Instead, the authorized user stated that he considered a written directive to be part of a process and that he considered the prescribed treatment dose to be the dose as determined at the conclusion of treatment and documented in his treatment summary. The authorized user acknowledged that the failure to complete a written directive had been discussed with him on several occasions by members of the RSC.

The inspector also noted that the use and format of treatment plans varied widely among the cases reviewed during the inspection. Some variation in document format and content was expected since DMC's authorized users had different medical physicists assisting them in developing treatment plans and three different computer systems had been used. However, the variances observed in this group of cases was unusual in several respects. The most notable issue involved the use of a single treatment plan for several patients. Specifically, in reviewing patient charts and records maintained of

treatments performed during the previous two years, the inspector identified one treatment plan which appeared to have been used for treatments administered to three different patients, a second treatment plan which appeared to have been used for two different patients, and a third instance in which a single treatment plan was used for the same patient on two different occasions. This was noted as unusual in that the isodose plots and source strengths were identical despite the fact that several months had elapsed (in one instance treatments were completed 11 months apart) and the data used to calculate doses to critical organs was the same (it would be unusual for two patients to have the same body measurements).

In discussing this issue with the authorized user associated with these treatments (a member of physician Group 1), the inspector was informed that the authorized user maintained a "library" of treatment plans and that often, dose calculations were initially completed using a similar case that had been done in the past. According to the authorized user, this allowed him to telephone the medical physicist who worked with him and determine an approximate exposure period. The authorized user then documented information necessary for treatment planning (a hand drawing using simulation radiographs to identify critical points for dosimetry calculations) and faxed the information to the physicist who performed his work in Casper, Wyoming. The physicist was never provided the original simulation radiographs in order to complete a treatment plan.

The inspector discussed several concerns regarding this practice with licensee representatives. In particular, the inspector noted that because the authorized user had not provided the hospital with a copy of the correct or final treatment plan, the staff was unable to verify through QM program reviews that some treatments were administered in accordance with the applicable written directives. In addition, the practice resulted in a number of examples in which a treatment plan was not in accordance with the applicable written directive. Further, in a few instances, the final treatment plan was not faxed to the physician until the brachytherapy sources were removed from the patient. As a result, the physician had not reviewed the final treatment plan prior to the completion of treatment. In addition, the physicist who performed treatment planning for this group acknowledged that he only performed independent (manual) checks of computer-generated dose tables if the isodose curves or calculated dose rates appeared unusual. Thus, treatment plans in some instances never received a second check prior to the completion of treatment and an important element of verifying that the correct dose would be administered to the patient was overlooked.

Because the practice described above raised significant concerns regarding the dose administered to each patient and insufficient information had been retained by DMC to verify the dose received by several patients, the licensee and authorized user were requested to review several cases and to provide the inspector with a copy of the final treatment plans. The authorized user was able to provide three treatment plans which were not previously found at DMC but was unable to locate other treatment plans in his office files. The physicist who performed treatment planning with the authorized user was also contacted and informed the inspector that he would assist the authorized user

and would provide any information requested if it was available in electronic format, but noted that he did not archive all patient cases.

Seven cases were identified in which the treatment plan maintained by the licensee did not match the written directive. Discrepancies between the treatment plan and the written directives included: (1) differences in source strengths specified in the written directive and treatment plan, (2) discrepancies between the documented implantation period and calculated total dose, and (3) differences between the documented total dose and the calculated total dose given the dose rates identified in the treatment plan. In some cases where a discrepancy was identified between the source strength specified in the treatment and the actual source activity, the physicist who completed the treatment plan stated that the discrepancy may be due to the fact that some shielding factors were used for certain applicators. However, the specific cases in which shielding factors were used were not identified by the authorized user and the inspector and RSO were unable to resolve some of the discrepancies. In other cases where source strengths differed between the written directive and the treatment plan, it appeared that the differences were greater than what would have been attributed to the use of shielding factors. In one case, the treatment plan and written directive clearly indicated that sources of different strengths were used to calculate dose rates used to determine the exposure period; however, the physician was unable to resolve the discrepancy due to a lack of backup information. (There was also a discrepancy in information logged in the brachytherapy inventory records.)

The issues discussed above were identified as an apparent violation of 10 CFR 35.32(a)(3) which specifies, in part, that a license must establish and maintain a QM program which meets the objective that final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directive (Apparent Violation 030-02388/9401-05).

In addition to the apparent violations discussed above, the inspector identified other significant weaknesses in the licensee's QM program. Specifically, the program failed to include any policies or procedures for verifying the accuracy of computer algorithms used to calculate dose rate tables and isodose curves which serve as the basis for determining the exposure period for any given treatment. Likewise, the program did not include any provisions for performing data entry checks to ensure that appropriate data was entered in treatment planning systems used to calculate dose rates and isodose plots. These oversights were noted as weaknesses because they involve checks which are designed to identify potential errors prior to treatment. In particular, the failure include requirements to verify the accuracy of computer algorithms for treatment planning systems or to ensure that treatment plan verification checks were performed correctly was of concern because an error which occurred in checking computer-generated dose rate tables was identified the root cause of two misadministrations. In addition, the inspector was informed by one physics consultant that routine verification checks of dose rate tables were not performed unless the isodose plots "appeared unusual or incorrect." The inspector noted to licensee management that a visual check of isodose curves or of dose tables is generally not sufficient to detect errors in calculations.

In addition to the concerns noted above, the inspector noted that DMC had failed to consider in its QM program the fact that one group of physicians had transmitted source position information via fax machine. This process involved a physician documenting on paper, by tracing from a radiograph, the position of brachytherapy sources along with some marking to indicate the magnification factor of the radiographs then transmitting the data to a remote location for use in treatment planning. The inspector noted that this process is subject to errors, not only from the manual process of tracing but also from changes in magnification which could occur during data transmission.

In addition to oversights regarding the provisions of DMC's QM program for treatment planning, the inspector also noted that the QM program did not require that treatment plans be retained by DMC. In fact, as noted above, the inspector identified several cases in which final treatment plans had not been maintained by DMC and for which it was impossible to verify whether the correct information had been used to develop the treatment plan. This was identified as a concern because the licensee was unable to conduct an adequate review to determine whether treatment plans were in accordance with the applicable written directive. In addition, at least one authorized user had specified treatments by source strength and exposure time and had often failed to record the serial number of the sources used for an implant (they instead recorded a nominal source strength). Thus, it was difficult, and in some cases impossible, to verify that the appropriate source strength had been used to complete the treatment plan.

In addition to concerns regarding oversights in the licensee's QM program relative to treatment planning, one apparent violation was identified that was related to this issue. Specifically, DMC's QM program was found inadequate to ensure that each administration of radiation from brachytherapy sources was in accordance with the applicable written directive. As a result of an error made in conducting independent checks of computer-generated dose tables, errors in dose calculations used in treatment plans were not identified and two misadministrations occurred. This was identified as an apparent violation of 10 CFR 35.32(a)(4) which specifies, in part, that a licensee must establish and maintain a written QM program which meets the objective that each administration (of radiation) is in accordance with the respective written directive (Apparent Violation 030-02389/9401-06).

These issues were highlighted to licensee management as items warranting further review in order to ensure that sufficient controls were implemented to prevent errors in treatment.

As noted above, the QM program established by DMC did contain provisions for conducting annual reviews of the effectiveness of the program. In addition, the RSC, with assistance from the technical staff, had conducted reviews of some aspects of the QM program on a quarterly basis. The inspector noted that although the latter reviews had identified some failures of the authorized users to comply with the requirement to prepare a written directive, the corrective actions taken by the committee had been largely ineffective since the same authorized user was associated with each instance in which a written directive was either not prepared or was incomplete. In addition, the reviews conducted by the RSC were very limited in scope and were not of sufficient

detail to identify deviations from written directives or errors in treatment. In particular, the quarterly reviews were only intended to focus on records maintained in the nuclear medicine department. As a result, the only records reviewed by RSC members were the written directives prepared by authorized users; treatment plans had not been reviewed since the inception of the program.

The provisions of the QM program applicable to annual reviews, described in Item 11 under a section titled "Annual Reviews," specified that final treatment plans were to be reviewed by the radiation oncology quality management physician and RSO to ensure that the plans were in accordance with the respective written directive. This section of the QM program identified elements of the review including items applicable to written directives, training of individuals working under the supervision of authorized users, and compliance with requirements to implement corrective actions when deviations from written directives were identified. However, based upon interviews of DMC staff, it appeared that neither a physician nor the RSO had conducted an annual review that included evaluation of treatment plans, training, or other elements of the licensee's QM program. The failure to conduct an annual review of the QM program was identified as an apparent violation of 10 CFR 35.32(b)(1) which specifies, in part, that a licensee must develop procedures for and conduct a review of the QM program including an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations and that such reviews must be conducted at intervals no greater than 12 months (Apparent Violation 030-02389/9401-07).

The inspector noted that the licensee's new RSO had identified the oversight in conducting an annual review of the QM program; however, because he had only recently joined the staff and was authorized as the RSO during the first week of the inspection, he had not yet had sufficient time to conduct a review. Following his identification of the misadministrations which prompted the inspection, the RSO had initiated a review of the program and had reviewed the majority of the brachytherapy treatments completed at DMC since January 1992. The RSO had identified several of the issues discussed above but had not yet had time to complete his review at the time of the inspection.

5 BRACHYTHERAPY PROGRAM OVERSIGHT (87100)

Based upon interviews of DMC staff members, authorized user physicians, and the licensee's consulting physicists, several concerns were identified regarding the oversight which licensee management and the RSO had provided for DMC's brachytherapy program. These concerns involved weaknesses in communications between the various individuals who participated in performing and planning brachytherapy procedures as well as a failure of the former RSO to conduct reviews of activities associated with the brachytherapy program. However, as discussed below, DMC had recently appointed a new individual to serve as the RSO and this individual had aggressively investigated the circumstances associated with two misadministrations as well as other areas of concern associated with the licensee's implementation of its QM program. Three apparent violations related to records of radiation surveys associated with brachytherapy treatments and brachytherapy source usage and inventory

records were identified during the inspection. The apparent violations and other concerns identified by the inspector are discussed below.

5.1 Communications

During the inspection, DMC's staff, authorized users, and consulting physicists expressed concerns regarding communications issues related to the licensee's brachytherapy program. These issues were primarily focused on problems associated with scheduling patients for brachytherapy treatments and the fact that in some cases, the technical staff had very little notice regarding when sources were to be implanted which made it difficult for them to ensure that a staff member would be available to perform the required radiation surveys. In several instances, the technical staff stated that they had not been informed that a brachytherapy treatment was ongoing until several hours after sources were implanted. In addition, some authorized users expressed concerns that they had been provided very little information regarding the specifics of documentation requirements and had not received much support in performing brachytherapy treatments at DMC. The latter issued was primarily limited to the fact that some of the authorized users were relatively new to the staff and had not been provided information on where they might find handling tools for the sources or survey instruments for use in performing surveys following source implantation.

The most notable communication problem appeared to involve the relationships established between the hospital and authorized users and consulting physicists. Although the specific reasons were not fully discussed during the inspection, DMC representatives expressed concerns that they were unable to review certain information maintained by the some of the consulting physicists or the physicists' methods for performing treatment planning. In addition, the staff had not visited with the consulting physicists and the inspector found that the staff was unaware of some aspects of the treatment planning programs maintained by the authorized users. In some cases the inspector identified reluctance on the part of the physics consultants to permit DMC to review their treatment planning systems and processes; however, in other cases, the physicists appeared receptive to further involvement of the DMC staff.

Overall, communication problems expressed by various individuals to the inspector appeared to have resulted in lapses of communication among the various individuals involved in brachytherapy activities and reluctance of individuals to share information. In addition, communication problems contributed to some apparent violations.

5.2 Oversight Provided by the RSO

Through discussions with the former RSO, the inspector identified a number of concerns regarding the oversight provided by him for the brachytherapy program. Specifically, the former RSO acknowledged that he had not routinely reviewed brachytherapy activities and had relied upon the technical staff to bring problems to his attention. However, the inspector noted that the technical staff did not have full access to information necessary to perform adequate program reviews and had not been specifically trained in

brachytherapy procedures. The technical staff had done a satisfactory job in performing radiation surveys associated with brachytherapy treatments, but they were not prepared to perform program reviews of sufficient detail to identify errors in treatment or problems in the treatment delivery process.

The former RSO, who was primarily involved in diagnostic radiology and nuclear medicine procedures, also acknowledged that he did not have sufficient experience to review treatment plans to determine whether they were in accordance with written directives and had relied upon the consulting physicists to perform such checks on their own without further review by him. Based upon discussions with the RSO, it appeared that he had largely relied upon others to ensure that the brachytherapy activities for which they were responsible were carried out correctly and in accordance with the licensee's and NRC's requirements. The only review of brachytherapy activities in which the RSO had routinely participated were the document reviews conducted during the RSC meetings.

Notwithstanding the issues identified above, the new RSO, who assumed his position in March 1994, was well prepared to provide oversight of both routine nuclear medicine procedures and the brachytherapy program. The new RSO had identified several concerns regarding DMC's QM program prior to the inspection and had proposed several changes to the RSC. However, based upon the findings of the inspection, the RSO was considering other modifications to the program at the conclusion of the inspection. The inspector noted that although the RSO quickly became involved in an ongoing NRC inspection and a special NRC task group review, he had completed a thorough review of the misadministrations and had worked with hospital management to develop corrective actions to address the root causes of the misadministrations and other concerns associated with the licensee's brachytherapy program.

5.3 Records Maintained for Brachytherapy Treatments

In reviewing the various records maintained for brachytherapy treatments, the inspector identified several issues warranting further review by the licensee. The most notable issues involved maintenance of records documenting brachytherapy treatments as discussed in Sections 3 and 4 of this report. However, the inspector also identified three apparent violations involving other records maintained to document activities associated with brachytherapy treatments.

The first issue involved records of surveys conducted following implantation and explantation of brachytherapy sources. Both the technical staff and authorized users had completed surveys of patients, the patients' room and surrounding areas after brachytherapy sources were implanted. On those occasions when sources were implanted during the evening hours the authorized users had conducted the surveys. With one exception, the surveys appeared to have included all areas surrounding the patient's room and based upon interviews with the staff and a review of the survey records, it appeared that the technical staff had restricted the surrounding areas appropriately when required. The exception noted above involved a stairwell which is adjacent to the room routinely used for brachytherapy treatments. This area is an unrestricted area which is frequented by members of the public and was rarely

included in surveys of unrestricted areas adjacent to the patient's room following source implantation. This issue was identified as a violation to licensee representatives and is described in a Notice of Violation issued with this report. However, the inspector evaluated data recorded for surveys conducted within the patient's room following implantation of brachytherapy sources and concluded that based upon radiation levels recorded for the room surveys, the radiation levels in the stairwell area would not have exceeded regulatory limits.

The inspector also noted that records of area surveys maintained by DMC did not include all required information. Specifically, the staff had maintained records of each survey which included the time and date of the survey, the points and areas surveyed, the measured dose rates, and the initials of the individual who conducted the survey. However, the records did not include information regarding the instrument used to conduct the survey. This was identified as an apparent violation of 10 CFR 35.415(a)(4) which requires, in part, that records of surveys conducted to demonstrate compliance with this section be retained for a period of 3 years and that the record contain the time and date of the survey, a plan of the area surveyed or a list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey (Apparent Violation 030-02389/9401-08).

Likewise, the licensee had retained records of patient surveys completed after brachytherapy sources were explanted but these records were also found to lack some information required by NRC. Specifically, licensee representatives had only recorded a dose rate (as measured at a distance of approximately 1 meter) and the date and initials of the individual who completed the survey. There was no information recorded regarding the instrument used to conduct the survey. In addition, in two cases no record was maintained of surveys conducted following explantation of brachytherapy sources and prior to releasing the patients. This was identified as an apparent violation of 10 CFR 35.404(b) which requires, in part, that records of surveys conducted in accordance with 10 CFR 35.404(a) be retained for a period of 3 years and include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour, the survey instrument used, and the initials of the individual who made the survey (Apparent Violation 030-02396/9401-09).

The inspector also noted that the licensee's records of brachytherapy source usage and inventory were incomplete in that they did not account for the full inventory of sources, including the number and activity of the sources removed/returned from storage as well as the number and activity of those remaining in storage. The records only contained information on the total activity of sources removed from storage and the initials or name of the individual who removed the sources. Thus, neither the individuals who used the sources or those who monitored this activity were able to account for the full inventory of brachytherapy sources at any given time without conducting a physical inventory. In addition, on at least one occasion, the authorized user who removed brachytherapy sources from their storage location in order to perform a treatment failed to note that the sources had been removed from storage on the inventory log. The authorized user stated that this was the

first case that he had performed at DMC and that he had not been informed of where the inventory log was located. These findings were identified as an apparent violation of 10 CFR 35.406(b) which requires, in part, that a licensee make a record of brachytherapy source use which must include: (1) the names of individuals permitted to handle the sources; (2) the number and activity of sources removed from storage, as well as the number and activity of sources remaining in storage after source removal; and (3) the number and activity of sources returned to storage, along with the number and activity of sources in storage following return of sources (Apparent Violation 030-02396/9401-10).

None of the above noted apparent violations had been identified by the former RSO. Although the former RSO had reviewed records of area and patient surveys during the quarterly reviews of the licensee's QM program, he failed to note that all required information was not documented. The RSO had not reviewed the source inventory records during periodic program reviews and had instead relied upon one of the licensee's consultants to review the aforementioned records. The failure of the RSO to conduct program reviews of sufficient detail to identify these oversights was identified as a concern relating to the RSO's oversight of the brachytherapy program.

ATTACHMENT 1

1 Persons Contacted

Mr. Lane Basso, Chief Executive Officer
Thomas Cherewick, M.S., Physics Consultant
Fred Deigert, M.D., Radiation Oncologist
Mark Dion, M.D., Radiation Oncologist
Mr. Robert H. Doolan, Vice President
Mark Edwards, Ph.D., Radiation Safety Officer (present)
Mr. Pat Garret, Chief Operating Officer
Michael T. Gillin, Ph.D., Physics Consultant
Ross Kachaniwsky, Manager, Quality Assurance, Theratronics Ltd.
Frank Lamm, M.D., Radiation Oncologist
Edward Martell, Vice President, Quality Assurance & Regulatory Affairs, Theratronics Ltd.
William Powers, M.D., Radiation Oncologist (Consultant)
J. R. Rub, Manager, Radiology
David Switzer, M.S., Physics Consultant
John Terry, M.D., Radiation Oncologist
Steve Wharton, Chief Technologist, Nuclear Medicine
Jerry Wolf, M.D., Radiation Safety Officer (former)

Other staff members working at Deaconess Medical Center were also interviewed.

2 Exit Briefing

On April 1, 1994, a public interim exit briefing was conducted in Billings, Montana, to review the findings of the initial segment of the inspection. A telephonic exit briefing was conducted on April 29, 1994, with Dr. Mark Edwards of the Deaconess Medical Center staff to review the inspection findings as presented in this report.

APPENDIX C

PROPOSED ENFORCEMENT CONFERENCE AGENDA
DEACONESS MEDICAL CENTER

June 28, 1994 8:15 a.m. (CDT)

I.	INTRODUCTION AND PURPOSE	L. J. CALLAN
II.	EXPLANATION OF ENFORCEMENT POLICY	G. F. SANBORN
III.	NRC DISCUSSION OF APPARENT VIOLATIONS	C. L. CAIN L. L. KASNER
IV.	LICENSEE COMMENTS AND RESPONSE/CORRECTIVE ACTION	L. BASSO M. EDWARDS F. LAMM
V.	CLOSING COMMENTS	S. J. COLLINS

APPENDIX D

Two-Year Trial Program for Conducting Open Enforcement Conferences; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing this policy statement on the implementation of a two-year trial program to allow selected enforcement conferences to be open to attendance by all members of the general public. This policy statement describes the two-year trial program and informs the public of how to get information on upcoming open enforcement conferences.

DATES: This trial program is effective on July 10, 1992. Comments on the program are requested. Submit comments before the conclusion of the trial program scheduled for July 11, 1992. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch.

Hand deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, MD between 7:45 a.m. to 4:15 p.m., Federal workdays.

Copies of comments may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-504-2741).

SUPPLEMENTARY INFORMATION:

Background

The NRC's current policy on enforcement conferences is addressed in Section V of the latest revision to the "General Statement of Policy and Procedure for Enforcement Actions" (Enforcement Policy) 10 CFR part 2, appendix C that was published on February 18, 1992 (57 FR 5791). The Enforcement Policy states that, "enforcement conferences will not normally be open to the public." However, the Commission has decided to implement a trial program to determine whether to maintain the current policy with regard to enforcement conferences or to adopt a new policy that would allow most enforcement conferences to be open to attendance by all members of the public.

Policy Statement

Position

The NRC is implementing a two-year trial program to allow public observation of selected enforcement conferences. The NRC will monitor the program and determine whether to establish a permanent policy for conducting open enforcement conferences based on an assessment of the following criteria:

(1) Whether the fact that the conference was open impacted the NRC's ability to conduct a meaningful conference and/or implement the NRC's enforcement program;

(2) Whether the open conference impacted the licensee's participation in the conference;

(3) Whether the NRC expended a significant amount of resources in making the conference public; and

(4) The extent of public interest in

I. Criteria For Selecting Open Enforcement Conferences

Enforcement conferences will not be open to the public if the enforcement action being contemplated—

(1) Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed wrongdoing;

(2) Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;

(3) Is based on the findings of an NRC Office of Investigations (OI) report; or

(4) Involves safeguards information, Privacy Act information, or other information which could be considered proprietary.

Enforcement conferences involving medical misadministrations or overexposures will be open assuming the conference can be conducted without disclosing the exposed individual's name. In addition, enforcement conferences will not be open to the public if the conference will be conducted by telephone or the conference will be conducted at a relatively small licensee's facility. Finally, with the approval of the Executive Director for Operations, enforcement conferences will not be open to the public in special cases where good cause has been shown after balancing the benefit of public observation against the potential impact on the agency's enforcement action in a particular case.

The NRC will strive to conduct open enforcement conferences during the two-year trial program in accordance with the following three goals:

(1) Approximately 25 percent of all eligible enforcement conferences conducted by the NRC will be open for public observation;

(2) At least one open enforcement conference will be conducted in each of the regional offices; and

(3) Open enforcement conferences will be conducted with a variety of the types of licensees.

To avoid potential bias in the selection process and to attempt to meet the three goals stated above, every fourth eligible enforcement conference involving one of three categories of licensees will normally be open to the public during the trial program. However, in cases where there is an ongoing adjudicatory proceeding with one or more intervenors, enforcement conferences involving issues related to the subject matter of the ongoing adjudication may also be opened. For the purposes of this trial program, the three categories of licensees will be commercial operating reactors, hospitals, and other licensees, which will consist of the remaining types of licensees.

II. Announcing Open Enforcement Conferences

As soon as it is determined that an enforcement conference will be open to public observation, the NRC will orally notify the licensee that the enforcement conference will be open to public observation as part of the agency's trial program and send the licensee a copy of this *Federal Register* notice that outlines the program. Licensees will be asked to estimate the number of participants it will bring to the enforcement conference so that the NRC can schedule an appropriately sized conference room. The NRC will also notify appropriate State liaison officers that an enforcement conference has been scheduled and that it is open to public observation.

The NRC intends to announce open enforcement conferences to the public normally at least 10 working days in advance of the enforcement conference through the following mechanisms:

(1) Notices posted in the Public Document Room;

(2) Toll-free telephone messages; and

(3) Toll-free electronic bulletin board messages.

Pending establishment of the toll-free message systems, the public may call (301) 492–4732 to obtain a recording of upcoming open enforcement conferences. The NRC will issue another Federal Register notice after the toll-free message systems are established.

To assist the NRC in making appropriate arrangements to support public observation of enforcement conferences, individuals interested in attending a particular enforcement conference should notify the individual identified in the meeting notice announcing the open enforcement conference no later than five business days prior to the enforcement conference.

III. Conduct of Open Enforcement Conferences

In accordance with current practice, enforcement conferences will continue to normally be held at the NRC regional offices. Members of the public will be allowed access to the NRC regional offices to attend open enforcement conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251). These procedures provide that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 36" be permitted, and that disruptive persons may be removed.

Each regional office will continue to conduct the enforcement conference proceedings in accordance with regional practice. The enforcement conference will continue to be a meeting between the NRC and the licensee. While the enforcement conference is open for public observation, it is not open for public participation.

Persons attending open enforcement conferences are reminded that (1) the apparent violations discussed at open enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action and (2) the statements of views or expressions of opinion made by NRC employees at open enforcement conferences or the lack thereof, are not intended to represent final determinations or beliefs.

In addition to providing comments on the agency's trial program in accordance with the guidance in this notice, persons attending open enforcement conferences will be provided an opportunity to submit written comments anonymously to the regional office. These comments will subsequently be forwarded to the Director of the Office of Enforcement for review and consideration.

Dated at Rockville, MD, this 7th day of July 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92–16233 Filed 7–9–92; 8:45 a.m.]

BILLING CODE 7590–01–M

Deaconess
Medical
Center

ATTACHMENT 2

April 27, 1992

U.S. Nuclear Regulatory Commission
Material Radiation Section
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

RE: License #25-01051-0[illegible]

Gentlemen:

Enclosed is the final draft of the "Brachytherapy Quality Management Program" for Deaconess Medical Center. This program has been reviewed and approved by the Radiation Safety Committee and will be implemented as of May 1, 1992.

Sincerely,

Jerry D. Wood, M.D.
Radiation Safety Officer

JDW:su

Enclosure

Deaconess
Medical Center
[illegible]

[illegible]
South Central North
P.O. Box [illegible]
Billings, Montana 59[illegible]

Telephone 406-657-4000