SECY-97-037

February 12, 1997

FOR: The Commissioners

FROM: Hugh L. Thompson, Jr. /s/
Acting Executive Director for Operations

SUBJECT: ASSESSMENT OF THE QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE

PURPOSE:

To respond to a Staff Requirements Memorandum (SRM) dated June 19, 1991, that approved the final Quality Management Program and Misadministrations Rule (QM Rule) and directed the staff to assess the effectiveness of the rule three years after the rule became effective, including recommendations on the need for a rulemaking on comprehensive quality management.

SUMMARY:

In SECY-93-244, dated August 31, 1993, the staff proposed to include status reports on the implementation of the QM Rule in its proposed plan for management of the medical use regulatory program. This plan addressed major policy issues associated with the medical use program.

On October 13, 1994, in SECY-94-256, the staff provided a status report on the medical management plan, including the implementation progress of the QM Rule. At that time, the staff recommended that no changes in the scope nor focus of the rule be initiated until: further data was collected regarding the adequacy of the implemented quality management program (QMP) during inspections; a determination of the root causes of misadministrations was made; violations of the QM Rule were identified; and collection and analysis of licensee data regarding the number of procedures performed requiring written directives were completed.

This report was developed to compile and correlate the findings associated with the review of the written QMPs, and inspection of licensee's implementation of those QMPs. It provides a preliminary analysis that enables the staff to assess the implementation of the QM Rule, and to respond to the question provided in the SRM dated June 19, 1991, regarding the need for a rulemaking on comprehensive quality management. The staff intends to use this report as part of the effort to revise 10 CFR Part 35, and to provide recommendations on any changes to QM requirements in the context of that revision.

DISCUSSION:

On August 1, 1994, the revised Temporary Instruction (TI) (2800/025), "Quality Management Program and Misadministration Rule," became effective. This TI established areas of inspection, created a procedure for determining compliance with the rule, and provided a means of recording the inspection findings for later analysis. The TI was in effect until August 1, 1996. The resulting inspection results were analyzed to address the Commission's direction for assessing the effectiveness of the rule. The attached report: "Assessment of the Implementation of the Quality Management Program and Misadministrations Rule, 10 CFR 35.32 and 35.33," is submitted to respond to the SRM dated June 19, 1991. In addition, the staff intends to publish this report as a NUREG to provide information on the QM Rule to the regulated community and the public. Members of the regulated community and associated professional societies have expressed an interest in such information.

FINDINGS:

A total of 883 licensees, representing 1668 modalities, were inspected during the two years the TI was in effect. Seventy-seven percent (1286) of the inspected QMPs had previously been reviewed by Lawrence Livermore National Laboratories (LLNL) during the initial review of written submittals. During inspection, the implemented QMP was compared to the requirements in the rule, rather than to the submitted written QMP. Review of inspections findings for licensees' QMPs indicates that 43 percent of the QMPs failed to meet all of the objectives of the rule.

There has not been a significant reduction in the total number of misadministrations reported, the performance indicator most closely linked to QM Rule effectiveness. While the number of reports of diagnostic misadministrations has been significantly reduced due to changes in requirements as to what incidents must be reported, the net number of reported therapy misadministrations remains at approximately 30 to 40 per year. However, the distribution of errors that led to misadministrations, per modality, has changed. For example, strontium-90 eye applicator events have increased significantly. An ongoing investigation involving eye applicators is expected to add at least two more misadministrations, each involving multiple patients, to the database.

The staff examined the relationship between routine inspection findings, and reactive inspection findings associated with misadministrations. For those licensees who had a misadministration at some time since the rule became effective, only 29 percent had an inspection finding related to QMP implementation during their routine inspection. However, in 56 cases (45 percent of 138 misadministrations), the staff took enforcement actions related to some aspect of the QMP during the follow-up relating to the misadministration. Therefore, routine inspection findings are not necessarily predictors of the probability of the occurrence of a misadministration, and there is a better, although not a strong, correlation between the occurrence of a misadministration and an inspection finding related to the QM program at the time of the event.

In 1991, the causes of misadministrations and/or abnormal occurrences were characterized in the Statements of Consideration, published with the final QM Rule, as: insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail, and inadequate training. Since the QM Rule became effective, these same causes of misadministrations appear to persist. However, most of the current errors can be attributed to two of the

causes: inattention to detail and failure to follow procedures, both of which may be viewed as "human errors" as contrasted to "mechanical errors." The most frequent causes of the misadministrations reported to NRC since January 27, 1992, were as follows:

26 involved incorrect data entry and calculation errors,
23 involved wrong source, radiopharmaceutical, or dose (quantity),
18 involved the wrong treatment site,
10 involved source migration/dislodgement,
6 involved failure to administer the entire dose or dosage (the source or dosage (capsule) was left in the pig or tandem).

Many of the above errors that led to a misadministration could have been prevented by: (1) redundantly checking the data entry and calculations (QM Objective 3), or (2) immediately before administering the dose or dosage, comparing that which was to be administered to the written directive (QM Objective 4). Thus, with the exception of equipment failures and certain source migration/dislodgement events, it would appear that more complete adherence to meeting the objectives in the QM Rule should reduce the likelihood of a misadministration.

CONCLUSION:

Based on the four-year implementation of the QM Rule, the staff has concluded that the expansion of the current QM Rule into a comprehensive quality management program is not needed. Specific recommendations regarding proposed changes to the QM Rule will be provided in the staff's rulemaking plan for revision of 10 CFR Part 35.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

Hugh L. Thompson, Jr.
Acting Executive Directorfor Operations

Attachment: QM Rule Assessment

CONTACT: Sally L. Merchant, NMSS
(301) 415-7874

ATTACHMENT 1

ASSESSMENT OF THE IMPLEMENTATION OF THE QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE

10 CFR 35.32 AND 35.33

Contact: Sally L. Merchant, NMSS
(301) 415-7874

CONTENTS

- BRACHYTHERAPY
- STRONTIUM-90 EYE APPLICATOR
- TELETHERAPY
- GAMMA STEREOTACTIC RADIOSURGERY

DATA TABLES

- SUMMARY DATA
- INSPECTION FINDINGS
- ENFORCEMENT DATA
- SODIUM IODIDE I-125 or I-131 > 30 &#181 Ci
- RADIOPHARMACEUTICAL THERAPY
- HIGH-DOSE-RATE REMOTE AFTERLOADER BRACHYTHERAPY
- Brachytherapy
- STRONTIUM-90 EYE APPLICATORBRACHYTHERAPY
- TELETHERAPY
- GAMMA STEREOTACTIC RADIOSURGERY

ATTACHMENTS

1. Standard Review Plan
2. Regulatory Guide 8.33, "Quality Management Program"
3. Table 1: "Results Summary - All Regions," Findings of LLNL Review
4. Temporary Instruction (TI) (2800/025) "Quality Management Program and Misadministration Rule"
5. Table of Misadministrations

EXECUTIVE SUMMARY

QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE

In June 1991, when the final Quality Management Program (QMP) and Misadministrations Rule (QM Rule), 10 CFR 35.32 and 35.33, was approved, the Commission directed the staff to assess the effectiveness of the QM Rule three years after the rule became effective, and provide recommendations on the need for a rulemaking on comprehensive quality management. This report responds to that directive.

The QM Rule became effective on January 27, 1992. The rule requires licensees that administer therapeutic quantities of byproduct material and diagnostic quantities of greater than 30 microcuries of radioactive sodium iodide to develop and implement a QMP to ensure that byproduct material or radiation from byproduct material is administered as directed by an authorized user. It requires that on, or before the effective date, each existing licensee, as applicable, submit a copy of its QMP and written certification that the program had been implemented to the appropriate U.S. Nuclear Regulatory Commission regional office.

A portion of the QM Rule, 10 CFR 35.32(a), requires licensees to establish and maintain a QMP that meets five objectives: (1) a written directive for each administration must be prepared, containing information specific to each modality (listed in 10 CFR 35.2, "Definitions"), dated and signed by an authorized user physician; (2) the patient or research subject's identity must be verified, using more than one method, as the individual named in the written directive; (3) final plans of treatment and related calculations must be in accordance with the written directive; (4) administration must be in accordance with the written directive; (5) any unintended deviation from the written directive must be identified and evaluated, and that appropriate action must be taken. Additional requirements are listed in 10 CFR 35.2, and in 35.32(b) through (f), including a requirement to develop procedures for and conduct a review of the QMP at intervals of no greater than 12 months.

In July 1993, Lawrence Livermore National Laboratory (LLNL) was contracted to review the licensee-submitted QMPs. Of the total, 2 percent of the submitted QMPs appeared to meet the requirements of 10 CFR 35.32; 16 percent appeared to meet the objectives, but appeared to have weaknesses; 72 percent of the submitted QMPs failed to fully meet one or more of the objectives; and ten percent acknowledged receipt of negative declaration letters stating they would not use the material until a QMP for that modality had been submitted.

On August 1, 1994, a revised Temporary Instruction (TI) (2800/025), "Quality Management Program and Misadministration Rule," (Attachment 4) became effective. The revised TI established areas of inspection and created a procedure for determining compliance with the QM Rule. This TI was in effect until August 1, 1996.

The number of TI Field Notes provided for data entry were 883, and the number of modalities represented on all submitted TIs was 1903. Since 235 modalities were inspected twice, the population for this analysis is 1668 modalities. This adjustment allows comparison between the results of the review of the written submittal and the implementation of the QMPs assessed during inspection.

The review of the TI found that 8 percent of inspected QMPs did not meet Objective 1. Most missed the Objective because the contents of the written directive did not meet the requirements in 10 CFR 35.2, "Definitions."

Three percent of inspected QMPs did not meet Objective 2. However, only 3 misadministrations reported to NRC since January 27, 1992, were caused by selection of the wrong patient. This compares favorably with the total of 11 misadministrations caused by administrations to the wrong patient for years

1989 and 1990.

Eleven percent of inspected QMPs failed to implement procedures to meet Objectives 3, and 9 percent of inspected QMPs did not meet Objective 4. One hundred and three of the misadministrations reported to NRC since January 27, 1992, involved a violation of either Objective 3 or 4.

For Objective 5, 18 percent of modalities did not implement procedures to meet the requirement. In addition, 12 percent of applicable licensees did not perform a review of their program within each 12-month period, and an additional 29% performed a 12-month review of their QMP that did not meet the requirements. The reason for this level of non-compliance is not clear.

There has not been a significant reduction in the total number of misadministrations, the performance indicator most closely linked to this issue due to changes in the requirements of what must be reported. While the number of reports of diagnostic misadministrations has been significantly reduced, the net number of therapy misadministrations remains at approximately 30 to 40 per year. However, the distribution of errors that led to misadministrations, per modality, has changed. For example, strontium-90 eye applicator events have increased significantly. An ongoing investigation involving eye applicators is expected to add at least two more misadministrations, each involving multiple patients, to the database.

The staff examined the relationship between routine inspection findings and reactive inspection findings associated with misadministrations. For those licensees who had a misadministration at some time since the rule became effective, only 29 percent had an inspection finding related to QMP implementation during their routine inspection. However, in 56 cases (45 percent of 138 misadministrations), the staff took enforcement actions related to some aspect of the QMP during the follow-up relating to the misadministration. Therefore, routine inspection findings are not necessarily predictors of the probability of the occurrence of a misadministration, and there is a better, although not a strong, correlation between the occurrence of a misadministration, and an inspection finding related to the QM program at the time of the event.

INTRODUCTION

The Quality Management Program (QMP) and Misadministrations Rule (QM Rule), 10 CFR 35.32 and 35.33, became effective on January 27, 1992. The rule required licensees that administer therapeutic quantities of byproduct material and diagnostic quantities of greater than 30 microcuries of radioactive sodium iodide to develop and implement a QMP to ensure that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. It required that on, or before the effective date, each existing licensee, as applicable, must submit a copy of their QMP and written certification that the program had been implemented to the appropriate U.S. Nuclear Regulatory Commission regional office.

The rule modified the notification, reporting, and record-keeping requirements related to misadministrations. In addition, the rule revised the definition for "misadministration" in 10 CFR 35.2, "Definitions," and distinguished between "misadministrations" and lesser "recordable events" for which reporting to the NRC is not necessary. This revision resulted in a greater than 10-fold reduction in the number of incidents that must be reported to NRC. Prior to this rule, errors in administration that met the, then, current misadministration criteria averaged more than 400 per year. This reduction resulted from two significant changes: (1) elevation of the reporting threshold for diagnostic misadministrations to 5 rem total effective dose equivalent and 50 rem effective dose equivalent to individual organs; and (2) essentially doubling the threshold for therapeutic misadministrations. The previous threshold (10 percent) became the threshold for a recordable event.

An additional modification was made to 10 CFR 35.25 "Supervision," which now requires supervised individuals to be instructed in the licensee's QMP, as appropriate to that individual's use of byproduct material.

A portion of the QM Rule, 10 CFR 35.32(a), requires licensees to establish and maintain a QMP that meets five objectives: (1) a written directive for each administration must be prepared, containing information specific to each modality (listed in 10 CFR 35.2, "Definitions"), dated and signed by an authorized user physician; (2) the patient or research subject's identity must be verified,using more than one method, as the individual named in the written directive; (3) final plans of treatment and related calculations must be in accordance with the written directive; (4) administration must be in accordance with the written directive; (5) any unintended deviation from the written directive must be identified and evaluated, and appropriate action taken. Additional requirements are listed in 10 CFR 35.2, and in 35.32(b) through (f), including a requirement to develop procedures for and conduct a review of the QMP at intervals of no greater than 12 months.

The rule requires licensees to submit their written QMPs to NRC for review. However, NRC made a decision before the rule was promulgated, not to add the specific QMP to the license as a license condition referencing a licensee submitted document (i.e., "tie-down" condition). This allows the licensee the flexibility to make modifications to the QMP as the licensee deems necessary, consistent with 10 CFR 35.32(e).

In June 1991, when the final QM Rule was approved, the Commission directed the staff to assess the effectiveness of the Quality Management Program and Misadministrations rule (QM Rule) three years after the rule became effective, and provide recommendations on the need for a rulemaking on comprehensive quality management. This report responds to that directive.

HISTORY

On October 2, 1987, NRC published a proposed prescriptive rule on quality assurance (QA) as directed by the Commission. Its objective was to reduce the number of errors in therapeutic administrations of radiopharmaceuticals or radiation from byproduct material and the administration of radioactive iodine. Public comments on the proposed rule indicated that the imposition of prescriptive requirements would interfere with the practice of medicine, because it did not afford sufficient flexibility for clinical practice. NRC's Advisory Committee on Medical Uses of Isotopes suggested that a performance-based rule should be promulgated, rather than a prescriptive rule. On June 3, 1988, the Commission directed the staff to develop a performance-based rule and regulatory guide, conduct a pilot program, and review and possibly revise the definition of a misadministration.

The proposed rule, published on January 16, 1990, contained amendments that would require Part 35 licensees to establish and implement a basic QA program. In addition, it provided modifications to the definition for "misadministration" and the associated reporting and record-keeping requirements.

In 1990, NRC conducted a pilot program to provide a "real-world" test of the proposed rule in licensee hospitals and clinics. Five 1-day workshops were held, one in each NRC region, to explain the over-all process for the pilot program and to discuss the proposed rule and draft guidance. Sixty-four institutions participated in the pilot study, 23 NRC and 41 Agreement State licensees. Following the workshops, licensees developed a QA program following the objectives proposed, and implemented the programs for 60 days. During the 60 days, NRC reviewed all of the written QA programs, and visited 18 of the implemented programs. At the end of the pilot program, five 2-day workshops were held to discuss problems with and recommendations for the proposed rule. The findings of the pilot program supported developing a performance-based rule. In addition, the findings suggested that QA programs, as implemented, were found to be more complete than applicable written programs. Most findings of the pilot were adopted in developing the final rule. A report on the pilot program was published with the final rule.

The final rule was published on July 25, 1991, to be effective on January 27, 1992. It contained numerous substantive changes as compared to the proposed rule. The most significant changes included:

0.A change in the name of the rule from "quality assurance" to "quality management," to avoid confusion or interference with the thousands of existing, hospital-wide, QA programs.

1. Elevation in the threshold for diagnostic misadministrations to 5 REM TEDE and 50 REM effective organ dose.

2. Changes in the definitions (10 CFR 35.2) for misadministrations for all modalities of medical use.

On December 24, 1991, NRC submitted an information collection requirements (ICR) approval request to the Office of Management and Budget (OMB), for the QM Rule which would be effective in January 1992. In communications with OMB, the American College of Nuclear Physicians and Society of Nuclear Medicine (ACNP/SNM) expressed strong opposition to the rule. In June 1992, OMB disapproved the record collection requirements of the rule. The NRC Commissioners, finding that public health and safety warranted institution of the ICR, overrode the OMB determination.

In an additional action, in February 1992, the ACNP/SNM filed a petition for review of the rulemaking, with the U.S. Court of Appeals in Washington, DC in American College of Nuclear Physicians and Society of Nuclear Medicine v. U.S. Nuclear Regulatory Commission. Only ten days after hearing arguments in the case, the court ruled in favor of the NRC, declaring that it saw "no need for a published opinion." 976 F.2d 45 (D.C. Cir. 1992)(Table). The court stated:

> On the record before us, we find no basis to overturn the QM Rule; accordingly, the petition for review is hereby denied, substantially for the reasons stated by the NRC in its rulemaking. The NRC, in promulgating the QM Rule, acted within the bounds of its broad statutory mandate to establish "such standards ... as the Commission may deem necessary or desirable to ... protect health or to minimize danger to life and property." 42 U.S.C. 2201(b) (West Supp. 1992) (emphasis added). Moreover, the substantive requirements imposed by the QM Rule are not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. 706(A) (1988).

In response to ACNP concerns, NRC held a public meeting on November 9, 1992, to meet publicly with the medical community and other interested paries to ensure a mutual understanding of the intent of the QM Rule, and to clarify the information collection requirements associated with the rule. As part of the meeting, the ACNP provided a presentation about its self-auditing guidelines.

In a letter dated November 28, 1995, in response to NRC's 1995 application to OMB for renewal of approval for the ICR associated with the QM Rule, the ACNP/SNM again requested that OMB disapprove the ICR associated with 10 CFR 35.32 and 35.33. The staff addressed the ACNP/SNM's concerns as part of its submission to OMB requesting continued authorization for the ICR. Subsequently, in February 1996, OMB approved the ICR for a 1-year period.

REVIEW OF WRITTEN QMPS

CONTRACTUAL SUPPORT FOR REVIEW OF SUBMITTED QMPS

In June 1992, proposals were sought to obtain contractor support to assist the staff in reviewing the submitted QMPs. The effort included a combination of: performing reviews of the approximately 1700 QMPs submitted by the licensees; preparing letters to licensees that pointed out weaknesses and/or omissions in the submitted QMPs, and preparing a letter to each licensee describing the findings of the individual review. In addition, the contract required the contractor to conduct a "pilot" program to compare the submitted written QMP with the implemented QMP in 10 applicable licensees' facilities. Lawrence Livermore National Laboratory (LLNL) was the only one to provide a proposal; it was awarded the contract in July 1993.

In September 1993, LLNL and NRC completed the "pilot" program that compared submitted written QMPs with the implemented QMPs in a small sample of licensees' facilities. Ten programs were selected based on location (Regions I and III) and inspection cycle (inspections due). An inspection team, consisting of regional inspectors, the QM coordinator from NRC's Headquarters, and the contractor, visited each facility to review the programs. In 9 of the 10 facilities visited, the implemented programs were found to better meet the requirements of the QM Rule than those of the submitted written programs. However, in the 1 case, a "broad-scope" licensee, the written program did not meet the five objectives listed in the rule, nor was an adequate program implemented. This limited sampling reinforced the staff's belief that many licensees implemented more complete programs than were documented in their submitted QMPs. This finding supported similar results from the earlier pilot program NRC conducted to provide a real world test of the proposed rule (findings published with final rule, July 25, 1991).

The 1993 NRC/LLNL pilot program also provided an opportunity for the staff, along with the contractor, to evaluate the procedures used by NRC inspectors in evaluating licensees' implementation of their QMP.

Review of NRC Licensee's Submitted QMP

A standard review plan (SRP) and checklist for the review of written QMPs were developed by the staff (Attachment 1). The information contained in Regulatory Guide 8.33, "Quality Management Program" (Attachment 2) was used as a general guideline in developing these review documents. The actual reviews were conducted by LLNL staff and physicians, medical physicists, dosimetrists, and technologists on the medical staff at the University of California, San Francisco Medical Center. LLNL maintained a database of findings, and generated draft letters to licensees that conveyed the findings of the review to NRC's regional staff.

Communication of Review Findings to Licensees

In April 1994, LLNL began providing the NRC regional offices with draft letters, addressed to licensees, outlining LLNL's findings from the review of the licensees' QMPs. Regional staff finalized and dispatched the letters to the licensees.

The letters were divided into four categories.

Type 1: QMP appears to meet the requirements of 10 CFR 35.32;
Type 2: QMP inadequate due to omissions or weaknesses in the program;
Type 3: Written QMP failed to meet at least one of the objectives;
Type 4: A response letter to those facilities that had submitted a negative declaration (applicable material was not in use at their facility).

The total number of letters sent to licensees was 1709. The types of letters included: 2 percent of the submitted QMPs appeared to meet the requirements of 10 CFR 35.32; 16 percent appeared to meet the objectives, but appeared to have weaknesses; 72 percent of the submitted QMPs failed to fully meet one or more of the objectives; and ten percent acknowledged receipt of negative declaration letters stating they would not use the material until a QMP for that modality had been submitted. Table 1: "Results Summary - All Regions," (Attachment 3) outlines the LLNL findings for each modality of use.

LLNL provided the following "brief summary" of the findings of the review of the originally submitted written QMPs:

Average percentages of missing any aspects of the objectives and other requirements:

Objective 1:	83%
Objective 2:	4%
Objective 3:	64%
Objective 4:	39%
Objective 5:	57%
Recordable Events:	70%
Annual Review:	93%

INSPECTION OF IMPLEMENTED QMPS:

On August 1, 1994, a revised Temporary Instruction (TI) (2800/025) "Quality Management Program and Misadministration Rule," became effective. The revised TI established areas of inspection and created a procedure for determining compliance with the rule. The inspection emphasis for this TI was directed at the licensee's implemented program for: 1) assuring that administration of applicable material was as directed by a physician authorized user, and 2) identification, evaluation, and correction of deficiencies to prevent recurrence. Inspectors were instructed to include inspection of QM programs with all routine inspections of applicable facilities. This TI was in effect until August 1, 1996.

Data, collected through the TI Field Notes, were saved for analysis to determine the effectiveness of the QM Rule, and to aid the staff in responding to the Commission's directive to analyze the implementation of the QM Rule three years after the effective date.

The NRC staff has conducted an analysis of the QMP data, collected by several NRC Offices, from February 1, 1992, to August 1, 1996. Databases used in the analysis of this data included: the LLNL database of written QMP data; the TI inspection database; the Licensing Tracking System; the Inspection Follow-up System; The Office of Enforcement Database; and the Nuclear Materials Event Database. The databases were managed using "Access," an off-the-shelf, relational database management system made by Microsoft Corporation.

There may be discrepancies observed in the data used in the analysis of misadministrations and enforcement actions when compared with some other NRC data collections. This discrepancy exists because criteria for data collected in the various databases differ, based on the needs of the various end-users.

The number of TI Field Notes provided for data entry was 883, and the number of modalities represented on all submitted TIs was 1903. Since certain modalities are inspected on a 1-year frequency, 235 modalities were inspected twice. Nine of the 235 QMPs that were previously inspected failed to meet an objective or requirement that they had met on the first inspection. Fifty-seven of the 235 QMPs that had been previously inspected showed improvement. Specific findings of these second inspections were not included in the analysis. Therefore, the population for this analysis is 1668 modalities. This adjustment allows comparison between the results of the LLNL review of the written submittal, and the implementation of the QMPs assessed during inspection.

In addition, LLNL had not reviewed the written QMPs of 58 of the inspected QMPs, representing 382 modalities. Reasons why these QMPs were not included in the LLNL review in 1993 include: new licenses that were subsequently issued, the addition of modalities to a license that did not previously require a QMP, and files missing from the regional file storage area because of licensing, inspection, and/or enforcement actions. QMPs that were not reviewed by LLNL were reviewed by NRC staff, using the same QM Standard Review Plan.

INSPECTION FINDINGS:

Licensee's QMPs must include written policies and procedures to meet the following objectives that are listed in 10 CFR 35.32(a). Since this requirement is performance-based, licensees may follow the suggestions for procedures that are contained in Regulatory Guide 8.33, "Quality Management Program" (Attachment 2), or implement their own procedures.

Objective 1: A written directive for each administration must be prepared, containing information specific to each modality (listed in 10 CFR 35.2, "Definitions"), dated and signed by an authorized user physician.

The percentage of licensees that did not implement procedures which met Objective 1 was:

Sodium Iodide >30 microcuries	6%
Radiopharmaceutical therapy	10%
High-Dose-Rate Afterloading Brachytherapy	6%
Brachytherapy	4%
Strontium-90 eye Applicators	16%
Teletherapy	15%
Gamma StereoTactic Radiosurgery	0

Teletherapy and Strontium-90 Eye Applicators failures appear high because of the small number of TIs (and licensees) for this modality.

Objective 2: The patient or research subject's identity must be verified using more than one method, as the individual named in the written directive.

The percentage of licensees that did not implement procedures which met Objective 2 was:

Sodium Iodide >30 microcuries	1%
Radiopharmaceutical therapy	7%
High-Dose-Rate Afterloading Brachytherapy	2%
Brachytherapy	.4%
Strontium-90 eye Applicators	0
Teletherapy	3%
Gamma StereoTactic Radiosurgery	0

Objective 3: That final plans of treatment and related calculations are in accordance with the written directive.

Licensees that did not implement procedures which met Objective 3:

Sodium Iodide >30 microcuries	Not applicable
Radiopharmaceutical therapy	Not applicable
High-Dose-Rate Afterloading Brachytherapy	3%
Brachytherapy	5%
Strontium-90 eye Applicators	14%
Teletherapy	41%
Gamma StereoTactic Radiosurgery	(1 of 4 did not meet)

Objective 4: That administration is in accordance with the written directive.

Licensees that did not implement procedures which met Objective 4:

Sodium Iodide >30 microcuries	7%
Radiopharmaceutical therapy	11%
High-Dose-Rate Afterloading Brachytherapy	6%
Brachytherapy	5%
Strontium-90 ye Applicators	18%
Teletherapy	14%
Gamma StereoTactic Radiosurgery	(1 of 4 did not meet)

Objective 5: That any unintended deviation from the written directive is identified and evaluated, and that appropriate action is taken.

Licensees that did not implement procedures which met Objective 5:

Sodium Iodide >30 microcuries	16%
Radiopharmaceutical therapy	21%
High-Dose-Rate Afterloading Brachytherapy	20%
Brachytherapy	13%
Strontium-90 ye Applicators	22%
Teletherapy	15%
Gamma StereoTactic Radiosurgery	(1 of 4 did not meet)

The review of the TI found that, for a total of all modalities, the percentage of objectives or requirements that were not met included:

Seven percent of inspected QMPs did not meet Objective 1. Most missed the Objective because the contents of the written directive did not meet the requirements in 10 CFR 35.2, "Definitions."

Three percent of inspected QMPs did not meet Objective 2. However, only 3 misadministrations reported to NRC since January 27, 1992, were caused by selection of the wrong patient. This compares favorably with the total of 11 misadministrations caused by administrations to the wrong patient for years 1989 and 1990.

Eleven percent of inspected QMPs failed to implement procedures to meet Objectives 3, and 9 percent of inspected QMPs did not meet Objective 4. One

hundred and three of the misadministrations reported to NRC since January 27, 1992, involved violations of Objectives 3 or 4.

For Objective 5, 18 percent of modalities did not implement procedures to meet the requirements. In addition, 12 percent of applicable licensees did not perform a review of their programs within each 12-month period, and an additional 29 percent performed 12-month reviews of their QMPs that did not meet the requirements. The reason for this level of non-compliance is not clear. Page 63 contains a table of the inspection findings which clarifies this data.

Comparison of Inspection of Implemented QMPs with Reviewed Written QMPs:

Drawing from the same population of inspected licensees, the following are percentages of implemented QMPs that missed objectives or requirements, compared with written QMPs as reviewed by LLNL:

	TI	LLNL
Objective 1	8%	41%
Objective 2	3%	36%
Objective 3	11%	60%
Objective 4	9%	37%
Objective 5	18%	50%
12 mo. review of QMP	29%	43%

The table above demonstrates that licensees appear to implement QMP that more closely meet the requirements in the rule then do their written QMP. A total of 883 licensees, representing 1668 modalities, were inspected during the two years the TI was in effect. Seventy-seven percent (1286) of the inspected QMPs had previously been reviewed by Lawrence Livermore National Laboratories (LLNL) during the initial review of written submittals. During inspection, the implemented QMP was compared to the requirements in the rule, rather than to the submitted written QMP. Review of inspections findings for licensees' QMPs indicates that 43 percent of the QMPs failed to meet all of the objectives of the rule.

MISADMINISTRATIONS AND EVENTS:

Since the January 1992 effective date of the QM Rule, there have been 138 misadministrations that met the criteria described in 10 CFR 35.2, "Definitions," involving one hundred and twenty-five NRC licensees, reported to NRC. The majority of the errors involved brachytherapy procedures (40 manual and 18 High-Dose-Rate); followed by administrations of greater than 30 microcuries sodium iodine (28); teletherapy (23); radiopharmaceutical therapy (12); and strontium-90 eye applications (4). Some of these incidents involved multiple patients.

The most frequent causes of the misadministrations reported to NRC since January 27, 1992, were as follows:

26 involved incorrect data entry and calculation errors,
23 involved wrong source, radiopharmaceutical, or dose (quantity),
18 involved the wrong treatment site,
10 involved source migration/dislodgement,
6 involved failure to administer the entire dose or dosage (the source or dosage (capsule) was left in the pig or tandem),

In addition, there were 14 incidents involving patient intervention/source migration. The QM Rule is silent on patient intervention. However, this issue has been viewed by the staff as a mitigating factor in determining if events are, in fact, misadministrations. This is consistent with the 10 CFR Part 35 "Statements of Consideration" regarding misadministrations which state that the "purpose in requiring misadministration reports to NRC is to identify their causes in order to correct them and prevent their recurrence. The Commission can do this by notifying other licensees if there is a possibility that they could make the same errors." The staff has reviewed these events on a case-by-case basis. A small number of such incidents were found not to be misadministrations. A table describing each misadministration is provided in Attachment 5.

The staff examined the relationship between routine inspection findings, and reactive inspection findings associated with misadministrations. For those licensees who had a misadministration at some time since the rule became effective, only 29 percent had an inspection finding related to QMP implementation during their routine inspection. However, in 56 cases (45 percent of 138 misadministrations), the staff took enforcement actions related to some aspect of the QMP during the follow-up relating to the misadministration. Therefore, routine inspection findings are not necessarily predictors of the probability of the occurrence of a misadministration, and there is a better, although not a strong, correlation between the occurrence of a misadministration and an inspection finding related to the QM program at the time of the event.

Based on the data collected, there were at least 125 recordable events identified for the 883 licensees for the two years the TI was in effect. Since licensees were not required to report to NRC, nor to extensively document these events, the actual number of such events was not requested. Therefore, the actual number of recordable events is not known.

ENFORCEMENT

From March to November 1993, an NRC Quality Management Committee met weekly to review all potential violations associated with the QM Rule, including those resulting from misadministrations. The committee consisted of representatives from the Office of Enforcement (OE), Nuclear Material Safety and Safeguards, the affected region, and the NRC Medical Visiting Fellow. The Committee review was intended to ensure uniformity in the issuance of all Notices of Violation and assignment of severity levels. This review was truncated since guidelines for consistent imposition of enforcement sanctions seemed to be functioning properly and the various NRC regions were imposing a uniform enforcement approach to violations of the QM rule.

Since the effective date of the QM Rule, OE has taken enforcement actions for 56 misadministrations, resulting in 3 Severity Level I violations, 4 severity Level II violations, 36 Severity Level III violations, and 7 Severity Level IV violations. The 6 remaining enforcement actions had not been assigned a Severity Level. A table, identifying the misadministrations, by modality, that resulted in enforcement actions, and identifying the Severity Levels, is provided on page 64. In addition, details of these misadministrations are included in Attachment 5.

SUMMARY/CONCLUSION

In summary, comparison of the implementation of the QMP as reviewed during inspection, with the written QMP (as reviewed by Lawrence Livermore National Laboratory) reveals that overall, the implemented programs met the QM Rule objectives more often than the written programs. However, review of inspections findings for licensees' QMPs indicates that a total of 43 percent of the QMPs failed to meet all of the objectives of the rule.

There has not been a significant reduction in the total number of reported misadministrations, the performance indicator most closely linked to this issue. While the number of reports of diagnostic misadministrations has been significantly reduced due to changes in the requirements of what must be reported, the net number of reported therapy misadministrations remains at approximately 30 to 40 per year. However, the distribution of errors that led to misadministrations, per modality, has changed. For example, strontium-90 eye applicator events have increased significantly. An ongoing investigation involving eye applicators is expected to add at least two more misadministrations, each involving multiple patients, to the database.

The staff examined the relationship between routine inspection findings and reactive inspection findings associated with misadministrations. For those licensees who had a misadministration at some time since the rule became effective, only 29 percent had an inspection finding related to QMP implementation during their routine inspection. However, in 56 cases (45 percent of 138 misadministrations), the staff took enforcement actions related to some aspect of the QMP during the follow-up relating to the misadministration. Therefore, routine inspection findings are not necessarily predictors of the probability of the occurrence of a misadministration, and there is a better, although not a strong, correlation between the occurrence of a misadministration and an inspection finding of a weakness in the QM program at the time of the event.

In 1991, the causes of misadministrations and/or abnormal occurrences were characterized in the Statements of Consideration, published with the final rule, as: insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail, and inadequate training. Since the QM Rule became effective, these same causes of events appear to persist. However, most of the current errors that led to misadministrations can be attributed to two of the causes: inattention to detail and failure to follow procedures, both of which may be viewed as "human errors" as contrasted to "mechanical errors." The most frequent causes of the misadministrations reported to NRC since January 27, 1992, were as follows:

26 involved incorrect data entry and calculation errors,
23 involved wrong source, radiopharmaceutical, or dose (quantity),
18 involved the wrong treatment site,
10 involved source migration/dislodgement,
6 involved failure to administer the entire dose or dosage (the source or dosage (capsule) was left in the pig or tandem).

Many of the above errors that led to misadministrations could have been prevented by: (1) redundantly checking the data entry and calculations (QM Objective 3), or (2) immediately before administering the dose or dosage, comparing that which was to be administered to the written directive (QM Objective 4). Thus, with the exception of equipment failures and certain source migration/dislodgement events, it would appear that more complete adherence to meeting the objectives in the QM Rule should reduce the likelihood of a misadministration.

Although the QM Rule, which was intended to ensure that byproduct material or radiation from byproduct material would be administered as directed by a physician authorized user, appears to have been generally successful from a programmatic standpoint, the staff has identified certain areas of concern. Specifically, significant percentages of licensees did not implement all aspects of the rule (refer to page 63). Particularly noteworthy were the findings associated with the requirement to conduct an adequate review of the QMP at 12-month intervals.

In addition, there were at least 125 recordable events identified for the 883 licensees during the two years the TI was in effect. Twelve percent (11) of the 92 recordable events self-identified by licensees were not evaluated, nor were appropriate corrective actions implemented. Since approximately 25 percent of the inspected licensees did not perform adequate reviews of their administrations within each 12 month period, and therefore, may not have identified such recordable events, the actual number may be much greater.

REVIEW FINDINGS

The following 48 pages contain a synopsis of the QM inspection findings. It is divided into modalities of use, and each modality compares the inspection findings to the LLNL review of the written QMP for those licensees.

GREATER THAN 30 MICROCURIES NaI I-125 or I-131

Inspection of Implemented QMPs:

Seven hundred and thirty sets of sodium iodide I-125 or I-131 TI field notes were entered into the database. Sixty-four of these had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 666.

Review of Written QMPs:

During the contracted review of the initially submitted written QMPs, LLNL reviewed 1568 sodium iodide I-125 or I-131 QMPs. However, only 491 of the 666 implemented QMPs inspected had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 666 licensees, over a 2-year period, was 39,819. For sodium iodide I-125 or I-131, there will *usually* be one written directive per administration.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for administration of greater than 30 microcuries of sodium iodide I-125 or I-131 must include the dosage.

TI Review Findings:

On inspection, 37 of 666 licensees failed to meet Objective 1 in that:

37 licensees did not consistently prepare written directives.
15 licensees did not include all necessary information on the written directive.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

9 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

10 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

18 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

7 licensees failed to meet Objective 2 in that, they did not implement procedures to redundantly identify patients and/or human research subjects.

LLNL Findings:

1 licensee had written procedures that met Objective 2, as reviewed by LLNL, but apparently did not implement them.

1 licensee, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

5 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 46 of 666 licensees who administered greater than 30 microcuries of sodium iodide I-125 or I-131, failed to meet Objective 4.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

7 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

25 licensees, who did not meet the objective upon inspection, did not meet the objective in their written QMP.

14 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Dosage Measured Prior to Administration**:

   TI Review Findings:
   12 licensees did not implement a procedure to assess the quantity of byproduct material in the prepared dosage prior to administration.

   LLNL Review Findings:
   5 licensees, who did not meet the objective upon inspection, did not meet the objective in their written QMP.
   7 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Dosage Confirmed Just Prior to Administration**:

   TI Review Findings:
   35 licensees did not implement procedures to confirm that the dosage matched the applicable written directive prior to administration.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 109 of 666 licensees who administered greater than 30 microcuries of sodium iodide I-125 or I-131, failed to meet Objective 5.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

16 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

59 licensees, who did not meet the objective upon inspection, did not meet the objective in their written QMP.

34 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:

   13 licensees did not implement procedures to maintain records of administration in an auditable form.

   LLNL Review Findings:
   2 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   4 licensees, who did not meet the objective upon inspection, did not meet the objective in their written QMP.

   7 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Procedures Implemented to Identify "Unintended Deviations"**:

   25 licensees did not implement procedures to identify unintended deviations from the written directive.

3. **Procedures to Evaluate and Respond to Recordable Events and Misadministrations Within 30 Days of Discovery**:

   TI Review Findings:
   96 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

   LLNL Review Findings:
   21 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   45 licensees did not meet the objective for their written or implemented QMP.

30 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures implemented to gather the relevant facts and to identify and implement corrective action to prevent recurrence:

TI Review Findings:
39 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

166 licensees (20%) did not implement procedures that met the requirement.

Expand the Review If Events Are Identified:
166 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.
Determine Effectiveness:
134 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.
Recordable Events:
46 recordable events were self-identified by the license since the last inspection.
16 previously unidentified recordable events were identified by the inspector during the inspection of the licensee's implemented QMP.
Misadministrations:
8 misadministrations were reported to NRC by the license since the last inspection.
1 licensee identified a misadministration that was not subsequently reported to NRC.

LLNL Review Findings:

72 licensees had written procedures to perform a review of the QMP, as reviewed by LLNL, but apparently did not implement them.

45 licensee's QMP did not include procedures to review the QMP.

49 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

RADIOPHARMACEUTICAL THERAPY

Inspection of Implemented QMP:

Five hundred and forty-eight sets of radiopharmaceutical therapy TI field notes were entered into the database. Sixty-one of these had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 487 (548-61).

Review of Written QMP:

During the contracted review of the initially submitted written QMPs, LLNL reviewed 1019 radiopharmaceutical therapy QMPs. However, only 418 of the 487 implemented QMPs inspected, had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 487 licensees, over a 2-year period, was 4,992. For radiopharmaceutical therapy, there will *usually* be one written directive per administration.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for radiopharmaceutical therapy must include: the radiopharmaceutical, the dosage, and the route of administration.

TI Review Findings:

On inspection, 48 of 487 licensees failed to meet Objective 1 in that:

40 licensees did not consistently prepare written directives.
48 licensees did not include all necessary information on the written directive.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

8 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

28 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

12 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

32 licensees failed to meet Objective 2 in that, they did not implement procedures to redundantly identify patients and/or human research subjects.

LLNL Findings:

19 licensee had written procedures that met Objective 2, as reviewed by LLNL, but apparently did not implement them.

4 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

9 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 53 of 487 radiopharmaceutical therapy licensees, failed to meet Objective 4.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

23 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

15 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

15 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Dosage Measured Prior to Administration**:

   TI Review Findings:
   59 licensees did not implement a procedure to assess the quantity of byproduct material in the prepared dosage prior to administration.

   LLNL Review Findings:
   24 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.
   24 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

11 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Dosage Confirmed Just Prior to Administration**:

TI Review Findings:
49 licensees did not implement procedures to confirm that the dosage matched the applicable written directive prior to administration.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 100 of 487 radiopharmaceutical therapy licensees failed to meet Objective 5.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

74 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

9 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

17 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
34 licensees did not implement procedures to maintain records of administration in an auditable form.

LLNL Review Findings:
25 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

9 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Procedures Implemented to Identify "Unintended Deviations"**:

38 licensees did not implement procedures to identify unintended deviations from the written directive.

3. **Procedures to Evaluate and Respond to Recordable Events and Misadministrations Within 30 Days of Discovery**:

TI Review Findings:
89 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

LLNL Review Findings:
61 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

13 licensees did not meet the objective for their written or implemented QMP.

15 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures implemented to gather the relevant facts and to identify and implement corrective action to prevent recurrence:

TI Review Findings:
57 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

155 licensees did not implement procedures that met the requirement:

Expand the Review If Events Are Identified:
155 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.
Determine effectiveness:
25 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.
Recordable Events:
22 recordable events were self-identified by the license since the last inspection.
8 previously unidentified recordable events were identified by the inspector during the inspection of the licensee's implemented QMP.
Misadministrations:
1 misadministration was reported to NRC by the license since the last inspection.
3 licensees identified misadministrations that were not subsequently reported to NRC.

LLNL Review Findings:

55 licensees had written procedures to perform a review of the QMP, as reviewed by LLNL, but apparently did not implement them.

76 licensee's QMPs did not include procedures to review the QMP.

24 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

HIGH DOSE RATE (HDR) BRACHYTHERAPY

Inspection of Implemented QMP:

One hundred and fifty-six sets of HDR TI field notes were entered into the database. Forty-six of these had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 109 (156-47).

Review of Written QMP:

During the contracted review of the initially submitted written QMPs, LLNL reviewed 101 HDR QMPs. However, only 82 of the 109 implemented QMPs inspected, had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 109 licensees, over a 2-year period, was 10,000. For HDR, there may be one written directive, ordering a dose in multiple fractions. Therefore, it is not possible to ascertain the number of administrations.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for HDR must include:

the radioisotope, the treatment site, and the total dose.

TI Review Findings:

On inspection, 7 of 109 HDR licensees failed to meet Objective 1 in that:

3 licensees did not consistently prepare written directives.

6 licensees did not include all necessary information on the written directive.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

2 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

4 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

1 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

2 brachytherapy licensees failed to meet Objective 2 in that, they did not implement procedures to redundantly identify patients and/or human research subjects.

LLNL Findings:

1 licensee, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

1 licensee's QMP had not been initially reviewed by LLNL.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive. Since acceptance testing of new and/or repaired equipment is not specifically required, licensees who did not have procedures for acceptance testing, but implemented other applicable procedures, met the objective.

TI Review Findings:

On inspection, 3 of 109 HDR licensees failed to meet Objective 3.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

1 licensee, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

2 licensee's initially submitted QMP was apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Check of Calculations**:
   Perform a check of the treatment calculations (whenever possible by another qualified individual) before beginning treatment.

   TI Review Findings:

   2 licensees did not implement procedures to check calculations before beginning treatment.

   LLNL Review Findings:

   2 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Acceptance Testing**:

   Perform an acceptance test on new or repaired equipment.

   TI Review Findings:

   9 licensees do not implement procedures to acceptance test new or repaired equipment.

   LLNL Review Findings:

   7 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   2 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 7 of 109 HDR licensees failed to meet Objective 4.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

5 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

2 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Treatment Plan**:
   A plan of treatment is prepared in accordance with the written directive.

   TI Review Findings:

   2 licensees did not implement procedure to prepare a treatment plan that was in accordance with the written directive.

   LLNL Review Findings:

   1 licensee, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

   1 licensee's initially submitted QMP was apparently not reviewed by LLNL.

2. **Confirm Parameters of Administration**:

   TI Review Findings:

   3 licensees did not implement procedures to confirm the prescribed radioisotope, treatment site, and total dose before administration.

   LLNL Review Findings:

   2 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   1 licensee's initially submitted QMP was apparently not reviewed by LLNL.

3. **Dwell Times and Positions Verified**:

   3 licensees did not implement procedures to verify dwell times and positions prior to the start of the treatment.

4. **Use of Dummy Sources or Fixed Geometry Applicators**:

   3 licensees did not implement procedures to verify the source positioning, within the treatment site, using dummy sources or fixed geometry applicators before inserting the radioactive sealed sources.

5. **Prompt Recording of Treatment Parameters**:

   5 licensees did not implement procedures for the prompt recording of the treatment parameters, and signing or initialing by the authorized user, in the patient's chart or record.

   LLNL Review Findings:

   4 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

   1 licensee's initially submitted QMP was apparently not reviewed by LLNL.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

TI Review Findings:

On inspection, 22 of 109 HDR licensees failed to meet Objective 5:

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

9 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

6 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

7 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
   2 licensees did not implement procedures to maintain records of administration in an auditable form.

2. **Procedures Implemented to Identify "Unintended Deviations"**:

   4 licensees did not implement procedures to identify unintended deviations from the written directive.

3. **Procedures to Evaluate and Respond to Recordable events and Misadministrations Within 30 Days of Discovery**:

   TI Review Findings:

   22 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

   LLNL Review Findings:

   9 licensee had written procedures, as reviewed by LLNL, but apparently did not implement them.

   6 licensees did not meet the objective for their written or implemented QMP.

   7 licensees' initially submitted QMPs were apparently not reviewed by LLNL.

4. **Procedures Implemented to Gather the Relevant Facts and To Identify and Implement Corrective Action to Prevent Recurrence**:

   TI Review Findings:

   8 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

25 licensees did not implement procedures that met the requirement:

Expand the Review if Events Are Identified:
25 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.
Determine Effectiveness:
7 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.
Recordable Events:
7 recordable events were self-identified by the license since the last inspection.
2 previously unidentified recordable events were identified by the inspector during the inspection of the licensee's implemented QMP.
Misadministrations:
1 misadministration was reported to NRC by the license since the last inspection.

LLNL Review Findings:

10 licensees had written procedures to perform a review of the QMP, as reviewed by LLNL, but apparently did not implement them.

8 licensee's QMP did not include procedures to review the QMP.

7 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

BRACHYTHERAPY

Inspection of Implemented QMP:

Three hundred and eleven sets of brachytherapy TI field notes were entered into the database. Forty-five of these had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 266 (311-45).

Review of Written QMP:

During the contracted review of the initially submitted written QMPs, LLNL reviewed 520 brachytherapy QMPs. However, only 230 of the 266 implemented QMPs inspected, had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 266 licensees, over a 2-year period, was 8,499.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for brachytherapy must include:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and
(ii) 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).

TI Review Findings:

On inspection, 11 of 266 brachytherapy licensees failed to meet Objective 1 in that:

2 licensees did not consistently prepare written directives.

9 licensees did not include all necessary information on the written directive.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

5 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

4 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

1 licensee's initially submitted QMP was apparently not reviewed by LLNL.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

1 brachytherapy licensee failed to meet Objective 2 in that, they did not implement procedures to redundantly identify patients and/or human research subjects.

LLNL Findings:

The licensee, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive. Since acceptance testing of new and/or repaired equipment is not specifically required, licensees who did not have procedures for acceptance testing, but implemented other applicable procedures, met the objective.

TI Review Findings:

On inspection, 14 of 266 brachytherapy licensees failed to meet Objective 3.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

3 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

7 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Preparation of Treatment Plans**:
   A plan of treatment is prepared in accordance with the written directive.

   TI Review Findings:

   4 licensees did not implement a procedure to assure that a treatment plan was prepared.

   LLNL Review Findings:

   2 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   2 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

2. **Check of Calculations**:

   Perform a check of the treatment calculations (whenever possible by another qualified individual) before beginning treatment.

   TI Review Findings:

   11 licensees did not implement procedures to check calculations.

   LLNL Review Findings:

   7 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

2. **Acceptance Testing**:

   Perform an acceptance test on new or repaired equipment.

   TI Review Findings:

   17 licensees do not implement procedures to acceptance test new or repaired equipment.

   LLNL Review Findings:

   9 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   4 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

   4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 13 of 266 brachytherapy licensees failed to meet Objective 4.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

5 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

5 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

3 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Confirmation of Treatment Plans**:
Licensees implements a procedure that required the person administering treatment to confirm the prescribed radioisotope, the number of sources, the source strengths, the treatment site, the loading sequence, and total dose.

   TI Review Findings:

   1 licensee did not implement procedures to confirm treatment plans.

   LLNL Review Findings:

   The licensee had written procedures, as reviewed by LLNL, but apparently did not implement them.

   Confirm Administration Parameters:

   Licensees implements procedures that required prompt recording of the number of sources, the actual loading sequence of sources implanted (location of each sealed source in a tube, tandem, or cylinder), and signing or initialing the patient's chart or appropriate record.

   TI Review Findings:

   13 licensees did not implement these procedures to confirm administration parameters.

3. **Prompt Recording of Treatment Parameters**:

   TI Review Findings:

   7 licensees did not implement procedures for the prompt recording of the treatment parameters, and signing or initialing in the patient's chart or record.

   LLNL Review Findings:

   2 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   2 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

   3 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 35 of 266 brachytherapy licensees failed to meet Objective 5:

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

10 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

22 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

3 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
   2 licensees did not implement procedures to maintain records of administration in an auditable form.

   Procedures Implemented to Identify "Unintended Deviations":

   2 licensees did not implement procedures to identify unintended deviations from the written directive.

2. **Procedures to Evaluate and Respond to Recordable Events and Misadministrations Within 30 Days of Discovery:**

   TI Review Findings:

   31 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

   LLNL Review Findings:

   10 licensee had written procedures, but apparently did not implement them.

   19 licensees did not meet the objective for their written or implemented QMP.

   2 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

3. **Procedures Implemented to Gather the Relevant Facts and to Identify and Implement Corrective Action to Prevent Recurrence**:

   TI Review Findings:

   15 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

65 licensees did not implement procedures that met the requirement:

Expand the Review If Events Are Identified:
65 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.
Determine Effectiveness:
7 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.
Recordable Events:
13 recordable events were self-identified by the license since the last inspection.
3 previously unidentified recordable events were identified by the inspector during the inspection of the licensee's implemented QMP.
Misadministrations:
2 misadministrations were reported to NRC by the license since the last inspection.
2 licensees identified misadministrations that were not subsequently reported to NRC.

LLNL Review Findings:

33 licensees had written procedures to perform a review of the QMP, but apparently did not implement them.

26 licensee's QMP did not include procedures to review the QMP.

6 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

STRONTIUM-90 EYE APPLICATOR

Inspection of Implemented QMP:

Seventy-two sets of Strontium-90 eye applicator TI field notes were entered into the database. Nine facilities had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 63.

Review of Written QMP:

At the time the QM Rule was promulgated, Strontium-90 eye applicators were not identified as a separate modality from brachytherapy. No specific guidance was provided to licensees in Regulatory Guide 8.33, "Quality Management Programs," nor was a standard review plan for review of Strontium-90 eye applicators developed. Therefore, this modality was not reviewed by LLNL.

Written Directives:

The total number of written directives for these 63 licensees, over a 2-year period, was 2,341.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI).

Objective 1:

Criteria:

A written directive for Strontium-90 eye applicator administrations should include: the treatment site, the source strength and exposure time, or total dose. The contents of a written directive for Strontium-90 eye applicators is *not* described in 10 CFR 35.2.

TI Review Findings:

On inspection, 10 of 63 Strontium-90 eye applicator licensees failed to meet

Objective 1 in that:

9 licensees did not consistently prepare written directives.

10 licensees did not include all necessary information on the written directive.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

All inspected Strontium-90 eye applicator licensee met Objective 2.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive. Since acceptance testing of new and/or repaired equipment is not specifically required, licensees who did not have procedures for acceptance testing, but implemented other applicable procedures, met the objective.

TI Review Findings:

On inspection, 9 of 63 Strontium-90 eye applicator licensees failed to meet Objective 3.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Preparation of Treatment Plans**:
   A plan of treatment is prepared in accordance with the written directive.

   TI Review Findings:

   4 licensees did not implement a procedure to assure that a treatment plan was prepared.

2. **Check of Calculations**:

   Perform a check of the treatment calculations (whenever possible by another qualified individual) before beginning treatment. At a minimum, assess the quantity of material remaining after decay (decay chart or other method)

   TI Review Findings:

7 licensees did not implement procedures to check calculations.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 11 of 63 Strontium-90 eye applicator licensees failed to meet Objective 4.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Confirmation of Treatment Plans**:
   Person administering treatment confirms the written directive including, the total dose, the prescribed treatment site, the source strength, and the method used to time the administration.

   TI Review Findings:

   11 licensee did not implement procedures to confirm treatment plans.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 14 of 63 Strontium-90 eye applicator licensees failed to meet Objective 5:

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
   2 licensees did not implement procedures to maintain records of administration in an auditable form.

   Procedures Implemented to Identify "Unintended Deviations":

   6 licensees did not implement procedures to identify unintended deviations from the written directive.

2. **Procedures to Evaluate and Respond to Recordable Events and Misadministrations Within 30 Days of Discovery**:

   TI Review Findings:

   14 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

3. **Procedures Implemented to Gather the Relevant Facts and To Identify and Implement Corrective Action to Prevent Recurrence**:

   TI Review Findings:

   8 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

31 licensees did not implement procedures that met the requirement:

1. **Expand the Review If Events Are Identified**:
   31 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.

Determine Effectiveness:

7 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.

Recordable Events:

1 recordable event was self-identified by the license since the last inspection.

1 previously unidentified recordable events was identified by the inspector during the inspection of the licensee's implemented QMP.

Misadministrations:

No misadministrations were reported to NRC by the license since the last inspection.

TELETHERAPY

Inspection of Implemented QMP:

Eighty-one sets of teletherapy TI field notes were entered into the database. Eight of these had been inspected (and entered) twice. Therefore, the total number of QM inspections included is 73 (81-8).

Review of Written QMP:

During the contracted review of the initially submitted written QMPs LLNL reviewed 129 teletherapy QMPs However, only 63 of the 73 implemented QMPs inspected, had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 73 licensees, over a 2-year period, was 9,407. For teletherapy, there will usually be one written directive, ordering a dose in multiple fractions. Therefore, it is not possible to ascertain the number of administrations.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for teletherapy must include: the total dose, the dose per fraction, treatment site, and overall treatment period.

TI Review Findings:

On inspection, 11 of 73 Teletherapy licensees failed to meet Objective 1 in that:

TI Review Findings:
Although all licensees consistently prepared written directives,
11 licensees did not include all necessary information on the written directive.

LLNL Findings:

When compared to the LLNL review of the initially submitted written QMPs:

9 licensees had written procedures that met Objective 1, as reviewed by LLNL, but apparently did not implement them.

1 licensee, who did not implement procedures to meet Objective 1, also did not initially submit a written QMP that included procedures that met Objective 1.

1 licensee's QMP had not been initially reviewed by LLNL.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

2 Teletherapy licensees failed to meet Objective 2 in that, they did not implement procedures to redundantly identify patients and/or human research subjects.

LLNL Findings:

1 licensee had written procedures that met Objective 2, as reviewed by LLNL, but apparently did not implement them.

1 licensee's QMP had not been initially reviewed by LLNL.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive. Since acceptance testing of new and/or repaired equipment is not specifically required, licensees who did not have procedures for acceptance testing, but implemented other applicable procedures, met the objective.

TI Review Findings:

On inspection, 30 of 73 teletherapy licensees failed to meet Objective 3.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

11 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

12 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

7 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Check of Calculations**:
   Perform a check of the treatment calculations (whenever possible by another qualified individual) before beginning treatment.

   TI Review Findings:

   3 licensees did not implement procedures to check calculations.

   LLNL Review Findings:

   2 licensees did not provide written procedures that required a check of calculations before beginning treatment.

2. **Acceptance Testing**:

   Perform an acceptance test on new or repaired equipment.

   TI Review Findings:

   15 licensees do not implement procedures to acceptance test new or repaired equipment.

   LLNL Review Findings:

   10 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   5 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

3. **Determining Transmission Factors for Beam Modifying Devices Before First Use and After Source Replacement**:

   TI Review Findings:

   9 licensees do not implement such procedures.

   LLNL Review Findings:

   3 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

2 licensees did not meet the objective for their written or implemented QMP.

4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

4. **Physical Measurement of the Teletherapy Output for Treatment Parameters not Fully Addressed in the Most Recent Full Calibration**:

   TI Review Findings:

   22 licensees did not implement this procedure.

   LLNL Review Findings:

   15 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

   3 licensees did not meet the objective for their written or implemented QMP.

   4 licensee's initially submitted QMPs was apparently not reviewed by LLNL.

5. **Checking Dose Calculations for Administrations in Fractions**: (this procedure should include consideration of the number of fractions and the specified time within which the check should be performed)

   TI Review Findings:

   5 licensees did not implement this procedure.

   LLNL Review Findings:

   1 licensee had written procedures, as reviewed by LLNL, but apparently did not implement them.

   2 licensees did not meet the objective for their written or implemented QMP.

   2 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]

TI Review Findings:

On inspection, 10 of 73 teletherapy licensees failed to meet Objective 4.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

3 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

3 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Treatment Plan**:
   A plan of treatment is prepared in accordance with the written directive

   TI Review Findings:

   7 licensees did not implement a procedure to assure that a treatment plan was prepared.

2. **Confirmation of Treatment Plans**:

   Person administering treatment confirms the written directive and plan of treatment. At a minimum, the verification of treatment site and dose per fraction.

TI Review Findings:

8 licensees did not implement these procedures.

LLNL Review Findings:

3 licensees did not meet the objective for their written or implemented QMP.

10 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

4 licensees did not meet the objective for their written or implemented QMP.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 11 of 73 teletherapy licensees failed to meet Objective 5:

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

3 licensees had written procedures, as reviewed by LLNL, but apparently did not implement them.

5 licensees, who did not meet the objective upon inspection, did not meet the objective in the written QMP.

3 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
   3 licensees did not implement procedures to maintain records of administration in an auditable form.

2. **Procedures implemented to identify "unintended deviations"**:

   3 licensees did not implement procedures to identify unintended deviations from the written directive.

3. **Procedures to Evaluate and Respond to Recordable events and Misadministrations Within 30 Days of Discovery:**

   TI Review Findings:

   12 licensees did not implement procedures to evaluate and respond to recordable events and misadministrations.

   LLNL Review Findings:

   3 licensee had written procedures, as reviewed by LLNL, but apparently did not implement them.

   5 licensees did not meet the objective for their written or implemented QMP.

   4 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

4. **Procedures Implemented to Gather the Relevant Facts and to Identify and Implement Corrective Action to Prevent Recurrence**:

   TI Review Findings:

   10 licensees did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

41 licensees did not implement procedures that met the requirement.

1. **Expand The Review If Events Are Identified**:
   41 licensees did not implement procedures to expanded the review if recordable events or misadministrations were identified.

2. **Determine Effectiveness**:

   2 licensees did not evaluate their QMP after each review to determine the effectiveness of the program.

3. **Recordable Events**:

   3 recordable events were self-identified by the license since the last inspection.

4. **3 previously unidentified recordable events were identified by the inspector during the inspection of the licensee's implemented QMP**.

5. **Misadministrations**:

   1 misadministration was reported to NRC by the license since the last inspection.

   No misadministrations identified by the license, were not subsequently reported to NRC.

LLNL Review Findings:

26 licensee had written procedures, as reviewed by LLNL, but apparently did not implement them.

5 licensees did not meet the objective for their written or implemented QMP.

10 licensee's initially submitted QMPs were apparently not reviewed by LLNL.

GAMMA STEREOTACTIC RADIOSURGERY

Inspection of Implemented QMP:

Five sets of Gamma Stereotactic radiosurgery (gamma Knife) TI field notes were entered into the database. One facility had been inspected (and entered) twice. Therefore, the total number of QM inspections included is four.

Review of Written QMP:

During the contracted review of the initially submitted written QMPs, LLNL reviewed 3 gamma knife QMPs. However, only 2 of the 4 implemented QMPs inspected, had been previously reviewed by LLNL.

Written Directives:

The total number of written directives for these 4 licensees, over a 2-year period, was 694.

QMP Review Findings:

The following is a review of the findings of the inspection of the implemented QMPs (QM TI), compared to the LLNL findings of the review of the written QMPs. The LLNL data provided in each response, matches the specific QMP findings provided by the TI (same population).

Objective 1:

Criteria:

As described in 10 CFR 35.2, a written directive for gamma stereotactic radiosurgery must include the target coordinates, collimator size, plug pattern, and total dose.

TI Review Findings:

On inspection, All inspected implemented QMP met Objective 1.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs:

The 2 submitted written QMPs met Objective 1.

OBJECTIVE 2:

Criteria:

The licensee must implement procedures to ensure that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

TI Review Findings:

All inspected implemented QMPs met Objective 2.

LLNL Findings:

The 2 submitted written QMPs met Objective 2.

OBJECTIVE 3:

Criteria:

The licensee must implement procedures to ensure that final plans of treatment and related calculations are in accordance with the respective written directive. Since acceptance testing of new and/or repaired equipment is not specifically required, licensees who did not have procedures for acceptance testing, but implemented other applicable procedures, met the objective.

TI Review Findings:

On inspection, 1 of 4 gamma knife licensees failed to meet Objective 3.

LLNL Review Findings:

When compared to the LLNL review of the initially submitted written QMPs,

The licensee that failed to meet Objective 3, had not been reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Preparation of Treatment Plans**:
   A plan of treatment is prepared in accordance with the written directive.

   TI Review Findings:

   All inspected licensees implemented procedures to assure that a treatment plan was prepared.

   The 2 submitted written QMPs met the objective.

2. **Check of Calculations**:

   Perform a check of the treatment calculations (whenever possible by another qualified individual) before beginning treatment.

   TI Review Findings:

   1 licensee did not implement procedures to check calculations.

   LLNL Review Findings:

   The licensee that failed to implement procedures to check calculations, had not been reviewed by LLNL.

   The 2 submitted written QMPs met the objective.

2. **Acceptance Testing**:

   Perform an acceptance test on new or repaired equipment.

   TI Review Findings:

   All inspected QMP implemented procedures to acceptance test new or repaired equipment.

LLNL Review Findings:

The 2 submitted written QMPs met the objective.

Assure Precision of Imaging and Localization:

1 licensee did not assure precision of imaging and localization (this includes ensuring that imaging films are correctly centered and labeled; and that the stereotactic frame is aligned and correctly affixed.

Verify That the Correct Helmet and Plug Pattern:

1 licensee did not verify that the correct helmet and plug pattern were selected.

Verify Correct Data Entry:

All licensees verified that computer generated dose calculations were correctly entered into unit and that the computer print out shows correct data for the patient were used in the calculations

Objective 4:

Criteria:

The licensee must implement procedures to verify, prior to administration, that the specific details are in accordance with written directive.

TI Review Findings:

On inspection, 1 of 4 gamma knife licensees failed to meet Objective 4.

LLNL Review Findings:

The licensee that failed to meet Objective 4, had not been reviewed by LLNL.

Procedures that the licensee may have implemented (several are requirements elsewhere in Part 35) include, but were not limited to:

1. **Confirmation of Treatment Plans**:
   Person administering treatment confirms the written directive including the prescribed target coordinates, collimator size, plug pattern, and total dose prior to administration.

   TI Review Findings:

   All inspected licensees implemented procedures to confirm treatment plans.

   LLNL Review Findings:

   The 2 submitted written QMPs met the objective.

2. **Confirm Administration Parameters**:

   Licensees implements procedures to verify the parameters of the treatment plan, at a minimum, assure that the stereotactic frame coordinates on the patient's skull match the plan of treatment.

   TI Review Findings:

   1 licensee did not implement procedures to confirm administration parameters.

3. **Prompt Recording of Treatment Parameters**:

   TI Review Findings:

   1 licensee did not implement procedures for the prompt recording of the treatment parameters, and signing or initialing in the patient's chart or record.

   LLNL Review Findings:

   The same licensee that did not implement procedures for the prompt recording of the treatment parameters, and signing or initialing in the patient's chart or record, had not been reviewed by LLNL.

   The 2 submitted written QMPs met the objective.

OBJECTIVE 5:

Criteria:

The licensee must implement procedures to ensure that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

On inspection, 1 of 4 gamma knife licensees failed to meet Objective 5:

LLNL Review Findings:

The licensee that failed to meet Objective 4, had not been reviewed by LLNL.

Procedures that the licensee must have implemented include, but were not limited to:

1. **Maintain Record of Administration**:
   1 licensee did not implement procedures to maintain records of administration in an auditable form.

   Procedures implemented to identify "unintended deviations":

   1 licensee did not implement procedures to identify unintended deviations from the written directive.

2. **Procedures to evaluate and respond to recordable events and misadministrations within 30 days of discovery**:

   TI Review Findings:

   1 licensee did not implement procedures to evaluate and respond to recordable events and misadministrations.

   LLNL Review Findings:

   The same licensee was not reviewed by LLNL.

   Procedures implemented to gather the relevant facts and to identify and implement corrective action to prevent recurrence:

   TI Review Findings:

   1 licensee did not implement procedures to gather the relevant facts regarding recordable events and/or misadministrations, and to identify and implement corrective action to prevent recurrence.

Periodic Review of the QMP:

Criteria:

The licensee shall develop procedures for and conduct a review of the QMP, including: a representative sample of all administrations; all recordable events; and all misadministrations. These reviews shall be conducted at intervals of no greater than 12 months.

TI Review Findings:

1 licensee did not implement procedures that met the requirement:

Recordable Events:
No recordable events were self-identified by the licenses since the last inspection.
No recordable events were identified by the inspector during the inspection of the licensee's implemented QMP.
Misadministrations:
No misadministrations were reported to NRC by the license since the last inspection.

LLNL Review Findings:

1. licensee had written procedures to perform a review of the QMP, but apparently did not implement them.

SUMMARY DATA

Total Number of Licensees inspected: 883, representing 1668 modalities.

	Iodide	Radiopharm	Brachytherapy	HDR	Teletherapy	ST-90, Eye	GKnife

						app.	
No. of TIs received:	730	548	311	156	81	72	5
Number of facilities inspected 2 TIMES:	64	61	45	46	8	9	1
Number of separate facilities inspected under this TI for this modality:	666	487	266	109	73	63	4
Number of written QMP reviewed by LLNL for this modality:	1568	1019	520	101	129	0	3
Number of written QMP (from TI implementation sample) reviewed by LLNL:	491	418	230	82	63	0	2
Approx. number of Written Directives prepared (total of 2 years, in response to 2 questions: "How many for current year (1), and How many previous year (2)):*	* Total: 39819	* Total: 4992	* Total: 8499	* Total: 10000	* Total: 9407	* Total: 2341	* Total: 694

* On many of the TIs, the years were summed and written in one column, therefore, an accurate estimate for each year was not possible.

INSPECTION FINDINGS

	Sodium Iodide	Radiopharma-ceutical Therapy	HDR	Brachytherapy	Sr-90 Eye applicator	Teletherapy	Total Each Modality
Number of licensees Included for this modality	666	487	109	266	63	73	*1668
Number of written directives prepared (total for 2 years)	39819	4992	10000	8499	2341	9407	
Missed Objective 1	6% (37)	10% (48)	6% (7)	4% (11)	16% (10)	15% (11)	7% (124)
Missed Objective 2	1% (7)	7% (32)	2% (2)	.4% (1)	All met	3% (2)	3% (44)
Missed Objective 3	N/A	N/A	3% (3)	5% (14)	14% (9)	41% (30)	*11% (57)
Missed Objective 4	7% (46)	11% (53)	6% (7)	5% (13)	18% (11)	14% (10)	9% (141)
Missed Objective 5	16% (109)	21% (100)	20% (22)	13% (35)	22% (14)	15% (11)	18% (292)
Did not conduct an adequate review of the QMP at 12 mo. intervals	25% (166)	32% (155)	23% (25)	24% (65)	49% (31)	56% (41)	29% (483)
Self-identified recordable events	7% (46)	5% (22)	6% (7)	5% (13)	2% (1)	4% (3)	
Inspector identified recordable events	2% (16)	2% (8)	2% (2)	1% (3)	2% (1)	4% (3)	

* The divisor for Objective 3 is 515 (Total minus Iodides and RPT (N/A)), instead of 1668 (Total, all modalities)

ENFORCEMENT DATA

	Sodium Iodide	Radiopharmaceutical Therapy	Brachytherapy	HDR	Sr-90 Eye Applicator	Teletherapy
Misadministrations	28	12	40	18	4	23

Misadministrations resulting in Enforcement	10	2	17	8	2	17
Severity Levels	1 SL 1 3 SL 2 5 SL 3	1 SL 3 1 SL 4	1 SL 1 1 SL 2 10 SL 3 2 SL 4	1 SL 1 2 SL 3 3 SL 4	1 SL 3 1 SL 4	17 SL 3

Severity Levels 1 and 2 (Sodium Iodide):In each case, the wrong dosage was administered by a technologist without a written directive from an authorized user. Resulted in significant thyroid doses.

Severity Level 1 (Brachytherapy):112 seeds, with activity 10 times that which was ordered were implanted into a patients prostate. The seed activity was not verified before being implanted. Resulted in several attempts to surgically remove the seeds.

Severity Level 2 (Brachytherapy):A data entry error lead to a 40% underdose.

Severity Level 1 (HDR):Treatment interrupted, source inadvertently left in patient. Resulted in patient death.

SODIUM IODIDE I-125 or I-131 > 30 µ Ci

SUMMARY OF FINDINGS:

Number of TI Field Notes included for this modality: 666

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	37 of 666 TI responses did not meet objective	9 met the objective	10 did not meet the objective	18 not reviewed
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	7 of 666 TI responses did not meet objective	1 met the objective	1 did not meet the objective	5 not reviewed
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	**Not applicable**			
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	46 of 666 TI responses did not meet objective	7 met the objective	25 did not meet the objective	14 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	109 of 666 TI responses did not meet objective	16 met the objective	59 did not meet the objective	34 not reviewed
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	166 of 666 TI responses did not meet requirement	72 met the requirement	45 did not meet the requirement	49 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	46			
Recordable events identified by inspector [35.32(c), 35.2]	16			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	8			
Licensee identified misadministrations that were not subsequently reported	1			

[35.33(a)]				

RADIOPHARMACEUTICAL THERAPY

SUMMARY OF FINDINGS:
Number of TI Field Notes included for this modality: 487

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	48 of 487 TI responses did not meet objective	8 met the objective	28 did not meet the objective	12 not reviewed
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	32 of 487 TI responses did not meet objective	19 met the objective	4 did not meet the objective	9 not reviewed
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	**Not applicable**			
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	53 of 487 TI responses did not meet objective	23 met the objective	15 did not meet the objective	15 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	100 of 487 TI responses did not meet objective	74 met the objective	9 did not meet the objective	17 not reviewed
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	155 of 487 TI responses did not meet requirement	55 met the requirement	76 did not meet the requirement	24 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	22			
Recordable events identified by inspector [35.32(c), 35.2]	8			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	1			
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	3			

HIGH-DOSE-RATE REMOTE AFTERLOADER BRACHYTHERAPY

SUMMARY OF FINDINGS:
Number of TI Field Notes included for this modality: 109

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	7 of 109 TI responses did not meet objective	2 met the objective	4 did not meet the objective	1 not reviewed

OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	2 of 109 TI responses did not meet objective	none met the objective	1 did not meet the objective	1 not reviewed
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	3 of 109 TI responses did not meet objective	none met the objective	1 did not meet the objective	2 not reviewed
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	7 of 109 TI responses did not meet objective	5 met the objective	none did not meet the objective	2 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	22 of 109 TI responses did not meet objective	9 met the objective	6 did not meet the objective	7 not reviewed
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	25 of 109 TI responses did not meet requirement	10 met the requirement	8 did not meet the requirement	7 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	7			
Recordable events identified by inspector [35.32(c), 35.2]	2			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	1			
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	0			

Brachytherapy

SUMMARY OF FINDINGS:

Number of TI Field Notes included for this modality: 266

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	11 of 266 TI responses did not meet objective	5 met the objective	4 did not meet the objective	1 not reviewed
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	1 of 266 TI responses did not meet objective	none met the objective	1 did not meet the objective	
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	14 of 266 TI responses did not meet objective	3 met the objective	7 did not meet the objective	4 not reviewed
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	13 of 266 TI responses did not meet objective	5 met the objective	5 did not meet the objective	3 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	35 of 266 TI responses did not meet objective	10 met the objective	22 did not meet the objective	3 not reviewed

Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	65 of 266 TI responses did not meet requirement	33 met the requirement	26 did not meet the requirement	6 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	13			
Recordable events identified by inspector [35.32(c), 35.2]	3			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	2			
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	2			

STRONTIUM-90 EYE APPLICATOR BRACHYTHERAPY

SUMMARY OF FINDINGS:

Number of TI Field Notes included for this modality: 63

* Written QMP for Strontium-90 Eye Applicators were not reviewed by LLNL

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	10 of 63 responses did not meet objective
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	All TI responses met the objective
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	9 of 63 TI responses did not meet objective
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	11 of 63 TI responses did not meet objective
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	14 of 63 TI responses did not meet objective
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	31 of 63 TI responses did not meet requirement
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	1
Recordable events identified by inspector [35.32(c), 35.2]	1
Licensee reported misadministration(s) since the last inspection [35.33(a)]	0
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	0

TELETHERAPY

SUMMARY OF FINDINGS:

Number of TI Field Notes included for this modality: 73

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized	11 of 73 TI responses did not	9 met the	1 did not	1 not

user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	meet objective	objective	meet the objective	reviewed
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	2 of 73 TI responses did not meet objective	1 met the objective		1 not reviewed
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	30 of 73 TI responses did not meet objective	11 met the objective	12 did not meet the objective	7 not reviewed
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	10 of 73 TI responses did not meet objective	3 met the objective	3 did not meet the objective	4 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)]:	11 of 73 TI responses did not meet objective	3 met the objective	5 did not meet the objective	3 not reviewed
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	41 of 73 TI responses did not meet requirement	26 met the requirement	5 did not meet the requirement	10 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	3			
Recordable events identified by inspector [35.32(c), 35.2]	3			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	1			
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	0			

GAMMA STEREOTACTIC RADIOSURGERY

SUMMARY OF FINDINGS:
Number of TI Field Notes included for this modality: 4

10 CFR 35.32(a), (b), and (c): Failed to implement procedures for:	Inspection of Implemented (TI)	Written QMP Review Findings (LLNL), That Did Not Meet Objective on the TI:		
		Met Obj.	Did Not Meet	Not Reviewed
OBJECTIVE 1: A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)]:	All 4 TI responses met objective	2 TI responses met the objective		2 not reviewed
OBJECTIVE 2: Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]:	All 4 TI responses met objective	2 TI responses met the objective		2 not reviewed
OBJECTIVE 3 Procedures implemented to verify that final plans of treatment and related calculations are in accordance with written directives:	1 of 4 TI responses did not meet objective	2 TI response met the objective		2 not reviewed
OBJECTIVE 4 Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)]:	1 of 4 TI responses did not meet objective	2 TI response met the objective		2 not reviewed
OBJECTIVE 5 Procedures implemented to ensure that unintended deviations are identified,	1 of 4 TI responses did	1 TI response	1 did not meet	2 not

evaluated, and corrective action taken [35.32(a)(5)]:	not meet the objective	met the objective	the objective	reviewed
Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)]	1 of 4 TI responses did not meet requirement	1 TI response met the requirement	1 did not meet the requirement	2 not reviewed
Recordable event(s) self-identified since the last inspection [35.32(c), 35.2]	0			
Recordable events identified by inspector [35.32(c), 35.2]	0			
Licensee reported misadministration(s) since the last inspection [35.33(a)]	0			
Licensee identified misadministrations that were not subsequently reported [35.33(a)]	0			