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QUALITY MANAGEMENT PROGRAM (QMP) REPORT

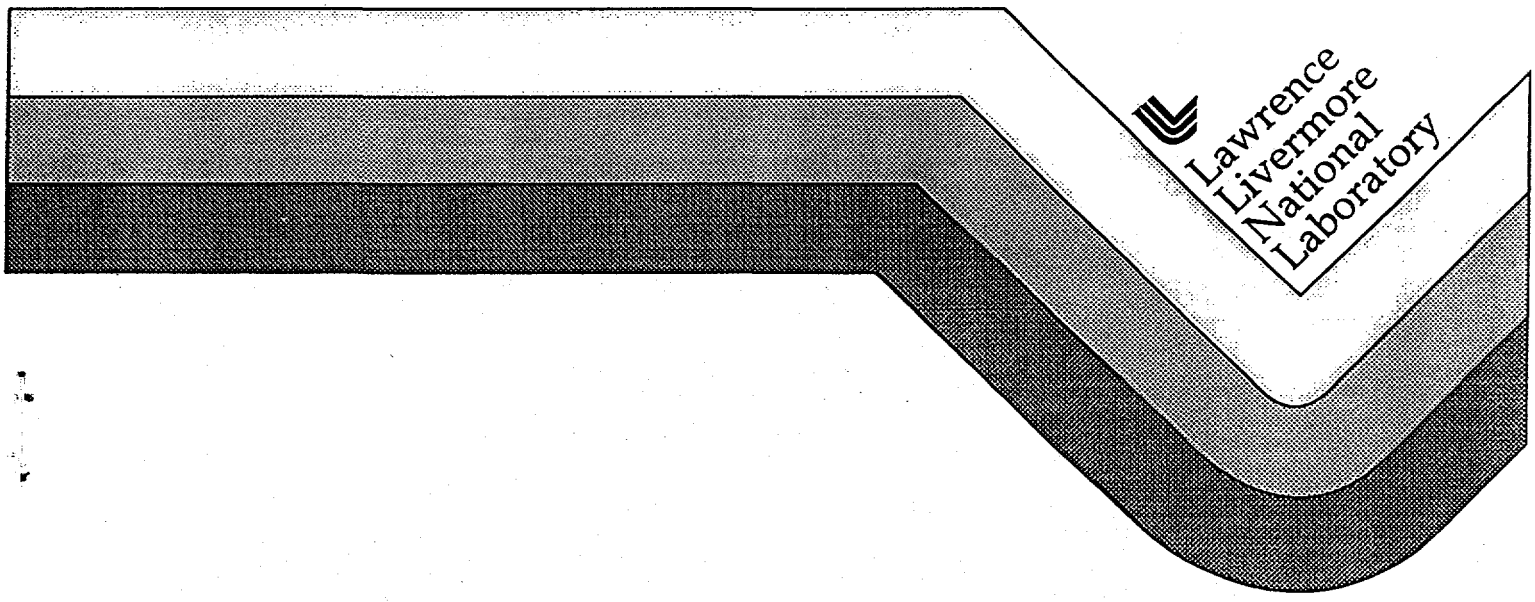
A Review of Quality Management Programs Developed in Response to Title 10, Section 35.32 of the Code of Federal Regulations

Monika C. Witte

Fission Energy and
Systems Safety Program

Prepared for the
United States Nuclear Regulatory Commission

October, 1994



DISCLAIMER

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QUALITY MANAGEMENT PROGRAM (QMP) REVIEW

1. INTRODUCTION AND BACKGROUND

In July of 1991, the Nuclear Regulatory Commission published a Final Rule in the Federal Register[1] amending regulations governing medical therapeutic administrations of byproduct material and certain uses of radioactive sodium iodide. These amendments required implementation of a Quality Management Program (QMP) to provide high confidence that the byproduct material—or radiation from byproduct material—will be administered as directed by an authorized user physician. Herein, this rule is referred to as the QM rule. The Final Rule was published after two proposed rules had been published in the Federal Register.

The first of these proposed rules, 52 FR 36942[2] would have required 10 CFR 35 licensees to implement some specific QA practices to reduce the number of mistakes in (1) the therapeutic administration of radiopharmaceuticals or radiation from byproduct material and (2) the administration of radioactive iodine. The public comments received as a result of the Federal Register notice suggested that a prescriptive rule would not allow for sufficient flexibility for all licensees. The NRC decided instead to develop a performance-based rule.

The second proposed rule, 55 FR 1439[3], was published in January 1990. A 90-day public comment period followed, along with a pilot program with 76 volunteer institutions to evaluate various aspects of the proposed rule. The NRC also conducted public workshops to obtain additional comments on the proposed rule. Following this effort, the NRC revised the proposed rule again, as discussed in the Federal Register on July 25, 1991 (56 FR 34104). To guide medical facilities in developing policies and procedures for a QM program, Regulatory Guide 8.33, *Quality Management Program*, was prepared by the NRC[4].

After the final QM rule was published in July of 1991, each licensee was required to submit two documents to the appropriate NRC Regional Office by January 27, 1992: written certification that a QM program had been established, and a copy of the QM plan. Lawrence Livermore National Laboratory (LLNL) was awarded a contract in July of 1993 to provide assistance to NRC staff in reviewing the roughly 1750 QM plans submitted to the NRC Regional offices. The tasks for the LLNL project included (1) development of a tracking system for the reviews, (2) sample review and inspection of QM programs for ten facilities, (3) review of the remaining approximately 1700 QM plans, and (4) a final report. This document is the final report for this project.

The primary goal of this project was, of course, to assist the NRC in providing feedback to the licensees on the adequacy of the QM programs which had been developed. This feedback included two steps: feedback on the review of the written plan, and results of the review of the program implemented at the facility. LLNL reviewed the written documents. NRC staff decided that by using a checklist to evaluate the QM plans, LLNL could verify that important elements of a QM plan were included in the written plans submitted. Once review was complete for each facility, LLNL prepared a letter documenting the results of the review. These letters were sent to the medical facilities by the NRC Regional offices. This effort was successful, with reviews of documents from approximately 1732 licensees completed.

Other goals of the project were (1) to provide feedback to NRC staff on the apparent usefulness of Regulatory Guide 8.33, (2) to provide feedback on the clarity of the wording in the Final Rule itself, and (3) to provide some analysis of the results of the reviews based on the responses to the checklist. These goals have also been successfully met. This report documents the review effort, and provides discussion of the results.

2. DISCUSSION OF REVIEWS

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[1]Federal Register. July 25, 1991. *Quality Management Program and Misadministrations.* Vol. 56, No. 143 (56 FR 34104).

[2]Federal Register. October 2, 1987. *Basic Quality Assurance in Radiation Therapy.* Vol. 52, No. 191 (52 FR 36942).

[3]Federal Register. January 16, 1990. *Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material.* Vol. 55, No. 10 (55 FR 1439).

[4]U.S. Nuclear Regulatory Commission. October 1991. *Quality Management Program.* Regulatory Guide 8.33.

The Quality Management Rule (10 CFR 35.32)[5] requires that licensees establish and maintain a *written* Quality Management Program which includes policies and procedures to meet a specific set of objectives. It also requires that each licensee provide certification that the program has been *implemented*. The reviews conducted within the scope of this project reported here were intended to determine whether the *written* plans submitted by licensees met the requirements of the rule, and verify whether certification of implementation had been provided. The checklist used (see Appendix A) split the review into six parts, one for each modality specified in 10 CFR 35.32(a): (1) teletherapy, (2) gamma stereotactic radiosurgery, (3) brachytherapy, (4) greater than 30 microcuries of sodium iodide I-125 or I-131, (5) any therapeutic radiopharmaceutical other than sodium iodide I-125 or I-131, plus (6) a separate section for high-dose-rate remote afterloading brachytherapy (HDR brachytherapy) because the definition of the *written directive* for HDR brachytherapy is somewhat different than that for other brachytherapy.

The checklist was based upon one developed by NRC staff, which was modified after the pilot study (See Section 7) by LLNL staff to facilitate its use. The first two questions for each modality ask (1) whether a QM plan for that modality was provided by the facility, and (2) whether certification of implementation of the plan was also provided. The remaining questions relate to the objectives described in 10 CFR 35.32 (a) and additional requirements of 10 CFR 35.32 (b) through (f). The review of each objective is discussed in general terms below (see primary checklist in Appendix A).

2.1 Review of Objective 1

> *" That, prior to administration, a written directive is prepared"*

The rule requires that a "written directive" be prepared prior to administration of any of the modalities, with the definition of "written directive" provided in 10 CFR 35.2. The checklist verifies that each required component of the "written directive" is included.

2.2 Review of Objective 2

> *"That, prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive"*

The rule requires that the patient's identity be verified by more than one method. The checklist verifies that a procedure to accomplish this is included in each QM plan.

2.3 Review of Objective 3

> *"That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directive."*

The checklist verifies that a treatment plan is prepared for teletherapy, gamma stereotactic radiosurgery, HDR brachytherapy and other brachytherapy. It also verifies that various calculations (manual or computer generated) are checked prior to use. A treatment plan is not required for the use of radiopharmaceuticals.

2.4 Review of Objective 4

> *"That each administration is in accordance with the written directive"*

The rule requires that policies and procedures be provided which ask that a check be made that each administration of byproduct material or radiation from byproduct material be in accordance with the written directive. According to suggestions provided in NRC Regulatory Guide 8.33, this would include verification of items such as dose, or dose per fraction, treatment site or route of administration, number of sources and source strengths, and loading sequence as appropriate for each modality. Use of the checklist verifies that these items are included in the written procedures.

2.5 Review of Objective 5

> *"That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken."*

The rule requires that unintended deviations from the written directive are identified, evaluated, and that appropriate action be taken. The term "deviation" is not defined in either the rule or in Regulatory Guide 8.33.

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[5] *Title 10 of the Code of Federal Regulations*. 1993 edition. Part 35 (10 CFR 35).

3. REVIEW PROCESS

LLNL staff photocopied medical facility licenses and QM plans from the NRC Region files based on a list which was provided by NRC staff of those licensees required to have a QM plan. (Only NRC licensees were included.) Transmittal letters sent from the facilities to NRC Regions stating that their programs had been implemented were also copied. These documents were obtained in August and September of 1993, so that facilities were reviewed with respect to current information from NRC files as of the late summer of 1993, unless the Regions forwarded updates to LLNL beyond that.

The QM plans were reviewed by LLNL staff (scientists and engineers), and by medical staff (technicians, dosimetrists, physicists, and physicians) at the University of California, San Francisco Medical Center, Department of Radiation Oncology (UCSF). In each case, LLNL conducted the license authorization portion of the review (i.e., where LLNL determined which modalities the facility was authorized to use based on the license). Figure 1 shows the distribution of licensed modalities for all NRC licenses, Figures 2 through 6 have the same information broken down by NRC Region. Whether a facility is authorized to use high-dose-rate remote afterloading brachytherapy (HDR) is not always clear from the license, so a list of HDR facilities was obtained from NRC staff. This list formed the basis for the HDR authorizations assumed for the reviews. All QM plans were reviewed by LLNL staff unless the facility was licensed for one or more of the following modalities: teletherapy, brachytherapy, or HDR brachytherapy, in which case the entire QM plan was reviewed by UCSF staff.

An agreement was made with NRC staff that a second review of the QM plans by LLNL staff would *not* be made. This meant that the reviews conducted by UCSF staff (first review by a technician or dosimetrist, second review by a medical physicist or a physician) were not checked again by LLNL staff. In addition, after the initial training and first twenty-five or so reviews were completed by any one LLNL reviewer, further reviews were not checked by a second LLNL reviewer, unless a problem was noted with a given reviewer's accuracy as a result of spot checks. A certain number of the questions on the checklist required the reviewer to use judgment; as a result, the responses to those questions are not necessarily consistent from one reviewer to another (or, for that matter, from one review to another). This was judged to be acceptable since the majority of the questions were deterministic (e.g., did the written directive require the authorized user's signature, yes or no?), so that the general tone of the reviews was determined primarily by fairly objective means.

3.1 Bookkeeping

After the checklist was completed for each licensee, a letter was generated by LLNL staff based on the results of the review. The primary checklist provided in Appendix A describes the approximate text of the letters. For each question in the checklist, a negative response meant that the letter generated for that licensee would contain the paragraph (approximately) corresponding to the question shown in Appendix A. Once the reviews were completed, the results on the checklist were entered into a preprocessor on an IBM PC which stored the responses (affirmative or negative) for each licensee for a given QM plan date. The data entry was performed by a capable secretary whose error rate was extremely low; the first seven hundred letters were checked carefully with only two errors total. The stored data was then fed into a relational database (ORACLE), that was used to sort the data and to develop the summaries provided in Tables 1 through 37. A computer code was written that used the ORACLE database and generated letters automatically, using addressee information provided by NRC staff (address, radiation safety officer, etc.).

3.2 Letters Generated

Four types of letters were generated: (1) those sent to facilities whose plans appeared to meet the requirements of 10 CFR 35.32, (2) those sent to facilities whose written plans were inadequate due to omissions or weaknesses in the program, (3) those sent to facilities whose written plan fails to meet at least one of the objectives listed in 10 CFR 35.32, and (4) those sent to facilities which had submitted a written declaration that no material requiring a QM plan was currently used at the facility. These four types of letters are denoted Type 1, Type 2, Type 3, and negative declarations, respectively, in this report. The distribution of letter types is shown in Figure 7 for all NRC licensees, and in Figures 8 through 12 for Regions 1 through 5, respectively. The method for determining which type of letter was prepared for a licensee is described below. The

negative declaration letters were sent, as discussed, to facilities submitting written certification of non-use of material requiring a QM plan, even though the facility is licensed for it. Each question on the checklist was given a code (one, two, or three) which determined what type of letter would be generated. For each licensee the highest question code determined the letter type for the letter, regardless of the number of responses for a given code. These codes are noted as "Type x" in the margin of each question in Appendix A. The other three letter types determined the introduction and closing paragraphs which would be appended to the paragraphs whose text is provided (as discussed) on the checklist in Appendix A. The generated letters were sent to the NRC Regions on disk, after which the regions proceeded to send the final letters to the licensees, with a copy to LLNL staff. The date stamped on the copies of these letters received at LLNL was then entered into the listing provided in Appendix D ("Date sent by Region to facility"). Examples of the letters are provided in Appendix C.

4. DISCUSSION OF STRONTIUM-90 EYE APPLICATOR QM PLAN REVIEWS

A separate checklist was developed by NRC staff to review QM plans from those licensees using SR-90 Eye Applicator therapy (see Appendix B). A decision was made by NRC staff to exclude the results of the SR-90 checklist in the ORACLE database, and to exclude the results in the summary provided in this report. Since eye applicator therapy using SR-90 is a form of brachytherapy, and since 10 CFR 35.32 does not require anything separate for eye applicator therapy beyond or different from what is required for brachytherapy, many facilities did not provide a separate QM plan for their use of eye applicators with SR-90. In this case, if the facility did provide a plan for brachytherapy, no additional checklist was completed specifically for eye applicator therapy. The SR-90 checklist provided in Appendix B was used for only those facilities licensed for SR-90 eye applicator therapy, but which did not submit a general brachytherapy QM plan.

Figure 1: Total Modalities Requiring QMP Licensed by NRC (3340)

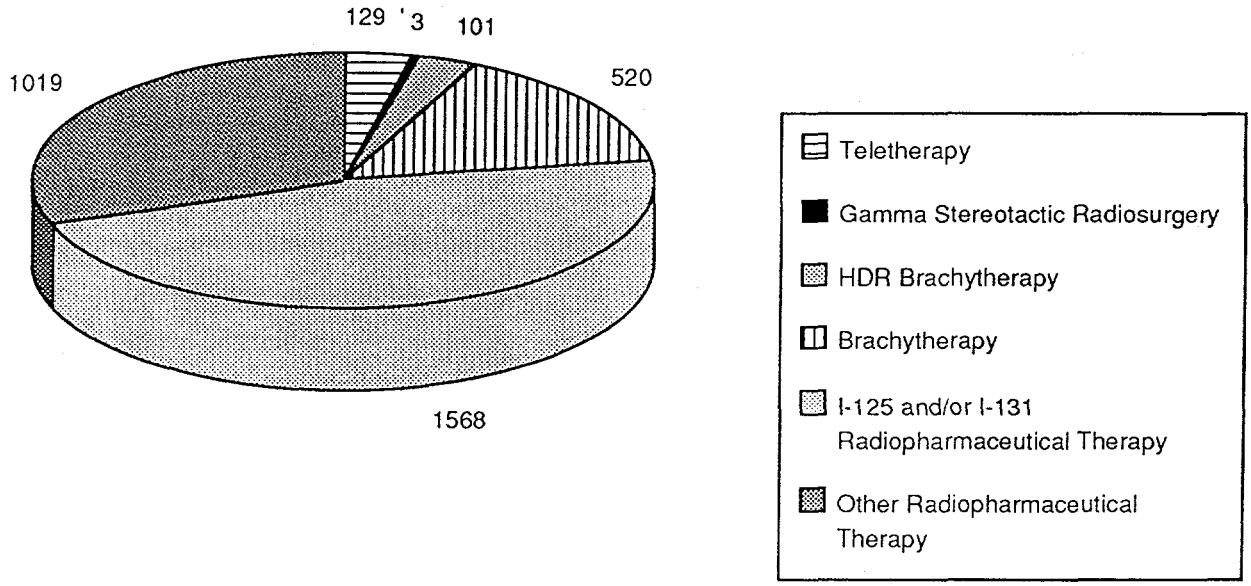


Figure 2: Region 1 Modalities Requiring QMP Licensed by NRC (1172)

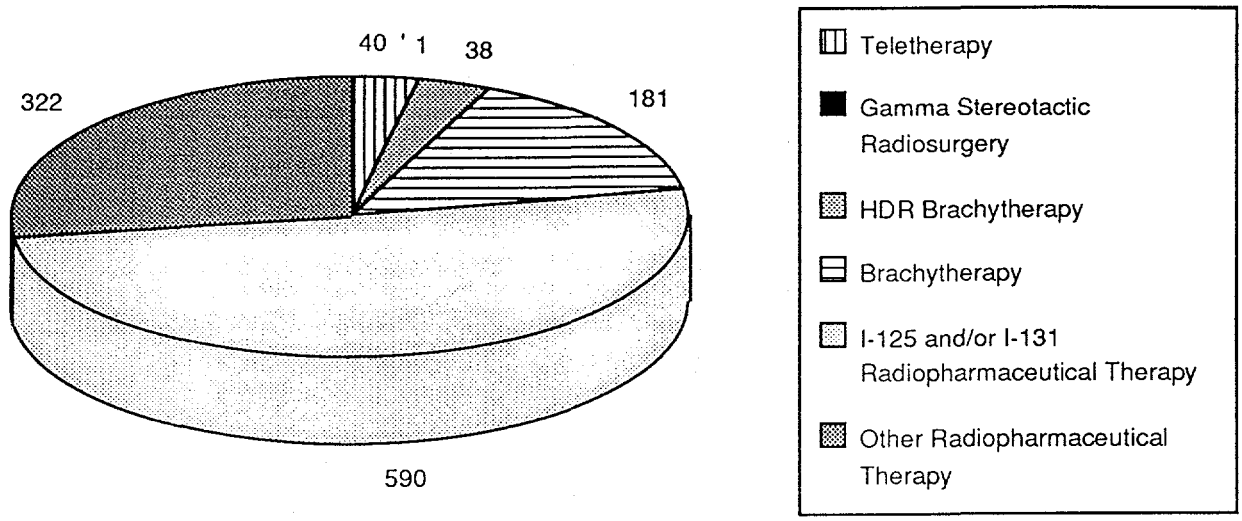


Figure 3: Region 2 Modalities Requiring QMP Licensed by NRC (383)

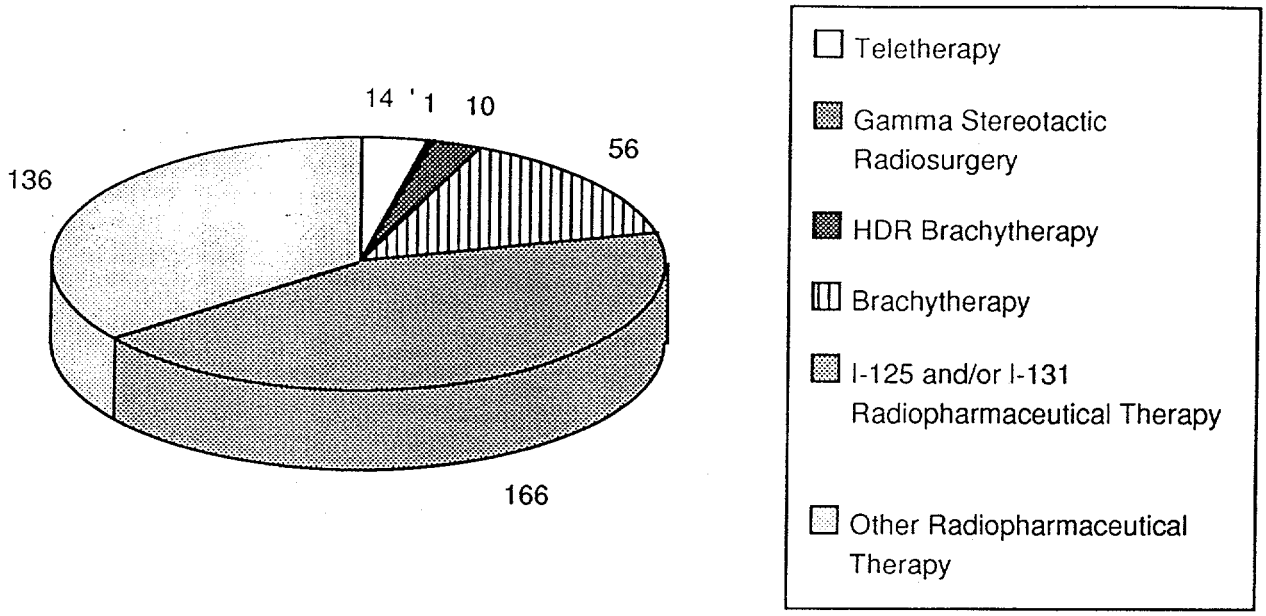


Figure 4: Region 3 Modalities Requiring QMP Licensed by NRC (1420)

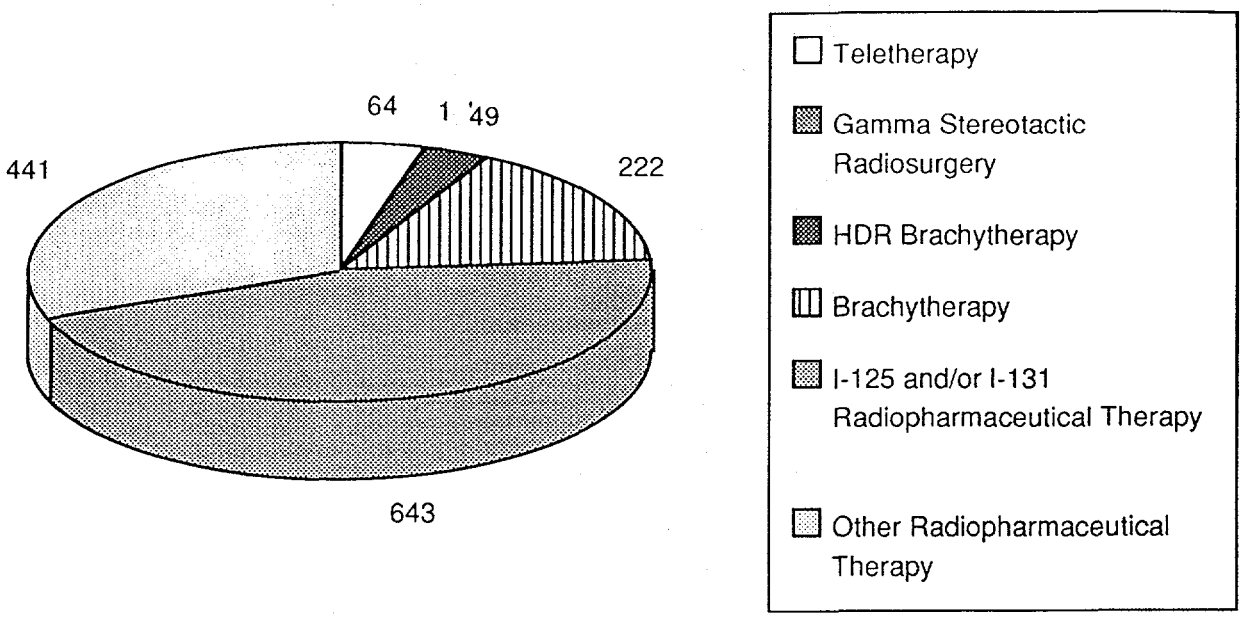


Figure 5: Region 4 Modalities Requiring QMP Licensed by NRC (268)

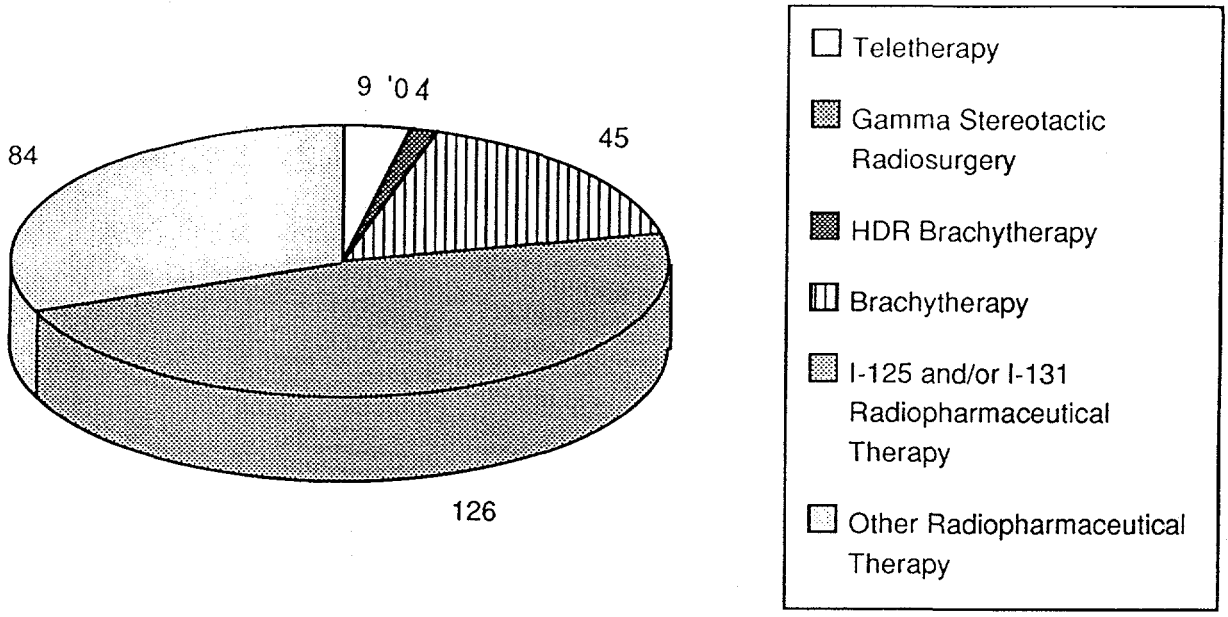


Figure 6: Region 5 Modalities Requiring QMP Licensed by NRC (93)

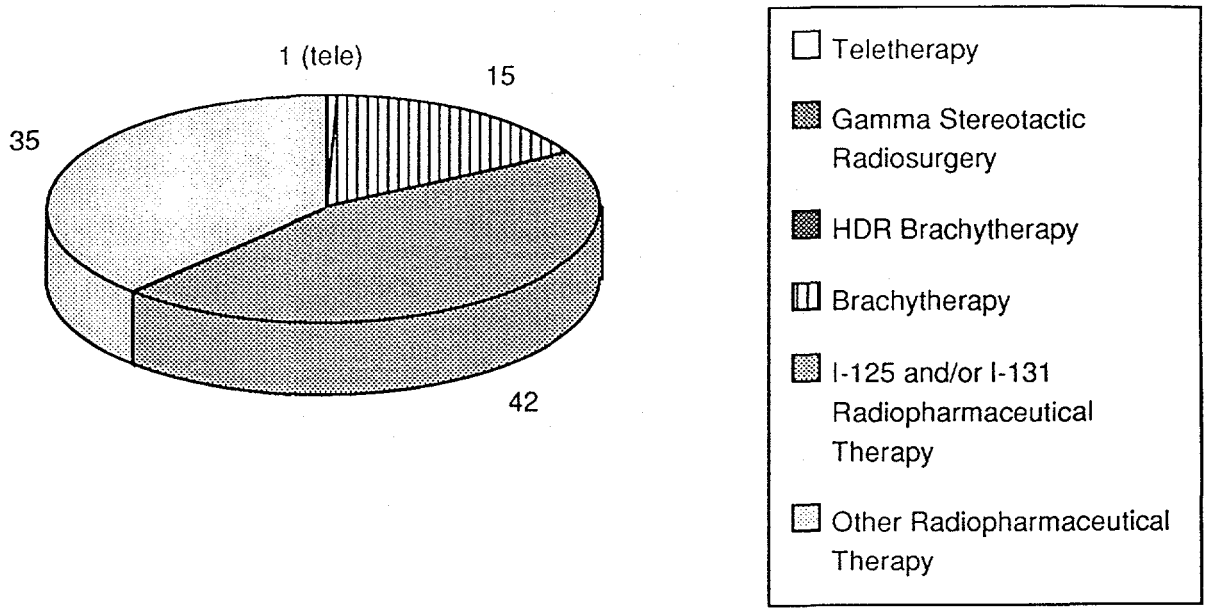


Figure 7: Total Letters (1709)

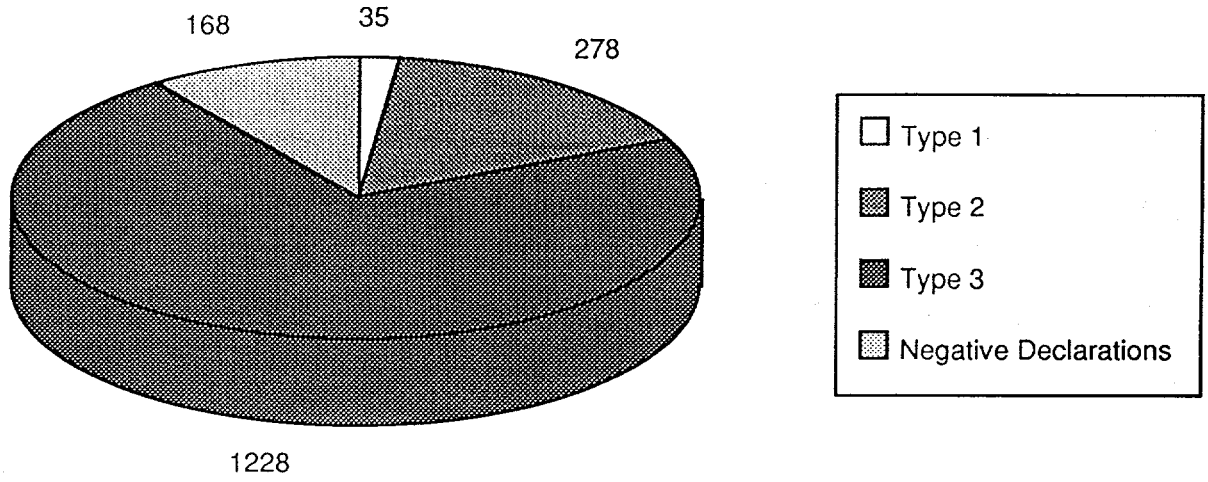


Figure 8: Region 1 Letters (635)

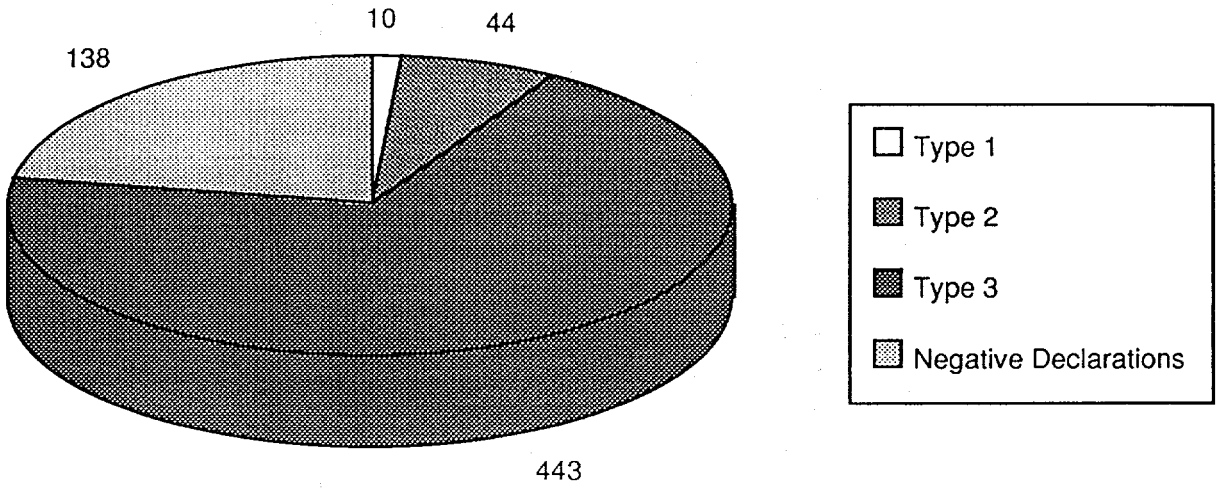


Figure 9: Region 2 Letters (183)

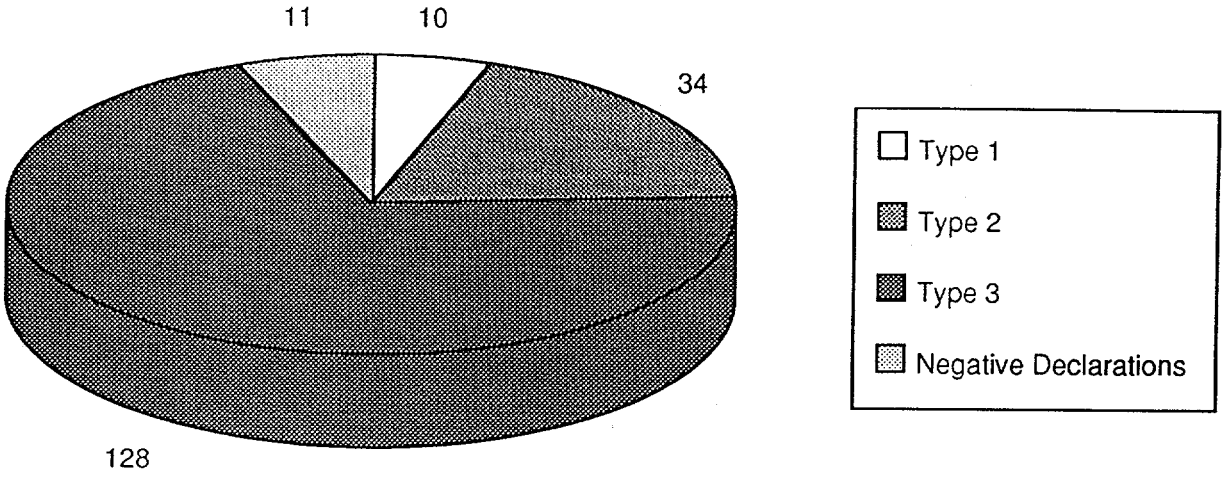


Figure 10: Region 3 Letters (711)

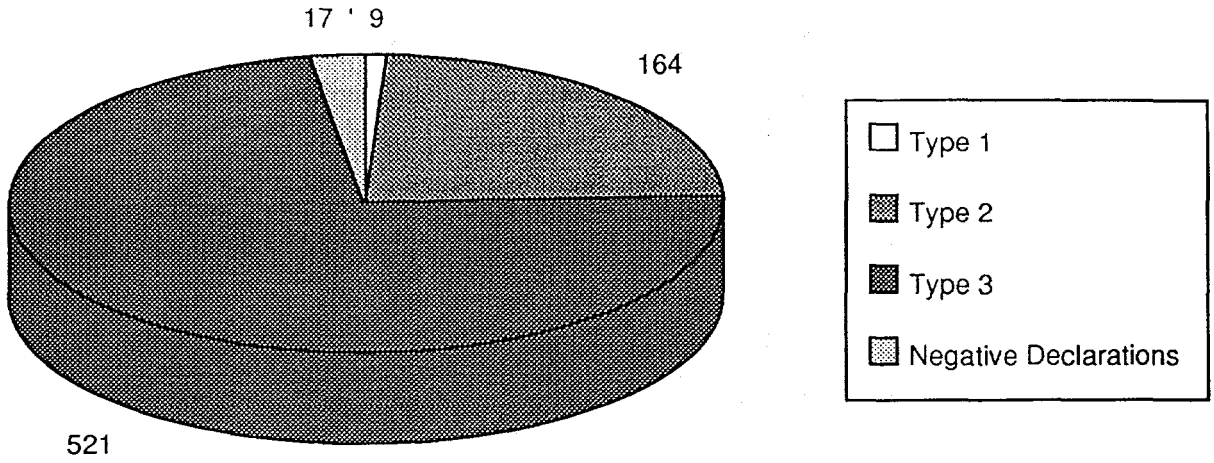


Figure 11: Region 4 Letters (135)

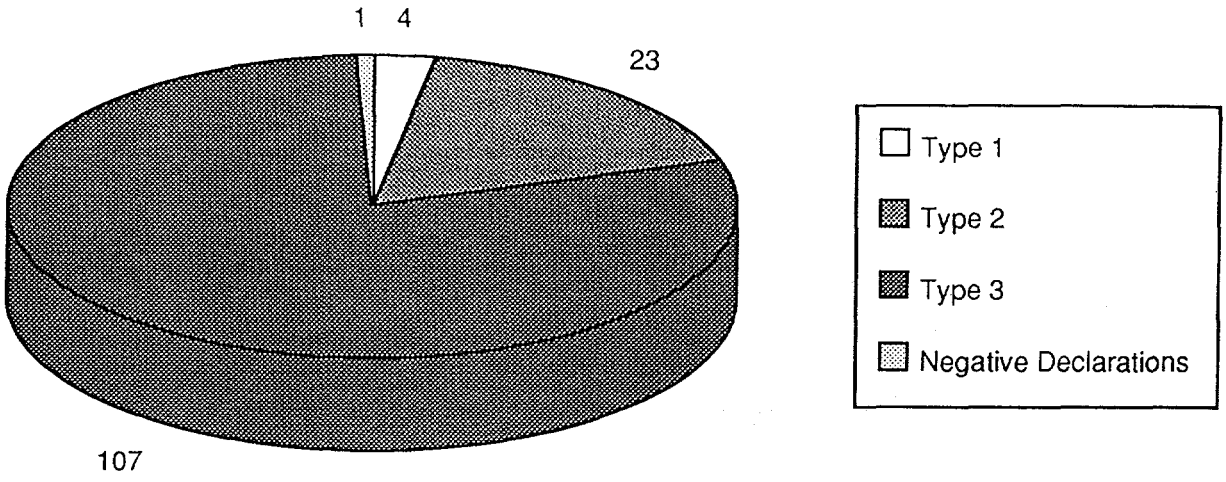


Figure 12: Region 5 Letters (43)

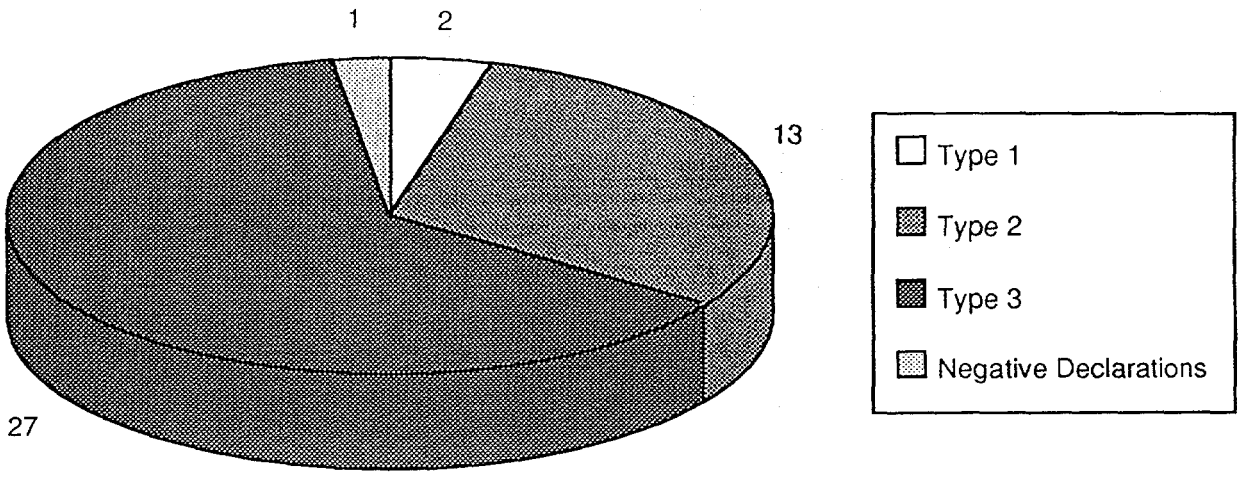
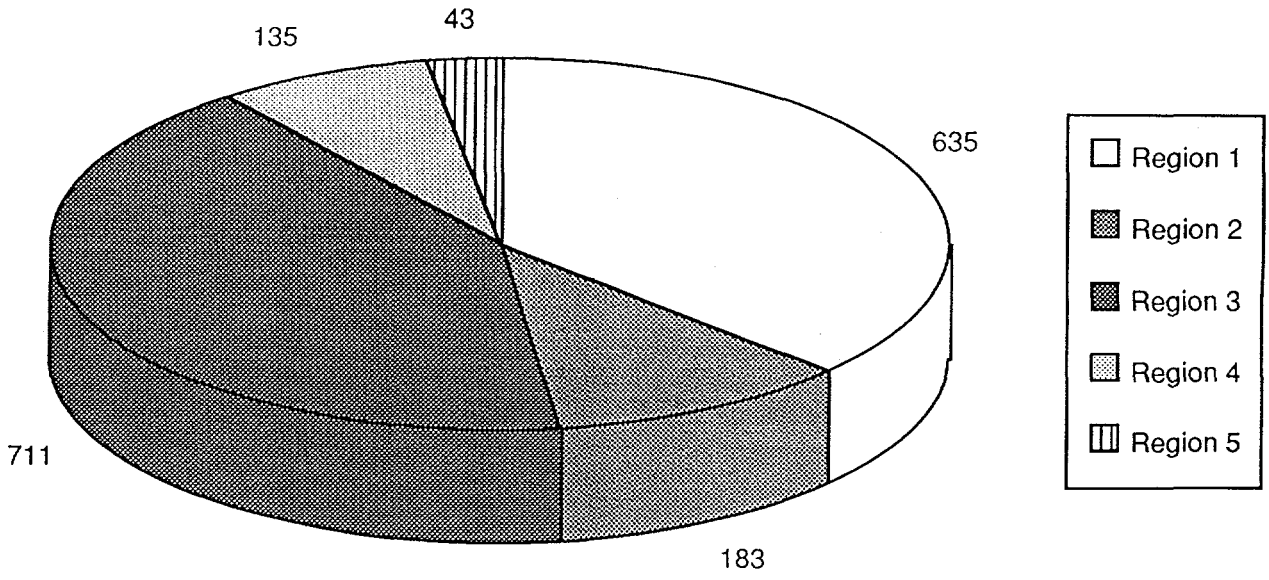


Figure 13: Number of Letters for Each Region



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5. RESULTS BASED ON PRIMARY CHECKLIST

All 1761 facilities appearing on the list provided by NRC staff in September 1993 were addressed in some manner in the review process. Some licensees are inactive, or their licenses had been terminated, as noted in the "Date Sent to NRC" column Appendix D. Some facilities provided a negative declaration letter to the Regions; however, LLNL never received a copy. These are denoted "Rnegdec" in the same column. (LLNL did not prepare the standard negative declaration letter for those cases.) Some licensees had already been reviewed by the Regions, these are denoted "regsntlet" in the same column. (No further action was taken by LLNL in this case.) Those items appearing on the primary checklist shown in Appendix A are included in the results summary tables. The summary tables begin with a general summary in Table 1, and a similar table for each region in Tables 2 through 6. Then Tables 7 through 12 provide detailed responses for each of the six modalities, summarized for all regions, of the checklist results for each question. For each of these tables, the total number of licensees reviewed is listed as the first item in the #responses column, the percentages listed are with respect to the number of licensees which provided a QM plan for that particular modality. Tables 13 through 37 provide the same detailed responses as provided in Tables 7 through 12, for each of the NRC regions.

5.1 Results of Review of Objective 1

Between 80% and 100%, depending on the modality, of the licensees reviewed missed some part of this objective (see Table 1). However, roughly 95% of licensees reviewed did require that some type of a written directive be prepared (see Tables 7 through 12). Between 13% and 57% of the licensees reviewed had procedures in place to require complete written directives, according to the items listed in the checklist. The worst case (13%) is for HDR brachytherapy QM plans.

Regulatory Guide 8.33 does not suggest the contents of the written directive, nor does it refer to the definition in 10 CFR 35.2. The checklist asks specifically for the items which are specified in the definition of the written directive in 10 CFR 35.2, except for the HDR brachytherapy modality. For this modality, the checklist asks for the total dose, the dose per fraction, the treatment site, the overall treatment period, order for a specific patient, and the authorized user signature and date. The rule asks for the radioisotope, the total dose, the treatment site, order for a specific patient, and the authorized user signature and date. It is therefore not surprising that only about 25% of the licensees who provided a QM plan for HDR brachytherapy had a procedure in place to require that dose per fraction and overall treatment period were included (see Table 8). Since the checklist did not ask about the specification of the radioisotope in the written directive, there are no responses in the database to that question; however, it might be assumed, based on the other results for Objective 1 shown in Table 8, that roughly 60% of the licensees did have a procedure to require that this be included in the written directive.

If the 13% of HDR brachytherapy licensees requiring complete written directives data point is discarded, then between 25% and 57% of the licensees reviewed provided sufficient procedures to require a complete written directive. The 25% case is for teletherapy (see Table 7). For the written directive, the most commonly missed items for teletherapy were the overall treatment period, which is clearly required by definition in 10 CFR 35.2, and the order for a specific patient, which is also clearly required by 10 CFR 35.2.

5.2 Results of Review of Objective 2

Nearly all licensees (between 93% and 100%, depending on the modality and based on the results shown in Table 1) successfully fulfilled the requirement that a procedure be in place to require that the patient's identification be verified by more than one method. The language in the rule and in Regulatory Guide 8.33 is very precise with regard to this objective.

5.3 Results of Review of Objective 3

Roughly 65% of the licensees reviewed missed some part of Objective 3 (see Table 1). This objective refers to "final plans of treatment," which are not defined in either Regulatory Guide 8.33 or the rule. For teletherapy, Regulatory Guide 8.33 in section C.2.3 suggests that the contents of the "plan of treatment" might include what the American College of Radiology recommends. Sections C.2.13, C.1.9, C.2.13, and C.4.10 of the Regulatory Guide suggest that acceptance testing be performed on each "treatment planning" computer program. For gamma stereotactic radiosurgery, Regulatory Guide 8.33 in section C.4.3 suggests that the licensee should

establish a procedure to have the radiation therapy physicist, the neurosurgeon, and the oncology physician date and sign a "plan of treatment" before administering treatment. For gamma stereotactic radiosurgery, the contents of the suggested "plan of treatment" in Regulatory Guide section C.4.3 are nearly identical to the written directive contents for gamma stereotactic radiosurgery as defined in the definition in 10 CFR 35.2.

The checklist in Objective 3 asks if a plan of treatment is prepared (for required modalities), and verifies that certain critical calculations as specified in Regulatory Guide 8.33 are checked. It does not verify signature.

Based on the results shown in Tables 7 through 9, 59% to 69% of the licensees required to prepare a treatment plan did have a procedure in place to prepare one. Since the majority of QM plans reviewed missed some part of this objective, however, it appears that Objective 3 may be misunderstood by some of the licensees.

5.4 Results of Review of Objective 4

For teletherapy and radiopharmaceutical administrations, roughly 30% of the licensees missed some part of this objective (see Table 1). However, for HDR brachytherapy and other brachytherapy administrations, between roughly 80% and 90% of the licensees reviewed missed some part of Objective 4. For these two modalities, the most commonly missed questions within this objective were questions #47a and #64b on the checklist, "The person administering the (high-dose-rate remote afterloading) brachytherapy treatment should confirm the prescribed isotope, the number of sources, the source strengths, the treatment site, the loading sequence, and the total dose."

The language for this objective in the rule is fairly general "that each administration is in accordance with the written directive" with respect to what should be checked. Regulatory Guide 8.33 recommends that the radioisotope, treatment site, and total dose should be confirmed for HDR brachytherapy (in Section C.3.1.3) and the radioisotope, number of sources, and source strengths should be confirmed for other brachytherapy (in Section C.3.2.3). In addition, Regulatory Guide 8.33 in Section C.3.2.5 recommends for other brachytherapy that the radioisotope, number of sources, source strengths, and loading sequence be verified by an authorized user, or someone under the supervision of an authorized user, prior to implantation. Perhaps the language of the Regulatory Guide could more precisely suggest what should be included for verification in a QM procedure.

Additionally, the checklist for HDR and other brachytherapy asks, in Objective 4, for a procedure to require prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted, and for the signature (or initials) on an appropriate record. There is a requirement for a record of each administered radiation dose in 10 CFR 35.32(d)(2); however, it does not specifically require signature or initials of anyone. Regulatory Guide 8.33 in sections 3.1.7 and 3.2.8 does recommend for HDR and other brachytherapy that a record be kept, and that it contain signature and initials of an authorized user. These paragraphs refer to 10 CFR 35.32(d)(2), however, and not to Objective 4. Roughly 35% (for HDR brachytherapy) and 57% (for other brachytherapy) provided procedures to fulfill this requirement on the checklist (see Tables 8 and 9). It should be noted that a record of administered radiation dose or radiopharmaceutical dosage is required for *all* modalities by 10 CFR 35.32(d)(2), and is discussed for all modalities in Regulatory Guide 8.33, and is addressed for all modalities with checklist questions # 12, 30, 48, 66, 83, and 100. However, this requirement is separate from the requirement for Objective 4.

5.5 Results of Review of Objective 5

Objective 5 of the QM rule asks that procedures be provided to identify and evaluate any unintended deviation from the written directive, and to take appropriate action. Unfortunately, this language does not appear to provide sufficient detail to the licensees to communicate what is expected. Additionally, Regulatory Guide 8.33 addresses this objective for one modality only, teletherapy. There is no mention of this objective for radiopharmaceutical uses in Regulatory Guide 8.33 section C.1. Section C.2.7 of the Regulatory Guide suggests, for teletherapy, that a weekly chart check be performed to detect mistakes that may have occurred in the daily and cumulative teletherapy dose administrations. There is no mention of this objective for any other modalities. Section 6 of Regulatory Guide 8.33 recommends that deviations be identified and corrective action taken for each

patient case reviewed as a part of the periodic review process. However, the implication in the rule is that this objective be met *separately* from the periodic review process, since it is addressed as a specific objective and not as a part of the periodic review requirement.

Between 55% and 67%, depending on the modality, of the licensees reviewed did not provide procedures to satisfy this objective. It is clear from a review of the QM plans that many licensees interpreted this requirement to mean that if a deviation from the written directive was found in the periodic review process, and appropriate action taken at that time, then this objective would be satisfied. It is not clear to the author what is actually intended by the wording for this objective in 10 CFR 35.32(a)(5). The reviewers have used judgment in their interpretation of this item on the checklist.

5.6 Results of Review of Other Requirements

Requirements of the QM rule other than procedures for Objectives 1 through 5 include (1) a periodic review, (2) response to recordable events, (3) record retention, (4) notification to the NRC of QM program modifications, and (5) that each new and existing licensee provide a copy of its QM plan to the NRC, along with written certification that the plan has been implemented. It should be noted that the rule specifically requires *written policies and procedures* only for Objectives 1 through 5. The QM rule does not specifically state that the additional requirements listed in the rule be included in a written QM plan. Nevertheless, the plans submitted by the licensees were reviewed according to the checklist provided in Appendix A, which asks about the specifics of the above five items. Data is available and summarized in the tables for the review of these items. Each is discussed in turn below.

The language of the rule, and the language of Regulatory Guide 8.33 in section 6, are each fairly precise and descriptive with respect to the requirement for at least an annual review. The results shown in Tables 7 through 12 show that roughly 83% to 91% of the licensees do have procedures in place to require at least an annual review. However, almost none (9% to 13%) of the licensees had a procedure in place to expand the review if recordable events or misadministrations were uncovered during the review process. This could be because that requirement is not listed in the rule, and the suggestion for it in the Regulatory Guide is provided in a somewhat confusing manner

> *If the difference between what was administered and what was prescribed exceeds the criteria for either a recordable event or a misadministration, that comparison is unacceptable. The number of 'unacceptable comparisons' that is allowed for each sample size and lot tolerance percent defective is provided in the acceptance sampling tables of 10 CFR 32.110.*

(See Regulatory Guide 8.33 section 6.) Also, only about 50% of the licensees understood what was required by the words "representative sample of all patient administrations," or by the also slightly confusing description for the same provided in Regulatory Guide 8.33. Procedures to evaluate the effectiveness of the QM program were only provided by roughly 40% to 50% of the licensees reviewed, although there is some evidence that this does in fact occur for more facilities on at least an annual basis, since the results of the review are usually presented for discussion at some management-level meeting. Procedures to retain the records of each review for at least three years were provided by only 25% to 39% of the licensees reviewed.

The QM rule requires, in 10 CFR 35.32(c), that licensees respond to recordable events in a fairly specific manner. No discussion of this requirement is included in Regulatory Guide 8.33. Roughly 70% of licensees reviewed omitted the procedure for evaluation and response to recordable events in their written QM plans.

The QM rule requires, in 10 CFR 35.32(d) (1) and (2), that records of the written directive and administered doses be maintained in an auditable form for three years. This requirement is also described in Regulatory Guide 8.33, in each of the modality sections. Only 17% to 26% of the licensees provided a procedure to require this in their QM plans (see Tables 7 to 12).

The QM rule requires, in 10 CFR 35.32(e), that licensees provide to the NRC any modifications to the QM plan within 30 days after the changes have been made. This requirement is not discussed in Regulatory Guide 8.33. Only roughly 14% of the licensees provided a procedure to require this in their QM plans (see Tables 7 to 12).

The QM rule requires, in 10 CFR 35.32(f)(2), that each licensee provide written certification that QM programs established at medical facilities be implemented. Nearly all licensees reviewed (roughly 80%) provided this certification.

6. DISCUSSION OF RESULTS

An overview of the results can be seen by looking at Figures 14 through 20. Figure 14 shows the distribution by each modality of a failure to meet required objectives. Although the total number of licenses summarized in this document is only 1709, the total number of modalities reviewed is 2867, since many licensees are licensed for more than one modality. (Note that this is less than the number of authorized modalities since some facilities provided negative declaration statements or failed to provide a QM plan.) Figures 15 through 20 show the failure to meet required objectives separately for each of the six modalities considered. A review of the results provided in the tables and discussed above shows that very few items included in Objectives 1 through 5 were described with procedures by 80% or more of the licensees reviewed. These described procedures are:

- licensees that included QM procedures for some type of written directive (roughly 95%)
- licensees that included QM procedures for the written directive to include authorized user signature and date (roughly 85%)
- licensees that included QM procedures for a patient identity to be verified by more than one method (roughly 98%)
- for teletherapy and HDR brachytherapy licensees, QM procedures included for a check of dose calculations (85%) as part of Objective 3
- for teletherapy licensees, QM procedures included for a check of full calibration measurements (82%) as part of Objective 3
- licensees that included QM procedures for some minimum policy to ensure that each administration is in accordance with written directive (roughly 83%) as part of Objective 4
- licensees that included QM procedures for an annual review of QM program (83% to 91%)

In addition to the procedures listed above,

- licensees that certified implementation of their QM program (80% to 85% for teletherapy, HDR, and other brachytherapy. The percentage for radiopharmaceuticals was lower.)

It needs to be noted that although some type of procedure *is* provided, as listed above, certainly this is no guarantee of completeness, as evidenced by the fact that 95% of licensees provided procedures for some type of written directive, but that only 25 to 57% of the licensees provided procedures to require a *complete* written directive according to the definition in 10 CFR 35.2. A review of the summary tables and section 5 of this report must be made to evaluate completeness for any item.

The items on the above list are there probably because clear guidance was provided by either 10 CFR 35.32, or by Regulatory Guide 8.33, or both in those specific areas.

Figure 14: Failure to Meet Required Objectives – All Modalities

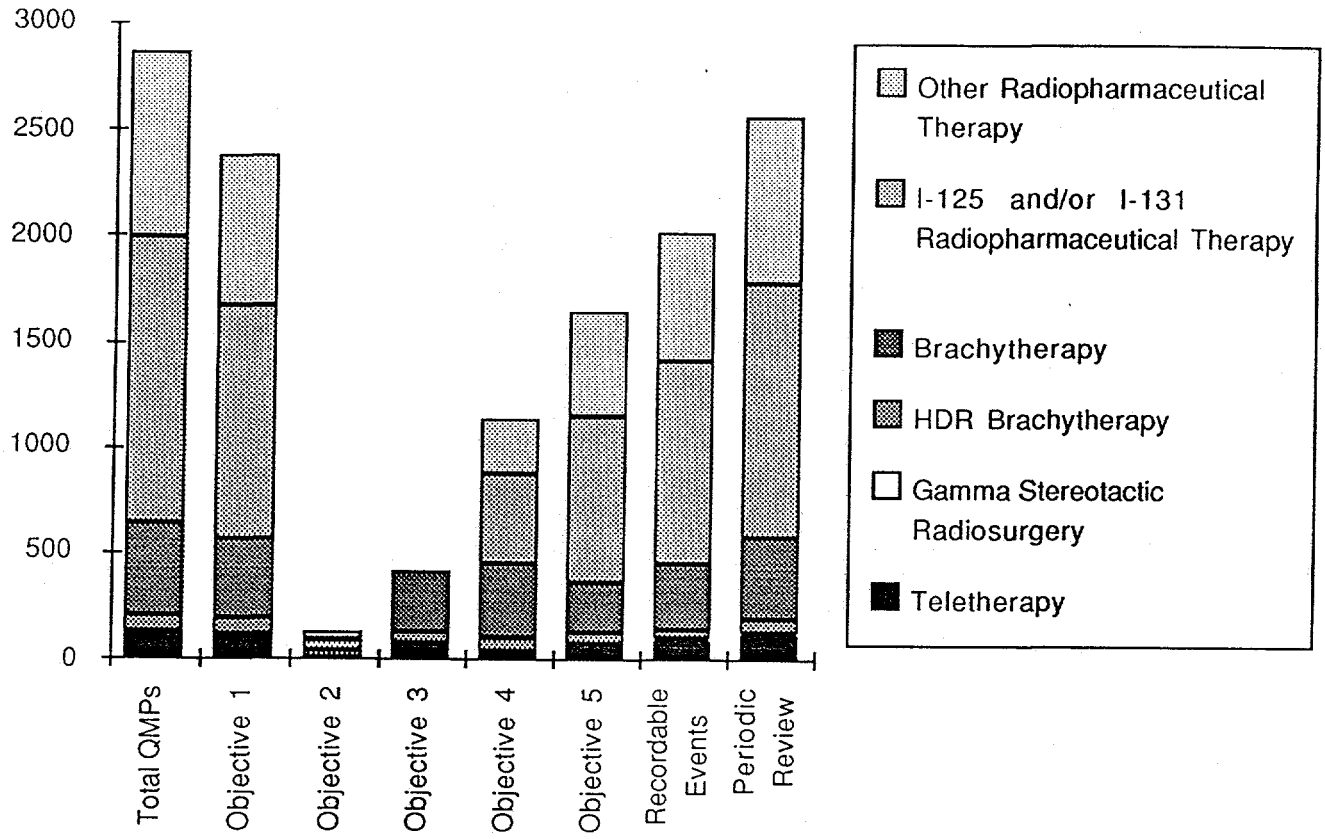


Figure 15: Failure to Meet Required Objectives – Teletherapy Modality (126 QMPs)

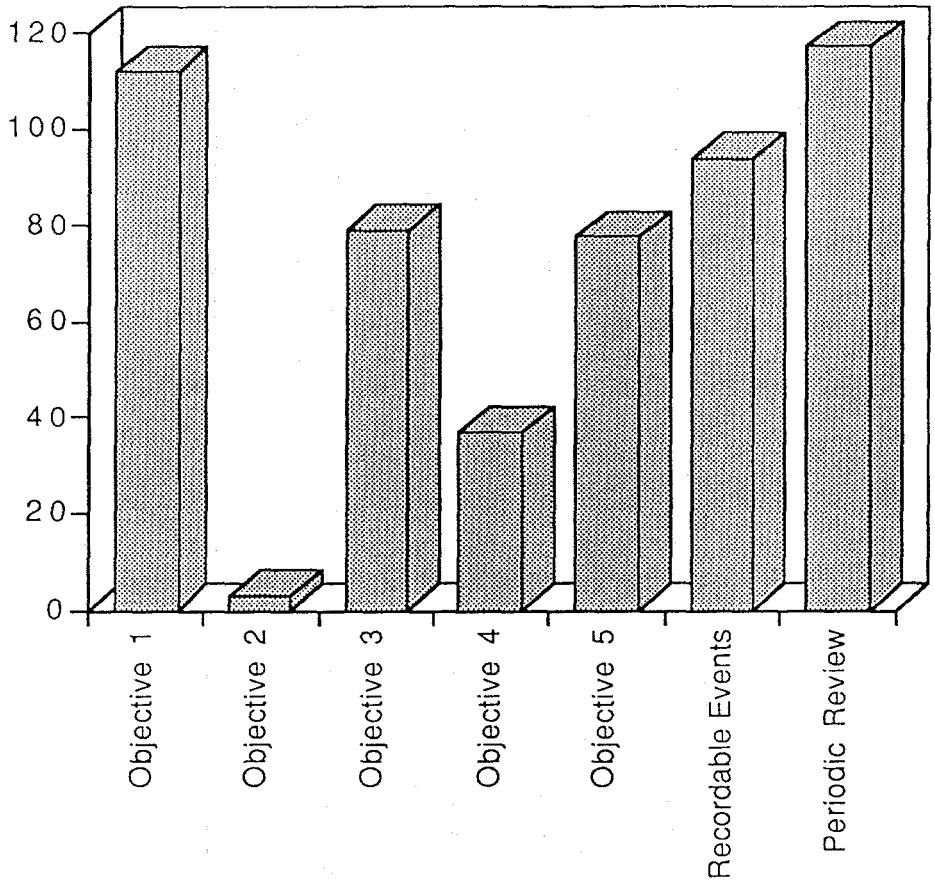


Figure 16: Failure to Meet Required Objectives – Gamma Stereotactic Radiosurgery Modality (3 QMPs)

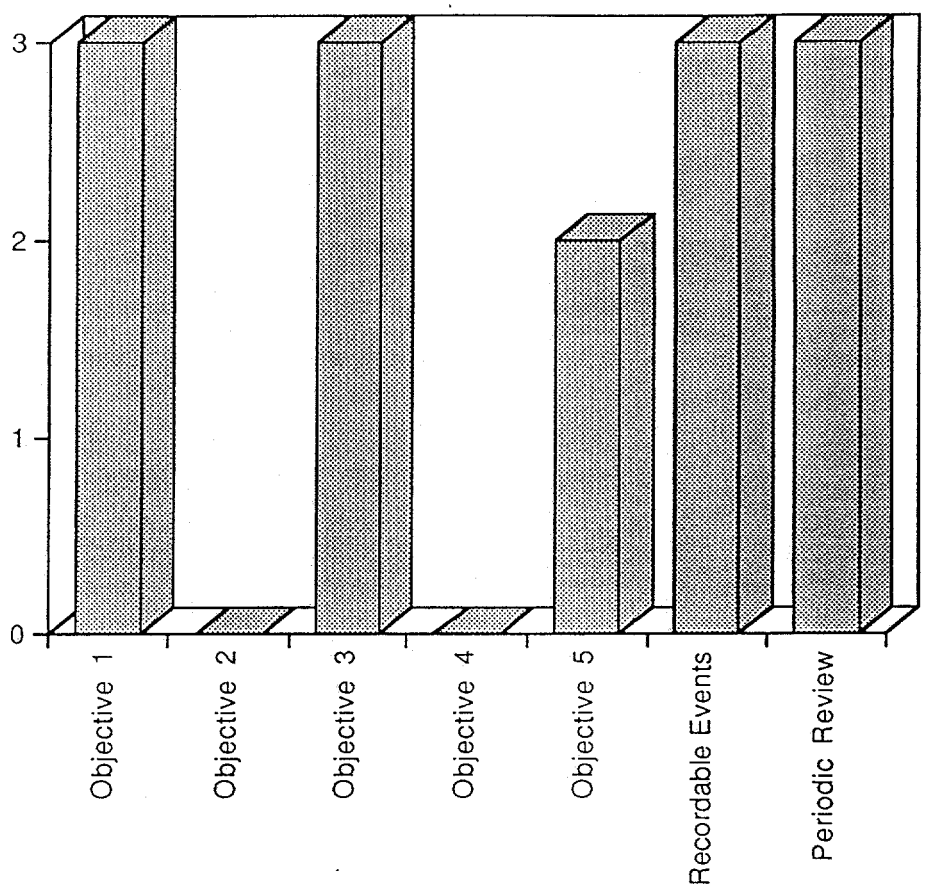


Figure 17: Failure to Meet Required Objectives – HDR Brachytherapy Modality (75 QMPs)

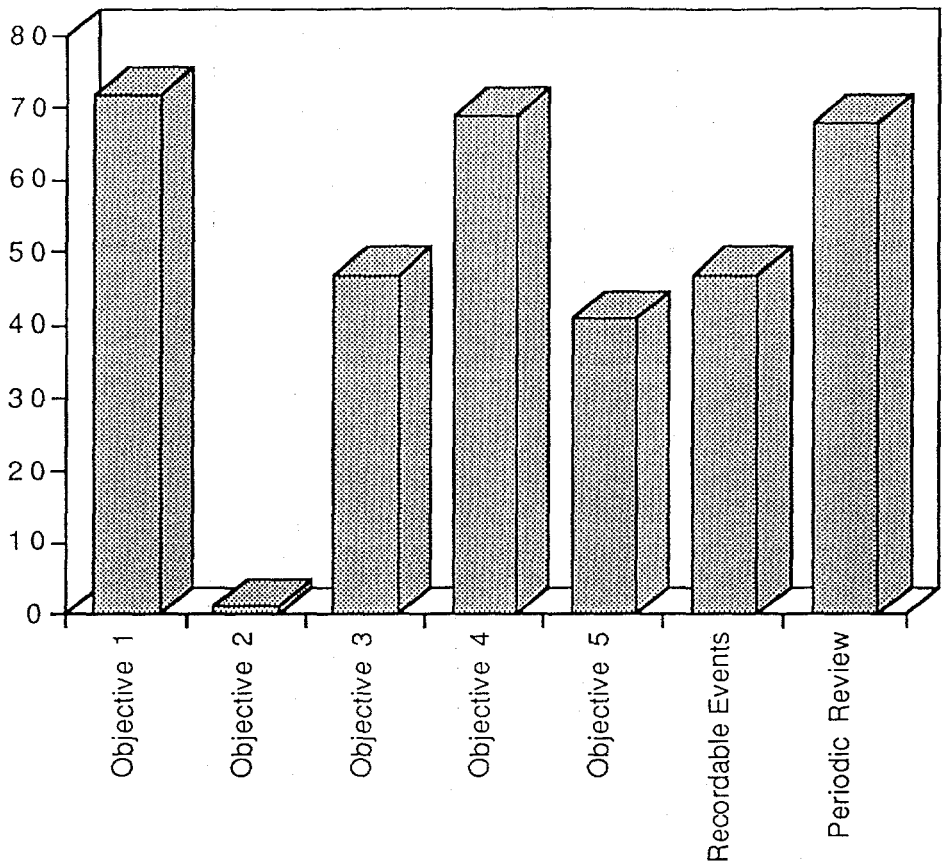


Figure 18: Failure to Meet Required Objectives – Brachytherapy Modality (435 QMPs)

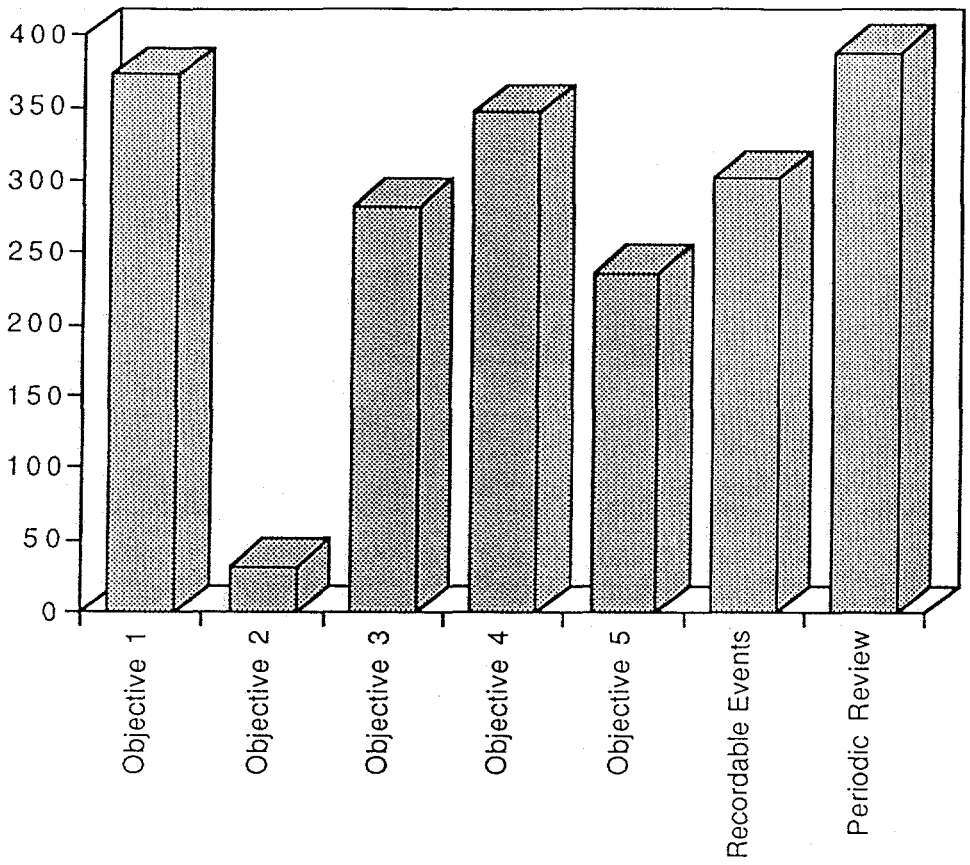


Figure 19: **Failure to Meet Required Objectives – I-125 and/or I-131 > 30μCi Modality (1347 QMPs)**

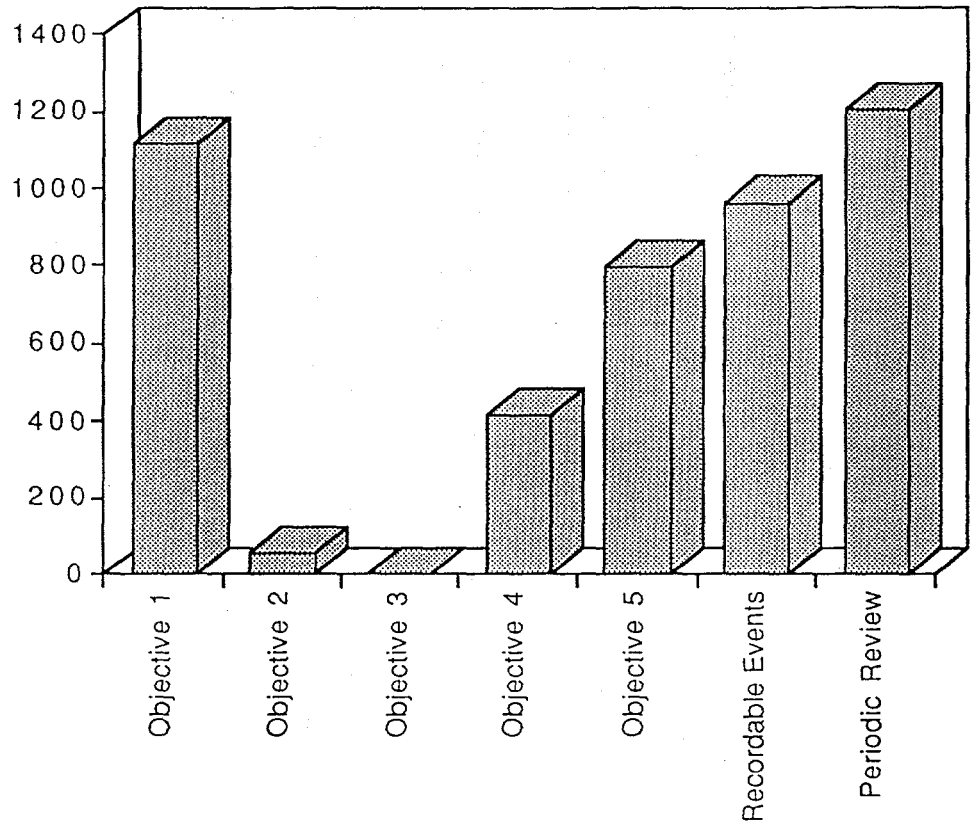
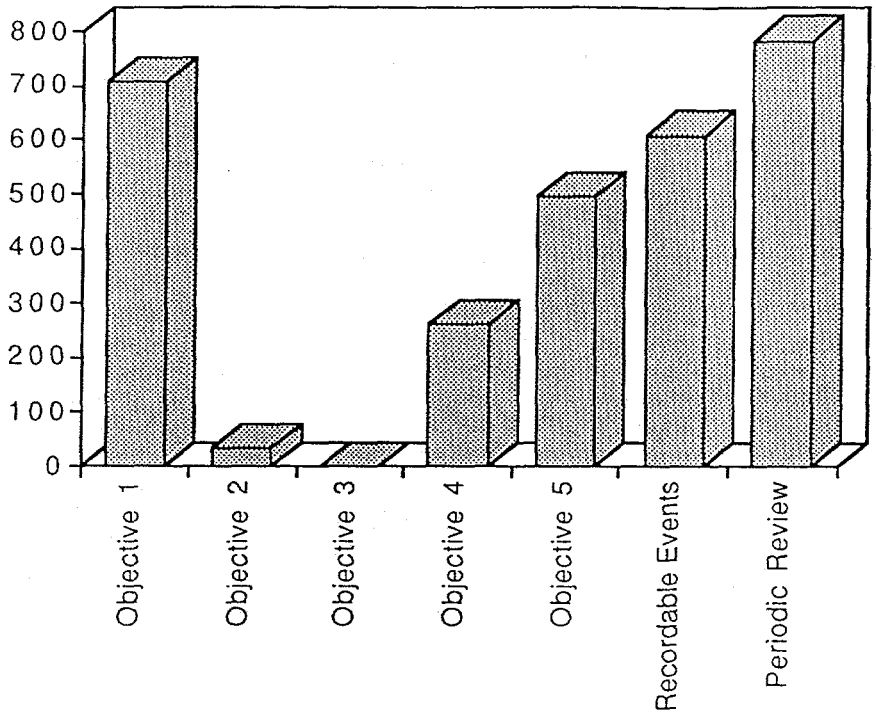


Figure 20: Failure to Meet Required Objectives – Other Radiopharmaceutical Therapy (881 QMPs)



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6.1 Objectives or Elements of the QM Rule Which are Not Typically Addressed Adequately in the QM plan

The checklist contains 181 questions. Of those, there were 31 questions (summarized above) for which 80% or more of the licensees provided satisfactory minimum procedures. The only objective adequately addressed by the QM rule is Objective 2, *"That, prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive . . ."*

6.2 Sections of 10 CFR 35.32 with Potential for Improvement of Regulatory Language

A decision was made by the NRC to provide a "performance-based" rule, rather than a prescriptive one, with the publication of the second proposed rule in January 1990 (55 FR 1439). As a result, the rule is written in a very general tone. The QM plans submitted were judged against a standard (the primary checklist) which asks for specific items to be included. Generally, the only items on the checklist which were satisfactorily included in most plans are those for which there was prescriptive guidance in either the QM rule, or in the Regulatory Guide, or both.

6.3 Suggestions for Additional Sections in Regulatory Guide 8.33

Suggestions for possible changes to Regulatory Guide 8.33 are based on the results. For those cases where licensees appeared to misunderstand what was required, perhaps some modifications to the Regulatory Guide would help.

- Include either a reference to the definition of "written directive" in 10 CFR 35.2, or (better) repeat the definition in the Regulatory Guide, so that licensees can readily determine what is required.

- Include more discussion in the Regulatory Guide on what is intended for the "final plans of treatment." The term "treatment planning" is used several times in the Regulatory Guide. This is the term which is used in the proposed rule 10 CFR 35.35 as published in the Federal Register in January of 1990 (55 FR 1439), and which was modified to "final plans of treatment" in order to suggest something static in the current rule (10 CFR 35.32). The guidance provided in the Regulatory Guide may have been developed to correspond to the proposed rule 10 CFR 35.35 rather than the current one.

- Clarify the sections C.3.2.3 and C.3.2.5. There is perhaps some duplication, what should be verified?

- If Objective 5 is to be addressed by the licensee separately from the requirement for a periodic review, as was suggested by the wording for the original objective in the proposed rule:

  ". . . ensure that any unintended deviation from a prescription or a diagnostic referral and clinical procedures manual is identified and evaluated . . ."

  then more discussion might be provided in the Regulatory Guide. Perhaps this objective could be interpreted for all modalities as a requirement for something similar to what is recommended by Regulatory Guide 8.33 for teletherapy only. That is, it is a systematic method for detecting mistakes separate from and more frequent than the annual review, and a procedure to require that all "deviations" be addressed as soon as they are discovered.

- More clear discussion of what is meant by "representative sample" for the periodic review.

- More clear discussion of what is meant by a procedure to expand the review if recordable events or misadministrations occur.

- Some discussion of the requirement to respond to recordable events (10 CFR 35.32(c)).

- More explicit discussion of the requirement to maintain, in an auditable form, a record of the written directive and administered doses for three years. (This is discussed in the Federal Register Notice (56 FR 34104). Consider repeating the discussion in the Regulatory Guide.)

- Some discussion of the requirement to provide to the NRC any modifications to the QM program within 30 days after the changes are made.

7. PILOT STUDY DISCUSSION

A pilot study of ten facilities only was conducted prior to the review of the rest of the 1761 facilities. A group of ten licensees was selected by NRC staff, including five each from NRC Regions 1 and 3. All modalities except teletherapy were included in the pilots with at least one QM plan. For these ten facilities, the QM plan was reviewed, LLNL staff accompanied NRC inspectors on unannounced inspection visits, and the results of the QMP review were compared to the on-site inspection results. The goals of the pilot study were (1) to evaluate the effectiveness of the QMP plan review process in light of the actual Quality Management program in use at the medical facilities, (2) to identify the most frequently missed requirements of the QM rule, and (3) to revise and refine the review process prior to initiating the bulk of the reviews.

These goals were met and, in addition, several other benefits resulted:

- the first reviewers were trained as a group with ten identical QM plans in order to develop consistency among the reviews
- seven UCSF and eight LLNL reviewers participated in these reviews, producing roughly seventy-five "training reviews" of these plans
- the review process was "debugged," with the result that the checklist was modified for clarity and ease of use
- the reviewers were forewarned of any common confusion regarding the checklist.

The results of the pilot study are summarized for each objective, below:

Objective 1: ***Prior to administration a written directive is prepared***

For nuclear medicine departments:

	Written QMP Plans	In-place QMP procedures
adequately included	3	2
not included	1	
not adequately included	5	7
unknown		

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	3	5
not included	1	1
not adequately included	4	2
unknown		

Observations regarding Objective 1 were as follows: (1) the lack of procedures to require complete written directives was probably the most common serious problem we found, and (2) this is an example of the value of the QM Rule: some facilities unbelievably *did not require a written directive* prior to the implementation of this rule.

Objective 2: ***Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive.***

For nuclear medicine departments:

	Written QMP Plans	In-place QMP procedures
adequately included	8	8
not included	1	
not adequately included		1
unknown		

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	7	7
not included	1	
not adequately included		
unknown		1

Observations regarding Objective 2: although many facilities do not document this verification, most facilities did require this check.

Objective 3: ***Final plans of treatment and related calculations are in accordance with the respective written directive.***

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	3	5
not included	2	1
not adequately included	3	1
unknown		1

Observations regarding Objective 3: the original checklist does not consistently place the requirement to check manual and computer calculations under Objective 3; therefore, the above results, as well as those for Objective 4, may be misleading. The final checklist was modified to correct this.

Objective 4: ***Each administration is in accordance with the written directive***

For nuclear medicine departments:

	Written QMP Plans	In-place QMP procedures
adequately included	2	7
not included	6	
not adequately included	1	
unknown		2

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	1	6
not included	5	1
not adequately included	2	
unknown		1

Observations regarding Objective 4: written procedures are frequently not adequate; however, the facilities do generally perform the required verifications.

Objective 5: ***Unintended deviations from the written directive are identified and evaluated, and appropriate action is taken.***

For nuclear medicine departments:

	Written QMP Plans	In-place QMP procedures
adequately included	5	7
not included	4	1
not adequately included		
unknown		1

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	4	5
not included	4	1
not adequately included		
unknown		2

Primary observations regarding Objective 5: this portion of the rule (and corresponding sections of the checklist and Interim Field Notes) are not consistently interpreted by the facilities, the inspectors, and the reviewers. Apparently, Objective 5 is confusing. Many thought that the periodic review satisfied this objective.

Required Periodic Reviews:

For nuclear medicine departments:

	Written QMP Plans	In-place QMP procedures
adequately included	1	5
not included	2	1
not adequately included	6	3
unknown		

For brachytherapy departments:

	Written QMP Plans	In-place QMP procedures
adequately included	1	7
not included	2	1
not adequately included	5	
unknown		

Generally, the review of the *written* plans appeared to provide a representative review of the *in-place* programs, that is, the in-place programs were at least as good as the written plans, and usually better. Some general conclusions from the pilot study were:

(1) Most objectives were adequately addressed most of the time, both at the facilities and on paper.

(2) Objective 2 is the only objective which appeared to be adequately understood and implemented by (nearly) all of the facilities. Some improvement might be hoped for all of the other objectives.

(3) In a few instances, a plan would provide a procedure to do something which was in fact not done: - no written directives, - incomplete written directives, - no periodic review at all. This was the most worrisome result. However, it occurred at facilities with generally inadequate written plans.

8. SUMMARY AND CONCLUSIONS

The primary goal of the QM rule, as stated in the rule itself, is to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. It remains to be seen whether this goal has been accomplished, since an evaluation will be necessary of recordable events, misadministrations, and other deviations in the years after the QM programs have been implemented and reviewed. However, the effort reported here was a necessary first step in achieving this goal, and it has been successfully completed. LLNL provided the review of QM plans from 1732 facilities, generated letters to each facility, and provided a brief review of the guidance documents used by the licensees to develop their QM plans.

In general, the licensees' efforts to adequately address the QM rule in their written plans were not successful. A brief summary shows that the average percentages of *missing* any aspects of the objectives and other requirements are:

- Objective 1: 83%
- Objective 2: 4%
- Objective 3: 64%
- Objective 4: 39%
- Objective 5: 57%
- Recordable events: 70%
- Periodic Review: 93%

These results occur for several reasons: the checklist used in the review does not precisely match the suggestions of the Regulatory Guide or the requirements of the Rule, the Regulatory Guide is occasionally confusing, the Rule does not state explicitly that anything other than the five objectives needs to be addressed in a written QM plan, Objectives 4 and 5 of the Rule are too vaguely stated to communicate what is required, and it simply might not be possible to expect that response to a "performance-based" rule can provide adequate policies and procedures which will be successfully evaluated with a checklist.

The Federal Register notice (56 FR 34104) which published the Final Rule includes data on misadministrations, abnormal occurrences, and other events which occurred during the period 1989 to 1990 in Table 1. In this table there are 67 events listed, including:

- 11 wrong patients
- 29 wrong doses
- 8 wrong treatment sites
- 13 wrong radiopharmaceutical or radioisotope
- 3 failures to detect dislodged sources
- 2 unintended doses to fetus or nursing infant
- fraudulent imaging films submitted for patients resulting in excess doses

Of these events, the fact that nearly all (96%) of the facilities satisfactorily provided a procedure to correctly identify the patient will hopefully eliminate the "wrong patient" events. Objectives 1, 3, and 4 address the "wrong doses," "wrong treatment sites," "wrong radiopharmaceutical or radioisotope," and "failure to detect dislodged sources" events. Objectives 1, 3, and 4 are not uniformly addressed adequately in the written plans submitted, however the QM rule clearly attempts to address these events. With the exception of the doses to nursing infants or fetuses, and fraudulent use of films, all events of the type listed in Table 1 of 56 FR 34104 are likely to be eliminated or reduced as a result of the QM rule, and the accompanying QM plan reviews and inspections.

TABLES

Table 1: Results Summary - All Regions

Total letters included	1709
Type 1	35
Type 2	278
Type 3	1228
Negative Declarations	168

	Teletherapy		Gamma Stereotactic Radiosurgery		HDR Brachy-therapy		Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		129		3		101		520		1568		1019
Licensees which provided a QMP for this modality		126		3		75		435		1347		881
Missed any part of Objective 1 (Written Directive)	89%	112	100%	3	96%	72	86%	373	83%	1114	80%	709
Missed Objective 2 (Patient ID Verification)	2%	3	0	0	1%	1	7%	32	4%	54	4%	32
Missed any part of Objective 3 (Treatment Plans Verification)	63%	79	100%	3	63%	47	65%	282	0	0	0	0
Missed any part of Objective 4 (Each administration in accordance with W.D.)	29%	37	0	0	92%	69	80%	347	31%	414	30%	263
Missed any part of Objective 5 (Unintended Deviations)	62%	78	67%	2	55%	41	54%	237	59%	794	56%	495
Missed evaluation and response to recordable events	75%	94	100%	3	63%	47	69%	301	71%	961	69%	608
Missed any part of periodic review requirements	93%	117	100%	3	91%	68	89%	388	89%	1201	89%	783
Missed any of "Other" requirements	90%	114	100%	3	91%	68	94%	407	93%	1256	93%	819

Table 2: Summary - Region 1

Total letters included	635
Type 1	10
Type 2	44
Type 3	443
Negative Declarations	138

	Teletherapy		Gamma Stereotactic Radiosurgery		HDR Brachy-therapy		Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		40		1		38		181		590		322
Licensees which provided a QMP for this modality		40		1		30		154		436		262
Missed any part of Objective 1 (Written Directive)	85%	34	100%	1	93%	28	90%	138	87%	378	83%	218
Missed Objective 2 (Patient ID Verification)	3%	1	0		3%	1	4%	6	4%	18	4%	11
Missed any part of Objective 3 (Treatment Plans Verification)	73%	29	100%	1	77%	23	74%	114	0		0	
Missed any part of Objective 4 (Each administration in accordance with W.D.)	38%	15	0		90%	27	84%	129	40%	174	40%	103
Missed any part of Objective 5 (Unintended Deviations)	55%	22	0		57%	17	53%	82	61%	265	58%	153
Missed evaluation and response to recordable events	68%	27	100%	1	60%	18	68%	104	74%	322	73%	190
Missed any part of periodic review requirements	93%	37	100%	1	90%	27	90%	139	90%	392	89%	234
Missed any of "Other" requirements	85%	34	100%	1	90%	27	94%	144	94%	410	95%	248

Table 3: Summary - Region 2

Total letters included	183
Type 1	10
Type 2	34
Type 3	128
Negative Declarations	11

	Teletherapy		Gamma Stereotactic Radiosurgery		HDR Brachy-therapy		Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		14		1		10		56		166		136
Licensees which provided a QMP for this modality		13		1		9		45		148		121
Missed any part of Objective 1 (Written Directive)	85%	11	100%	1	100%	9	73%	33	71%	105	69%	84
Missed Objective 2 (Patient ID Verification)		0		0		0	7%	3	6%	9	3%	4
Missed any part of Objective 3 (Treatment Plans Verification)	69%	9	100%	1	44%	4	58%	26		0		0
Missed any part of Objective 4 (Each administration in accordance with W.D.)	15%	2		0	100%	9	71%	32	23%	34	21%	26
Missed any part of Objective 5 (Unintended Deviations)	54%	7	100%	1	44%	4	71%	32	60%	89	58%	70
Missed evaluation and response to recordable events	85%	11	100%	1	56%	5	80%	36	75%	111	74%	90
Missed any part of periodic review requirements	100%	13	100%	1	67%	6	87%	39	88%	130	88%	107
Missed any of "Other" requirements	92%	12	100%	1	89%	8	93%	42	94%	140	94%	114

Table 4: Summary - Region 3

Total letters included	711
Type 1	9
Type 2	164
Type 3	521
Negative Declarations	17

	Teletherapy		Gamma Stereotactic Radiosurgery		HDR Brachy-therapy		Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		64		1		49		222		643		441
Licensees which provided a QMP for this modality		62		1		34		185		601		419
Missed any part of Objective 1 (Written Directive)	90%	56	100%	1	95%	33	85%	157	81%	489	75%	314
Missed Objective 2 (Patient ID Verification)	3%	2		0		0	9%	16	3%	16	3%	10
Missed any part of Objective 3 (Treatment Plans Verification)	53%	33	100%	1	53%	18	57%	106		0		0
Missed any part of Objective 4 (Each administration in accordance with W.D.)	27%	17		0	91%	31	77%	143	24%	142	22%	93
Missed any part of Objective 5 (Unintended Deviations)	71%	44	100%	1	53%	18	50%	92	57%	340	49%	207
Missed evaluation and response to recordable events	81%	50	100%	1	68%	23	70%	129	75%	452	66%	278
Missed any part of periodic review requirements	92%	57	100%	1	97%	33	88%	163	90%	542	83%	347
Missed any of "Other" requirements	94%	58	100%	1	91%	31	93%	172	96%	576	88%	370

Table 5: Summary - Region 4

Total letters included	135
Type 1	4
Type 2	23
Type 3	107
Negative Declarations	1

	Teletherapy		Gamma Stereotactic Radiosurgery	HDR Brachy-therapy		Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		9	0		4		45		126		84
Licensees which provided a QMP for this modality		9	0		2		40		123		77
Missed any part of Objective 1 (Written Directive)	100%	9	0	100%	2	93%	37	90%	111	88%	68
Missed Objective 2 (Patient ID Verification)		0	0		0	18%	7	9%	11	9%	7
Missed any part of Objective 3 (Treatment Plans Verification)	78%	7	0	100%	2	78%	31		0		0
Missed any part of Objective 4 (Each administration in accordance with W.D.)	33%	3	0	100%	2	88%	35	43%	53	39%	30
Missed any part of Objective 5 (Unintended Deviations)	44%	4	0	100%	2	63%	25	68%	84	69%	53
Missed evaluation and response to recordable events	56%	5	0	50%	1	65%	26	50%	62	51%	39
Missed any part of periodic review requirements	100%	9	0	100%	2	93%	37	89%	110	95%	73
Missed any of "Other" requirements	89%	8	0	100%	2	98%	39	76%	93	74%	57

Table 6: Summary - Region 5

Total letters included	43
Type 1	2
Type 2	13
Type 3	27
Negative Declarations	1

	Teletherapy		Gamma Stereotactic Radiosurgery	HDR Brachy-therapy	Brachy-therapy		I-125 and/or I-131 Radio-pharmaceutical uses		Other Radio-pharmaceutical Therapy	
Letters sent out to date for this modality		1	0	0		15		42		35
Licensees which provided a QMP for this modality		1	0	0		10		42		29
Missed any part of Objective 1 (Written Directive)	100%	1	0	0	70%	7	71%	30	83%	24
Missed Objective 2 (Patient ID Verification)		0	0	0		0		0		0
Missed any part of Objective 3 (Treatment Plans Verification)		0	0	0	50%	5		0		0
Missed any part of Objective 4 (Each administration in accordance with W.D.)		0	0	0	70%	7	26%	11	38%	11
Missed any part of Objective 5 (Unintended Deviations)		0	0	0	50%	5	38%	15	38%	11
Missed evaluation and response to recordable events	100%	1	0	0	50%	5	31%	13	34%	10
Missed any part of periodic review requirements		0	0	0	90%	9	62%	26	72%	21
Missed any of "Other" requirements	100%	1	0	0	90%	9	86%	36	100%	29

Table 7: Teletherapy Responses - All Regions

Teletherapy Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with Teletherapy authorized on license	tot	129	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	126	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	107	85%
Missed any part of Objective 1 (Written Directive)	obj1	112	89%
Prepared a written directive (Type 3)	5	120	95%
Written directive complete (Type 3)	5a	31	25%
W.D. includes total dose (Type 3)	5b	62	49%
W.D. includes dose per fraction (Type 3)	5c	74	59%
W.D. includes treatment site (Type 3)	5d	68	54%
W.D. includes overall treatment period (Type 3)	5e	47	37%
W.D. includes order for specific patient (Type 3)	5f	48	38%
W.D. includes authorized user signature and date(Type 3)	5g	107	85%
Policy for oral revision to written directive (Type 1)	6a	50	40%
Policy for oral directive (Type 1)	6b	49	39%
Policy for written revision to written directive (Type 2)	7	44	35%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	3	2%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	79	63%
Plan of treatment prepared (Type 3)	9a	87	69%
Procedures for performing check of dose calculations (Type 3)	9b	107	85%
Independent check of full calibration measurements (Type 3)	9c	103	82%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	97	77%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	82	65%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	93	74%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	92	73%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	37	29%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	106	84%
Administration confirmed by person administering treatment (Type 3)	10b	91	72%
Missed any part of Objective 5 (Unintended Deviations)	obj5	78	62%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	66	52%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	48	38%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	32	25%
Missed any part of periodic review requirements	review	117	93%
Time intervals do not exceed 12 months (Type 1)	15	110	87%
Acceptable sample reviewed (Type 1)	16	67	53%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	11	9%
Procedures for evaluating effectiveness of QM program (Type 1)	18	52	41%
Records of each review and evaluation maintained for 3 years (Type 1)	20	43	34%
Missed any of Other (see below)	other	114	90%
W.D. and records of each teletherapy maintained three years (Type 1)	12	23	18%

Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	19	15%
Commitment for all workers to seek guidance (Type 2)	11	107	85%

Table 8: HDR Brachytherapy Responses - All Regions

HDR Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	101	
Negative declarations for HDR Brachytherapy	neg	0	
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	75	
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	62	83%
Missed any part of Objective 1 (Written Directive)	obj1	72	96%
Prepared a written directive (Type 3)	41	71	95%
Written directive complete (Type 3)	41a	10	13%
W.D. includes total dose (Type 3)	41b	47	63%
W.D. includes dose per fraction (Type 3)	41c	18	24%
W.D. includes treatment site (Type 3)	41d	46	61%
W.D. includes overall treatment period (Type 3)	41e	19	25%
W.D. includes order for specific patient (Type 3)	41f	41	55%
W.D. includes authorized user signature and date(Type 3)	41g	65	87%
Policy for oral revision to written directive (Type 1)	42a	26	35%
Policy for oral directive (Type 1)	42b	28	37%
Policy for written revision to written directive (Type 2)	43	23	31%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	1	1%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	47	63%
Plan of treatment prepared (Type 3)	45a	44	59%
Procedures for performing check of dose calculations (Type 3)	45b	60	80%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	57	76%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	54	72%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	69	92%
Policy to ensure administration in accordance with W.D. (Type 3)	46	63	84%
Administration confirmed by person administering treatment (Type 3)	47a	6	8%
Recording of sources by authorized user (Type 3)	47b	26	35%
Missed any part of Objective 5 (Unintended Deviations)	obj5	41	55%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	39	52%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	34	45%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	28	37%
Missed any part of periodic review requirements	review	68	91%
Time intervals do not exceed 12 months (Type 1)	51	62	83%
Acceptable sample reviewed (Type 1)	52	38	51%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	9	12%
Procedures for evaluating effectiveness of QM program (Type 1)	54	33	44%
Records of each review and evaluation maintained for 3 years (Type 1)	56	19	25%
Missed any of Other (see below)	other	68	91%
W.D. and records of each teletherapy maintained three years (Type 1)	48	13	17%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	10	13%
Commitment for all workers to seek guidance (Type 2)	47c	55	73%

Table 9: Brachytherapy Responses - All Regions

Brachytherapy Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with Brachytherapy authorized on license	tot	520	
Negative declarations for Brachytherapy	neg	7	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	435	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	349	80%
Missed any part of Objective 1 (Written Directive)	obj1	373	86%
Prepared a written directive (Type 3)	59	414	95%
Written directive complete (Type 3)	59a	177	41%
W.D. includes order for a specific patient (Type 3)	59b	279	64%
W.D. includes authorized user signature and date (Type 3)	59c	365	84%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	329	76%
W.D. includes number of sources prior to implantation (Type 3)	59f	303	70%
W.D. includes source strengths prior to implantation (Type 3)	59g	306	70%
W.D. includes the radioisotope after implantation (Type 3)	59i	275	63%
W.D. includes treatment site after implantation (Type 3)	59j	265	61%
W.D. includes total dose after implantation (Type 3)	59k	293	67%
Policy for oral revision to written directive (Type 1)	60a	159	37%
Policy for oral directive (Type 1)	60b	161	37%
Policy for written revision to written directive (Type 2)	61	136	31%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	32	7%

Missed any part of Objective 3 (Treatment Plans Verification)	63	153	35%
Plan of treatment prepared (Type 3)	63a	275	63%
Procedures for performing check of dose calculations (Type 3)	63b	300	69%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	293	67%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	240	55%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	347	80%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	356	82%
Administration confirmed by person administering treatment (Type 3)	64b	96	22%
Recording of sources by authorized user (Type 3)	64c	246	57%
Missed any part of Objective 5 (Unintended Deviations)	obj5	237	54%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	244	56%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	204	47%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	134	31%
Missed any part of periodic review requirements	review	388	89%
Time intervals do not exceed 12 months (Type 1)	69	386	89%
Acceptable sample reviewed (Type 1)	70	243	56%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	55	13%
Procedures for evaluating effectiveness of QM program (Type 1)	72	207	48%
Records of each review and evaluation maintained for 3 years (Type 1)	74	146	34%

Other missed	other	407	94%
W.D. and records of each teletherapy maintained three years (Type 1)	66	88	20%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	66	15%
Commitment for all workers to seek guidance (Type 2)	65	315	72%

Table 10: I-125 and/or I-131 > 30μCi Responses- All Regions

I-125 and/or I-131 > 30μCi Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	1568	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	170	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	1347	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	1046	78%
Missed any part of Objective 1 (Written Directive)	obj1	1114	83%
Prepared a written directive (Type 3)	77	1295	96%
Written directive complete (Type 3)	77a	768	57%
W.D. includes order for specific patient (Type 3)	77b	865	64%
W.D. includes authorized user signature and date(Type 3)	77c	1095	81%
W.D. includes dosage to be administered (Type 3)	77d	948	70%
Policy for oral revision to written directive (Type 1)	78a	566	42%
Policy for oral directive (Type 1)	78b	579	43%
Policy for written revision to written directive (Type 2)	79	496	37%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	54	4%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	414	31%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	1187	88%
Administration confirmed by person administering treatment (Type 3)	81b	970	72%
Missed any part of Objective 5 (Unintended Deviations)	obj5	794	59%

Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	684	51%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	646	48%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	386	29%
Missed any part of periodic review requirements	review	1201	89%
Time intervals do not exceed 12 months (Type 1)	86	1224	91%
Acceptable sample reviewed (Type 1)	87	631	47%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	165	12%
Procedures for evaluating effectiveness of QM program (Type 1)	89	649	48%
Records of each review and evaluation maintained for 3 years (Type 1)	91	513	38%
Missed any of Other (see below)	other	1256	93%
W.D. and records of each teletherapy maintained three years (Type 1)	83	335	25%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	176	13%
Commitment for all workers to seek guidance (Type 2)	82	1040	77%

Table 11: Therapeutic Radiopharmaceutical Responses - All Regions

Therapeutic Radiopharmaceutical Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	1019	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	11	
Licensees which provided a QMP for Therapeutic Radio-pharmaceuticals (Type 3)	92	881	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	699	79%
Missed any part of Objective 1 (Written Directive)	obj1	709	80%
Prepared a written directive (Type 3)	94	847	96%
Written directive complete (Type 3)	94a	493	56%
W.D. includes radiopharmaceutical (Type 3)	94b	614	70%
W.D. includes dosage (Type 3)	94c	641	73%
W.D. includes route of administration (Type 3)	94d	573	65%
W.D. includes order for specific patient (Type 3)	94e	576	65%
W.D. includes authorized user signature and date(Type 3)	94f	734	83%
Policy for oral revision to written directive (Type 1)	95a	390	44%
Policy for oral directive (Type 1)	95b	409	46%
Policy for written revision to written directive (Type 2)	96	348	40%
Missed Objective 2 (Patient Verification) (Type 3)	97	32	4%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	263	30%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	785	89%

Administration confirmed by person administering treatment (Type 3)	98b	637	72%
Missed any part of Objective 5 (Unintended Deviations)	obj5	495	56%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	471	53%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	437	50%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	273	31%
Missed any part of periodic review requirements	review	783	89%
Time intervals do not exceed 12 months (Type 1)	103	793	90%
Acceptable sample reviewed (Type 1)	104	443	50%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	110	12%
Procedures for evaluating effectiveness of QM program (Type 1)	106	450	51%
Records of each review and evaluation maintained for 3 years (Type 1)	108	343	39%
Missed any of Other (see below)	other	819	93%
W.D. and records of each teletherapy maintained three years (Type 1)	100	228	26%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	124	14%
Commitment for all workers to seek guidance (Type 2)	99	697	79%

Table 12: Gamma Stereotactic Radiosurgery Responses

Gamma Stereotactic Radiosurgery Responses - All regions	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		1709	
Letters sent to facilities with Gamma Stereotactic Radiosurgery authorized on license	tot	3	
Negative declarations for Gamma Stereotactic Radiosurgery	neg	0	
Licensees which provided a QMP for Gamma Stereotactic Radiosurgery (Type 3)	21	3	
Licensees which certified implementation of the QMP for Gamma Stereotactic Radiosurgery (Type 3)	22	2	67%
Missed any part of Objective 1 (Written Directive)	obj1	3	100%
Prepared a written directive (Type 3)	23	3	100%
Written directive complete (Type 3)	23a	2	67%
W.D. includes target coordinates (Type 3)	23b	3	100%
W.D. includes collimator size (Type 3)	23c	3	100%
W.D. includes plug pattern (Type 3)	23d	3	100%
W.D. includes total dose (Type 3)	23e	3	100%
W.D. includes order for specific patient (Type 3)	23f	3	100%
W.D. includes authorized user signature and date(Type 3)	23g	2	67%
Policy for oral revision to written directive (Type 1)	24a	1	33%
Policy for oral directive (Type 1)	24b	1	33%
Policy for written revision to written directive (Type 2)	25	1	33%
Missed Objective 2 (Patient ID Verification) (Type 3)	26	3	100%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	3	100%
Plan of treatment prepared (Type 3)	27a	3	100%
Procedures for performing check of dose calculations (Type 3)	27b	0	100%

Verification of computer-generated dose calculations (Type 3)	27c	1	33%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	27d	1	33%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	0	0%
Policy to ensure administration in accordance with W.D. (Type 3)	28a	3	0%
Administration confirmed by person administering treatment (Type 3)	28b	3	100%
Missed any part of Objective 5 (Unintended Deviations)	obj5	2	67%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	31	3	100%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	32a	1	33%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	32b	0	0%
Missed any part of periodic review requirements	review	3	100%
Time intervals do not exceed 12 months (Type 1)	33	3	100%
Acceptable sample reviewed (Type 1)	34	0	0%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	35	0	0%
Procedures for evaluating effectiveness of QM program (Type 1)	36	0	0%
Records of each review and evaluation maintained for 3 years (Type 1)	38	0	0%
Missed any of Other (see below)	other	3	100%
W.D. and records of each Gamma Stereotactic Radiosurgery maintained three years (Type 1)	30	0	0%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	29	0	0%
Commitment for all workers to seek guidance (Type 2)	37	0	0%

Table 13: Teletherapy Responses - Region 1

Teletherapy Responses - Region 1	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		635	
Letters sent to facilities with Teletherapy authorized on license	tot	40	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	40	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	32	80%
Missed any part of Objective 1 (Written Directive)	obj1	34	85%
Prepared a written directive (Type 3)	5	38	95%
Written directive complete (Type 3)	5a	11	28%
W.D. includes total dose (Type 3)	5b	26	65%
W.D. includes dose per fraction (Type 3)	5c	28	70%
W.D. includes treatment site (Type 3)	5d	27	68%
W.D. includes overall treatment period (Type 3)	5e	18	45%
W.D. includes order for specific patient (Type 3)	5f	19	48%
W.D. includes authorized user signature and date(Type 3)	5g	34	85%
Policy for oral revision to written directive (Type 1)	6a	14	35%
Policy for oral directive (Type 1)	6b	15	38%
Policy for written revision to written directive (Type 2)	7	14	35%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	1	2%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	29	73%
Plan of treatment prepared (Type 3)	9a	30	75%
Procedures for performing check of dose calculations (Type 3)	9b	29	73%
Independent check of full calibration measurements (Type 3)	9c	28	70%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	28	70%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	18	45%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	28	70%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	24	60%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	15	38%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	32	80%
Administration confirmed by person administering treatment (Type 3)	10b	25	63%
Missed any part of Objective 5 (Unintended Deviations)	obj5	22	55%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	22	55%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	18	45%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	13	33%
Missed any part of periodic review requirements	review	37	93%
Time intervals do not exceed 12 months (Type 1)	15	36	90%
Acceptable sample reviewed (Type 1)	16	21	53%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	3	8%
Procedures for evaluating effectiveness of QM program (Type 1)	18	15	38%
Records of each review and evaluation maintained for 3 years (Type 1)	20	17	43%

Missed any of Other (see below)	other	34	85%
W.D. and records of each teletherapy maintained three years (Type 1)	12	11	28%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	8	20%
Commitment for all workers to seek guidance (Type 2)	11	30	75%

Table 14: HDR Brachytherapy Responses - Region 1

HDR Brachytherapy Responses - Region 1	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		635	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	38	
Negative declarations for HDR Brachytherapy	neg	0	
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	30	
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	22	73%
Missed any part of Objective 1 (Written Directive)	obj1	28	93%
Prepared a written directive (Type 3)	41	28	93%
Written directive complete (Type 3)	41a	5	17%
W.D. includes total dose (Type 3)	41b	18	60%
W.D. includes dose per fraction (Type 3)	41c	6	20%
W.D. includes treatment site (Type 3)	41d	16	53%
W.D. includes overall treatment period (Type 3)	41e	9	30%
W.D. includes order for specific patient (Type 3)	41f	15	50%
W.D. includes authorized user signature and date(Type 3)	41g	25	83%
Policy for oral revision to written directive (Type 1)	42a	11	37%
Policy for oral directive (Type 1)	42b	11	37%
Policy for written revision to written directive (Type 2)	43	10	33%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	1	3%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	23	77%
Plan of treatment prepared (Type 3)	45a	16	53%
Procedures for performing check of dose calculations (Type 3)	45b	23	77%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	23	77%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	19	63%

Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	27	90%
Policy to ensure administration in accordance with W.D. (Type 3)	46	23	77%
Administration confirmed by person administering treatment (Type 3)	47a	3	10%
Recording of sources by authorized user (Type 3)	47b	10	33%
Missed any part of Objective 5 (Unintended Deviations)	obj5	17	57%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	15	50%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	13	43%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	12	40%
Missed any part of periodic review requirements	review	27	90%
Time intervals do not exceed 12 months (Type 1)	51	21	70%
Acceptable sample reviewed (Type 1)	52	13	43%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	3	10%
Procedures for evaluating effectiveness of QM program (Type 1)	54	13	43%
Records of each review and evaluation maintained for 3 years (Type 1)	56	8	27%
Missed any of Other (see below)	other	27	90%
W.D. and records of each HDR Brachytherapy maintained three years (Type 1)	48	6	20%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	6	20%
Commitment for all workers to seek guidance (Type 2)	47c	18	60%

Table 15: Brachytherapy Responses - Region 1

Brachytherapy Responses - Region 1	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		635	
Letters sent to facilities with Brachytherapy authorized on license	tot	181	
Negative declarations for Brachytherapy	neg	1	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	154	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	104	68%
Missed any part of Objective 1 (Written Directive)	obj1	138	90%
Prepared a written directive (Type 3)	59	144	94%
Written directive complete (Type 3)	59a	42	27%
W.D. includes order for a specific patient (Type 3)	59b	83	54%
W.D. includes authorized user signature and date (Type 3)	59c	117	76%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	109	71%
W.D. includes number of sources prior to implantation (Type 3)	59f	96	62%
W.D. includes source strengths prior to implantation (Type 3)	59g	99	64%
W.D. includes the radioisotope after implantation (Type 3)	59i	76	49%
W.D. includes treatment site after implantation (Type 3)	59j	76	49%
W.D. includes total dose after implantation (Type 3)	59k	86	56%
Policy for oral revision to written directive (Type 1)	60a	50	32%
Policy for oral directive (Type 1)	60b	50	32%
Policy for written revision to written directive (Type 2)	61	41	27%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	6	4%
Missed any part of Objective 3 (Treatment Plans Verification)	63	40	26%
Plan of treatment prepared (Type 3)	63a	93	60%
Procedures for performing check of dose calculations (Type 3)	63b	99	64%

Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	97	63%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	68	44%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	129	84%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	118	77%
Administration confirmed by person administering treatment (Type 3)	64b	27	18%
Recording of sources by authorized user (Type 3)	64c	73	47%
Missed any part of Objective 5 (Unintended Deviations)	obj5	82	53%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	89	58%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	74	48%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	50	32%
Missed any part of periodic review requirements	review	139	90%
Time intervals do not exceed 12 months (Type 1)	69	132	86%
Acceptable sample reviewed (Type 1)	70	79	51%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	19	12%
Procedures for evaluating effectiveness of QM program (Type 1)	72	64	42%
Records of each review and evaluation maintained for 3 years (Type 1)	74	47	31%
Other missed	other	144	94%
W.D. and records of each brachytherapy maintained three years (Type 1)	66	34	22%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	30	19%
Commitment for all workers to seek guidance (Type 2)	65	95	62%

Table 16: I-125 and/or I-131 > 30μCi Responses- Region 1

I-125 and/or I-131 > 30μCi Responses - Region 1	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		635	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	590	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	140	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	436	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	280	64%
Missed any part of Objective 1 (Written Directive)	obj1	378	87%
Prepared a written directive (Type 3)	77	415	95%
Written directive complete (Type 3)	77a	206	47%
W.D. includes order for specific patient (Type 3)	77b	248	57%
W.D. includes authorized user signature and date(Type 3)	77c	308	71%
W.D. includes dosage to be administered (Type 3)	77d	289	66%
Policy for oral revision to written directive (Type 1)	78a	169	39%
Policy for oral directive (Type 1)	78b	167	38%
Policy for written revision to written directive (Type 2)	79	122	28%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	18	4%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	174	40%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	358	82%
Administration confirmed by person administering treatment (Type 3)	81b	279	64%
Missed any part of Objective 5 (Unintended Deviations)	obj5	265	61%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	220	50%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	192	44%

Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	114	26%
Missed any part of periodic review requirements	review	392	90%
Time intervals do not exceed 12 months (Type 1)	86	388	89%
Acceptable sample reviewed (Type 1)	87	188	43%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	50	11%
Procedures for evaluating effectiveness of QM program (Type 1)	89	182	42%
Records of each review and evaluation maintained for 3 years (Type 1)	91	150	34%
Missed any of Other (see below)	other	410	94%
W.D. and records of each I-125 and/or I-131 > 30μCi maintained three years (Type 1)	83	116	27%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	72	17%
Commitment for all workers to seek guidance (Type 2)	82	279	64%

Table 17: Therapeutic Radiopharmaceutical Responses- Region 1

Therapeutic Radiopharmaceutical Responses - Region 1	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		635	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	322	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	2	
Licensees which provided a QMP for Therapeutic Radio-pharmaceuticals (Type 3)	92	262	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	168	64%
Missed any part of Objective 1 (Written Directive)	obj1	218	83%
Prepared a written directive (Type 3)	94	247	94%
Written directive complete (Type 3)	94a	122	47%
W.D. includes radiopharmaceutical (Type 3)	94b	166	63%
W.D. includes dosage (Type 3)	94c	178	68%
W.D. includes route of administration (Type 3)	94d	149	57%
W.D. includes order for specific patient (Type 3)	94e	149	57%
W.D. includes authorized user signature and date(Type 3)	94f	188	72%
Policy for oral revision to written directive (Type 1)	95a	112	43%
Policy for oral directive (Type 1)	95b	115	44%
Policy for written revision to written directive (Type 2)	96	86	33%
Missed Objective 2 (Patient Verification) (Type 3)	97	11	4%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	103	39%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	217	83%
Administration confirmed by person administering treatment (Type 3)	98b	167	64%

Missed any part of Objective 5 (Unintended Deviations)	obj5	153	58%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	141	54%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	120	46%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	72	27%
Missed any part of periodic review requirements	review	234	89%
Time intervals do not exceed 12 months (Type 1)	103	228	87%
Acceptable sample reviewed (Type 1)	104	127	48%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	31	12%
Procedures for evaluating effectiveness of QM program (Type 1)	106	120	46%
Records of each review and evaluation maintained for 3 years (Type 1)	108	94	36%
Missed any of Other (see below)	other	248	95%
W.D. and records of each Therapeutic Radiopharmaceuticals maintained three years (Type 1)	100	66	25%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	49	19%
Commitment for all workers to seek guidance (Type 2)	99	172	66%

Table 18: Teletherapy Responses- Region 2

Teletherapy Responses - Region 2	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		183	
Letters sent to facilities with Teletherapy authorized on license	tot	14	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	13	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	10	77%
Missed any part of Objective 1 (Written Directive)	obj1	11	85%
Prepared a written directive (Type 3)	5	12	92%
Written directive complete (Type 3)	5a	4	31%
W.D. includes total dose (Type 3)	5b	6	46%
W.D. includes dose per fraction (Type 3)	5c	8	62%
W.D. includes treatment site (Type 3)	5d	7	54%
W.D. includes overall treatment period (Type 3)	5e	6	46%
W.D. includes order for specific patient (Type 3)	5f	7	54%
W.D. includes authorized user signature and date(Type 3)	5g	11	85%
Policy for oral revision to written directive (Type 1)	6a	5	38%
Policy for oral directive (Type 1)	6b	5	38%
Policy for written revision to written directive (Type 2)	7	3	23%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	9	69%
Plan of treatment prepared (Type 3)	9a	8	62%
Procedures for performing check of dose calculations (Type 3)	9b	12	92%
Independent check of full calibration measurements (Type 3)	9c	11	85%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	9	69%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	8	62%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	7	54%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	10	77%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	2	15%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	11	85%
Administration confirmed by person administering treatment (Type 3)	10b	11	85%
Missed any part of Objective 5 (Unintended Deviations)	obj5	7	54%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	6	46%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	6	46%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	2	15%
Missed any part of periodic review requirements	review	13	100%
Time intervals do not exceed 12 months (Type 1)	15	11	85%
Acceptable sample reviewed (Type 1)	16	7	54%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	0	0%
Procedures for evaluating effectiveness of QM program (Type 1)	18	4	31%
Records of each review and evaluation maintained for 3 years (Type 1)	20	2	15%
Missed any of Other (see below)	other	12	92%
W.D. and records of each teletherapy maintained three years (Type 1)	12	1	8%

Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	1	8%
Commitment for all workers to seek guidance (Type 2)	11	10	77%

Table 19: HDR Brachytherapy Responses- Region 2

HDR Brachytherapy Responses - Region 2	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		183	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	10	
Negative declarations for HDR Brachytherapy	neg	0	
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	9	
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	9	100%
Missed any part of Objective 1 (Written Directive)	obj1	9	100%
Prepared a written directive (Type 3)	41	9	100%
Written directive complete (Type 3)	41a	0	0%
W.D. includes total dose (Type 3)	41b	6	67%
W.D. includes dose per fraction (Type 3)	41c	2	22%
W.D. includes treatment site (Type 3)	41d	6	67%
W.D. includes overall treatment period (Type 3)	41e	1	11%
W.D. includes order for specific patient (Type 3)	41f	6	67%
W.D. includes authorized user signature and date(Type 3)	41g	9	100%
Policy for oral revision to written directive (Type 1)	42a	6	67%
Policy for oral directive (Type 1)	42b	7	78%
Policy for written revision to written directive (Type 2)	43	5	56%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	4	44%
Plan of treatment prepared (Type 3)	45a	8	89%
Procedures for performing check of dose calculations (Type 3)	45b	8	89%

Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	6	67%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	7	78%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	9	100%
Policy to ensure administration in accordance with W.D. (Type 3)	46	9	100%
Administration confirmed by person administering treatment (Type 3)	47a	0	0%
Recording of sources by authorized user (Type 3)	47b	1	11%
Missed any part of Objective 5 (Unintended Deviations)	obj5	4	44%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	6	67%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	5	56%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	4	44%
Missed any part of periodic review requirements	review	6	67%
Time intervals do not exceed 12 months (Type 1)	51	9	100%
Acceptable sample reviewed (Type 1)	52	9	100%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	3	33%
Procedures for evaluating effectiveness of QM program (Type 1)	54	6	67%
Records of each review and evaluation maintained for 3 years (Type 1)	56	3	33%
Missed any of Other (see below)	other	8	89%
W.D. and records of each HDR Brachytherapy maintained three years (Type 1)	48	2	22%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	1	11%
Commitment for all workers to seek guidance (Type 2)	47c	9	100%

Table 20: Brachytherapy Responses- Region 2

Brachytherapy Responses - Region 2	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		183	
Letters sent to facilities with Brachytherapy authorized on license	tot	56	
Negative declarations for Brachytherapy	neg	2	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	45	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	42	93%
Missed any part of Objective 1 (Written Directive)	obj1	33	73%
Prepared a written directive (Type 3)	59	42	93%
Written directive complete (Type 3)	59a	22	49%
W.D. includes order for a specific patient (Type 3)	59b	34	76%
W.D. includes authorized user signature and date (Type 3)	59c	38	84%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	36	80%
W.D. includes number of sources prior to implantation (Type 3)	59f	31	69%
W.D. includes source strengths prior to implantation (Type 3)	59g	33	73%
W.D. includes the radioisotope after implantation (Type 3)	59i	33	73%
W.D. includes treatment site after implantation (Type 3)	59j	30	67%
W.D. includes total dose after implantation (Type 3)	59k	32	71%
Policy for oral revision to written directive (Type 1)	60a	24	53%
Policy for oral directive (Type 1)	60b	25	56%
Policy for written revision to written directive (Type 2)	61	20	44%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	3	7%

Missed any part of Objective 3 (Treatment Plans Verification)	63	19	42%
Plan of treatment prepared (Type 3)	63a	34	76%
Procedures for performing check of dose calculations (Type 3)	63b	32	71%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	28	62%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	27	60%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	32	71%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	38	84%
Administration confirmed by person administering treatment (Type 3)	64b	13	29%
Recording of sources by authorized user (Type 3)	64c	31	69%
Missed any part of Objective 5 (Unintended Deviations)	obj5	32	71%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	21	47%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	14	31%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	9	20%
Missed any part of periodic review requirements	review	39	87%
Time intervals do not exceed 12 months (Type 1)	69	41	91%
Acceptable sample reviewed (Type 1)	70	25	56%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	6	13%
Procedures for evaluating effectiveness of QM program (Type 1)	72	16	36%
Records of each review and evaluation maintained for 3 years (Type 1)	74	11	24%

Other missed	other	42	93%
W.D. and records of each Brachytherapy maintained three years (Type 1)	66	6	13%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	4	9%
Commitment for all workers to seek guidance (Type 2)	65	36	80%

Table 21: I-125 and/or I-131 > 30μCi Responses - Region 2

I-125 and/or I-131 > 30μCi Responses - Region 2	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		183	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	166	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	11	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	148	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	122	82%
Missed any part of Objective 1 (Written Directive)	obj1	105	71%
Prepared a written directive (Type 3)	77	145	98%
Written directive complete (Type 3)	77a	84	57%
W.D. includes order for specific patient (Type 3)	77b	98	66%
W.D. includes authorized user signature and date(Type 3)	77c	120	81%
W.D. includes dosage to be administered (Type 3)	77d	105	71%
Policy for oral revision to written directive (Type 1)	78a	81	55%
Policy for oral directive (Type 1)	78b	90	61%
Policy for written revision to written directive (Type 2)	79	75	51%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	9	6%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	34	23%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	130	88%
Administration confirmed by person administering treatment (Type 3)	81b	119	80%
Missed any part of Objective 5 (Unintended Deviations)	obj5	89	60%

Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	70	47%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	66	45%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	37	25%
Missed any part of periodic review requirements	review	130	88%
Time intervals do not exceed 12 months (Type 1)	86	134	91%
Acceptable sample reviewed (Type 1)	87	72	49%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	18	12%
Procedures for evaluating effectiveness of QM program (Type 1)	89	78	53%
Records of each review and evaluation maintained for 3 years (Type 1)	91	60	41%
Missed any of Other (see below)	other	140	95%
W.D. and records of each I-125 and/or I-131 > 30μCi maintained three years (Type 1)	83	39	26%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	16	11%
Commitment for all workers to seek guidance (Type 2)	82	120	81%

Table 22: Therapeutic Radiopharmaceutical Responses - Region 2

Therapeutic Radiopharmaceutical Responses - Region 2	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		183	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	136	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	4	
Licensees which provided a QMP for Therapeutic Radiopharmaceuticals (Type 3)	92	121	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	103	85%
Missed any part of Objective 1 (Written Directive)	obj1	84	69%
Prepared a written directive (Type 3)	94	117	97%
Written directive complete (Type 3)	94a	73	60%
W.D. includes radiopharmaceutical (Type 3)	94b	93	77%
W.D. includes dosage (Type 3)	94c	94	78%
W.D. includes route of administration (Type 3)	94d	86	71%
W.D. includes order for specific patient (Type 3)	94e	84	69%
W.D. includes authorized user signature and date(Type 3)	94f	101	83%
Policy for oral revision to written directive (Type 1)	95a	67	55%
Policy for oral directive (Type 1)	95b	75	62%
Policy for written revision to written directive (Type 2)	96	62	51%
Missed Objective 2 (Patient Verification) (Type 3)	97	4	3%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	26	21%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	106	88%

Administration confirmed by person administering treatment (Type 3)	98b	99	82%
Missed any part of Objective 5 (Unintended Deviations)	obj5	70	58%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	61	50%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	57	47%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	31	26%
Missed any part of periodic review requirements	review	107	88%
Time intervals do not exceed 12 months (Type 1)	103	110	91%
Acceptable sample reviewed (Type 1)	104	63	52%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	14	12%
Procedures for evaluating effectiveness of QM program (Type 1)	106	67	55%
Records of each review and evaluation maintained for 3 years (Type 1)	108	50	41%
Missed any of Other (see below)	other	114	94%
W.D. and records of each Therapeutic Radiopharmaceutical maintained three years (Type 1)	100	36	30%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	12	10%
Commitment for all workers to seek guidance (Type 2)	99	99	82%

Table 23: Teletherapy Responses - Region 3

Teletherapy Responses - Region 3	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		711	
Letters sent to facilities with Teletherapy authorized on license	tot	64	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	61	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	55	89%
Missed any part of Objective 1 (Written Directive)	obj1	56	90%
Prepared a written directive (Type 3)	5	59	95%
Written directive complete (Type 3)	5a	15	24%
W.D. includes total dose (Type 3)	5b	26	42%
W.D. includes dose per fraction (Type 3)	5c	31	50%
W.D. includes treatment site (Type 3)	5d	29	47%
W.D. includes overall treatment period (Type 3)	5e	21	34%
W.D. includes order for specific patient (Type 3)	5f	20	32%
W.D. includes authorized user signature and date(Type 3)	5g	52	84%
Policy for oral revision to written directive (Type 1)	6a	30	48%
Policy for oral directive (Type 1)	6b	28	45%
Policy for written revision to written directive (Type 2)	7	26	42%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	1	3%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	33	53%
Plan of treatment prepared (Type 3)	9a	42	68%
Procedures for performing check of dose calculations (Type 3)	9b	57	92%
Independent check of full calibration measurements (Type 3)	9c	56	90%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	51	82%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	51	82%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	52	84%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	51	82%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	17	27%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	53	85%
Administration confirmed by person administering treatment (Type 3)	10b	47	76%
Missed any part of Objective 5 (Unintended Deviations)	obj5	44	71%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	29	47%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	18	29%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	12	19%
Missed any part of periodic review requirements	review	57	92%
Time intervals do not exceed 12 months (Type 1)	15	53	85%
Acceptable sample reviewed (Type 1)	16	33	53%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	7	11%
Procedures for evaluating effectiveness of QM program (Type 1)	18	28	45%
Records of each review and evaluation maintained for 3 years (Type 1)	20	18	29%
Missed any of Other (see below)	other	58	94%
W.D. and records of each teletherapy maintained three years (Type 1)	12	9	15%

Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	9	15%
Commitment for all workers to seek guidance (Type 2)	11	59	95%

Table 24: HDR Brachytherapy Responses - Region 3

HDR Brachytherapy Responses - Region 3	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		711	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	49	
Negative declarations for HDR Brachytherapy	neg	0	
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	34	
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	29	85%
Missed any part of Objective 1 (Written Directive)	obj1	33	97%
Prepared a written directive (Type 3)	41	32	94%
Written directive complete (Type 3)	41a	5	15%
W.D. includes total dose (Type 3)	41b	23	68%
W.D. includes dose per fraction (Type 3)	41c	10	29%
W.D. includes treatment site (Type 3)	41d	24	71%
W.D. includes overall treatment period (Type 3)	41e	9	26%
W.D. includes order for specific patient (Type 3)	41f	20	59%
W.D. includes authorized user signature and date(Type 3)	41g	29	85%
Policy for oral revision to written directive (Type 1)	42a	9	26%
Policy for oral directive (Type 1)	42b	10	29%
Policy for written revision to written directive (Type 2)	43	8	24%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	18	53%
Plan of treatment prepared (Type 3)	45a	20	59%
Procedures for performing check of dose calculations (Type 3)	45b	27	79%

Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	27	79%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	27	79%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	31	91%
Policy to ensure administration in accordance with W.D. (Type 3)	46	29	85%
Administration confirmed by person administering treatment (Type 3)	47a	3	9%
Recording of sources by authorized user (Type 3)	47b	15	44%
Missed any part of Objective 5 (Unintended Deviations)	obj5	18	53%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	18	53%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	16	47%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	11	32%
Missed any part of periodic review requirements	review	33	97%
Time intervals do not exceed 12 months (Type 1)	51	30	88%
Acceptable sample reviewed (Type 1)	52	16	47%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	3	9%
Procedures for evaluating effectiveness of QM program (Type 1)	54	14	41%
Records of each review and evaluation maintained for 3 years (Type 1)	56	8	24%

Missed any of Other (see below)	other	31	91%
W.D. and records of each HDR Brachytherapy authorized maintained three years (Type 1)	48	5	15%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	3	9%
Commitment for all workers to seek guidance (Type 2)	47c	26	76%

Table 25: Brachytherapy Responses - Region 3

Brachytherapy Responses - Region 3	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		711	
Letters sent to facilities with Brachytherapy authorized on license	tot	222	
Negative declarations for Brachytherapy	neg	3	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	185	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	160	86%
Missed any part of Objective 1 (Written Directive)	obj1	157	85%
Prepared a written directive (Type 3)	59	178	96%
Written directive complete (Type 3)	59a	99	54%
W.D. includes order for a specific patient (Type 3)	59b	134	72%
W.D. includes authorized user signature and date (Type 3)	59c	168	91%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	149	81%
W.D. includes number of sources prior to implantation (Type 3)	59f	142	77%
W.D. includes source strengths prior to implantation (Type 3)	59g	141	76%
W.D. includes the radioisotope after implantation (Type 3)	59i	141	76%
W.D. includes treatment site after implantation (Type 3)	59j	135	73%
W.D. includes total dose after implantation (Type 3)	59k	145	78%
Policy for oral revision to written directive (Type 1)	60a	71	38%
Policy for oral directive (Type 1)	60b	70	38%
Policy for written revision to written directive (Type 2)	61	64	35%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	16	9%

Missed any part of Objective 3 (Treatment Plans Verification)	63	79	43%
Plan of treatment prepared (Type 3)	63a	123	66%
Procedures for performing check of dose calculations (Type 3)	63b	137	74%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	134	72%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	114	62%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	143	77%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	157	85%
Administration confirmed by person administering treatment (Type 3)	64b	46	25%
Recording of sources by authorized user (Type 3)	64c	119	64%
Missed any part of Objective 5 (Unintended Deviations)	obj5	92	50%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	106	57%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	96	52%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	56	30%
Missed any part of periodic review requirements	review	163	88%
Time intervals do not exceed 12 months (Type 1)	69	167	90%
Acceptable sample reviewed (Type 1)	70	113	61%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	25	14%
Procedures for evaluating effectiveness of QM program (Type 1)	72	97	52%
Records of each review and evaluation maintained for 3 years (Type 1)	74	69	37%

Other missed	other	172	93%
W.D. and records of each Brachytherapy maintained three years (Type 1)	66	36	19%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	26	14%
Commitment for all workers to seek guidance (Type 2)	65	144	78%

Table 26: I-125 and/or I-131 > 30μCi Responses - Region 3

I-125 and/or I-131 > 30μCi Responses - Region 3	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		711	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	643	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	17	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	601	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	512	85%
Missed any part of Objective 1 (Written Directive)	obj1	489	81%
Prepared a written directive (Type 3)	77	580	97%
Written directive complete (Type 3)	77a	368	61%
W.D. includes order for specific patient (Type 3)	77b	401	67%
W.D. includes authorized user signature and date(Type 3)	77c	528	88%
W.D. includes dosage to be administered (Type 3)	77d	429	71%
Policy for oral revision to written directive (Type 1)	78a	264	44%
Policy for oral directive (Type 1)	78b	271	45%
Policy for written revision to written directive (Type 2)	79	250	42%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	16	3%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	142	24%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	560	93%
Administration confirmed by person administering treatment (Type 3)	81b	470	78%
Missed any part of Objective 5 (Unintended Deviations)	obj5	340	57%

Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	307	51%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	310	52%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	149	25%
Missed any part of periodic review requirements	review	542	90%
Time intervals do not exceed 12 months (Type 1)	86	559	93%
Acceptable sample reviewed (Type 1)	87	297	49%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	70	12%
Procedures for evaluating effectiveness of QM program (Type 1)	89	294	49%
Records of each review and evaluation maintained for 3 years (Type 1)	91	217	36%
Missed any of Other (see below)	other	576	96%
W.D. and records of each I-125 and/or I-131 > 30μCi maintained three years (Type 1)	83	107	18%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	43	7%
Commitment for all workers to seek guidance (Type 2)	82	524	87%

Table 27: Therapeutic Radiopharmaceutical Responses - Region 3

Therapeutic Radiopharmaceutical Responses - Region 3	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		711	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	441	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	5	
Licensees which provided a QMP for Therapeutic Radio-pharmaceuticals (Type 3)	92	389	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	336	86%
Missed any part of Objective 1 (Written Directive)	obj1	314	81%
Prepared a written directive (Type 3)	94	377	97%
Written directive complete (Type 3)	94a	233	60%
W.D. includes radiopharmaceutical (Type 3)	94b	273	70%
W.D. includes dosage (Type 3)	94c	284	73%
W.D. includes route of administration (Type 3)	94d	262	67%
W.D. includes order for specific patient (Type 3)	94e	263	68%
W.D. includes authorized user signature and date(Type 3)	94f	348	89%
Policy for oral revision to written directive (Type 1)	95a	175	45%
Policy for oral directive (Type 1)	95b	182	47%
Policy for written revision to written directive (Type 2)	96	168	43%
Missed Objective 2 (Patient Verification) (Type 3)	97	10	3%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	93	24%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	364	94%

Administration confirmed by person administering treatment (Type 3)	98b	300	77%
Missed any part of Objective 5 (Unintended Deviations)	obj5	207	53%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	207	53%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	210	54%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	111	29%
Missed any part of periodic review requirements	review	347	89%
Time intervals do not exceed 12 months (Type 1)	103	361	93%
Acceptable sample reviewed (Type 1)	104	206	53%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	49	13%
Procedures for evaluating effectiveness of QM program (Type 1)	106	199	51%
Records of each review and evaluation maintained for 3 years (Type 1)	108	143	37%
Missed any of Other (see below)	other	370	95%
W.D. and records of each Therapeutic Radiopharmaceutical maintained three years (Type 1)	100	80	21%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	33	8%
Commitment for all workers to seek guidance (Type 2)	99	338	87%

Table 28: Teletherapy Responses - Region 4

Teletherapy Responses - Region 4	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		135	
Letters sent to facilities with Teletherapy authorized on license	tot	9	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	9	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	8	89%
Missed any part of Objective 1 (Written Directive)	obj1	9	100%
Prepared a written directive (Type 3)	5	9	100%
Written directive complete (Type 3)	5a	1	11%
W.D. includes total dose (Type 3)	5b	3	33%
W.D. includes dose per fraction (Type 3)	5c	6	67%
W.D. includes treatment site (Type 3)	5d	4	44%
W.D. includes overall treatment period (Type 3)	5e	1	11%
W.D. includes order for specific patient (Type 3)	5f	2	22%
W.D. includes authorized user signature and date(Type 3)	5g	8	89%
Policy for oral revision to written directive (Type 1)	6a	0	0%
Policy for oral directive (Type 1)	6b	0	0%
Policy for written revision to written directive (Type 2)	7	0	0%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	7	78%
Plan of treatment prepared (Type 3)	9a	6	67%
Procedures for performing check of dose calculations (Type 3)	9b	7	78%
Independent check of full calibration measurements (Type 3)	9c	6	67%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	7	78%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	4	44%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	5	56%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	5	56%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	3	33%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	8	89%
Administration confirmed by person administering treatment (Type 3)	10b	6	67%
Missed any part of Objective 5 (Unintended Deviations)	obj5	4	44%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	7	78%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	5	56%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	4	44%
Missed any part of periodic review requirements	review	9	100%
Time intervals do not exceed 12 months (Type 1)	15	8	89%
Acceptable sample reviewed (Type 1)	16	5	56%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	0	0%
Procedures for evaluating effectiveness of QM program (Type 1)	18	4	44%
Records of each review and evaluation maintained for 3 years (Type 1)	20	5	56%
Missed any of Other (see below)	other	8	89%
W.D. and records of each teletherapy maintained three years (Type 1)	12	2	22%

Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	1	11%
Commitment for all workers to seek guidance (Type 2)	11	7	78%

Table 29: HDR Brachytherapy Responses - Region 4

HDR Brachytherapy Responses - Region 4	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		135	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	4	
Negative declarations for HDR Brachytherapy	neg	0	
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	2	
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	2	100%
Missed any part of Objective 1 (Written Directive)	obj1	2	100%
Prepared a written directive (Type 3)	41	2	100%
Written directive complete (Type 3)	41a	0	0%
W.D. includes total dose (Type 3)	41b	0	0%
W.D. includes dose per fraction (Type 3)	41c	0	0%
W.D. includes treatment site (Type 3)	41d	0	0%
W.D. includes overall treatment period (Type 3)	41e	0	0%
W.D. includes order for specific patient (Type 3)	41f	0	0%
W.D. includes authorized user signature and date(Type 3)	41g	2	100%
Policy for oral revision to written directive (Type 1)	42a	0	0%
Policy for oral directive (Type 1)	42b	0	0%
Policy for written revision to written directive (Type 2)	43	0	0%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	2	100%
Plan of treatment prepared (Type 3)	45a	0	0%
Procedures for performing check of dose calculations (Type 3)	45b	2	100%

Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	1	50%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	1	50%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	2	100%
Policy to ensure administration in accordance with W.D. (Type 3)	46	2	100%
Administration confirmed by person administering treatment (Type 3)	47a	0	0%
Recording of sources by authorized user (Type 3)	47b	0	0%
Missed any part of Objective 5 (Unintended Deviations)	obj5	2	100%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	0	0%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	0	0%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	1	50%
Missed any part of periodic review requirements	review	2	100%
Time intervals do not exceed 12 months (Type 1)	51	2	100%
Acceptable sample reviewed (Type 1)	52	0	0%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	0	0%
Procedures for evaluating effectiveness of QM program (Type 1)	54	0	0%
Records of each review and evaluation maintained for 3 years (Type 1)	56	0	0%
Missed any of Other (see below)	other	2	100%
W.D. and records of each HDR Brachytherapy maintained three years (Type 1)	48	0	0%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	0	0%
Commitment for all workers to seek guidance (Type 2)	47c	2	100%

Table 30: Brachytherapy Responses - Region 4

Brachytherapy Responses - Region 4	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		135	
Letters sent to facilities with Brachytherapy authorized on license	tot	45	
Negative declarations for Brachytherapy	neg	1	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	40	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	33	83%
Missed any part of Objective 1 (Written Directive)	obj1	37	93%
Prepared a written directive (Type 3)	59	40	100%
Written directive complete (Type 3)	59a	9	23%
W.D. includes order for a specific patient (Type 3)	59b	18	45%
W.D. includes authorized user signature and date (Type 3)	59c	33	83%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	24	60%
W.D. includes number of sources prior to implantation (Type 3)	59f	24	60%
W.D. includes source strengths prior to implantation (Type 3)	59g	23	58%
W.D. includes the radioisotope after implantation (Type 3)	59i	19	48%
W.D. includes treatment site after implantation (Type 3)	59j	18	45%
W.D. includes total dose after implantation (Type 3)	59k	21	53%
Policy for oral revision to written directive (Type 1)	60a	11	28%
Policy for oral directive (Type 1)	60b	12	30%
Policy for written revision to written directive (Type 2)	61	7	18%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	7	17%

Missed any part of Objective 3 (Treatment Plans Verification)	63	9	23%
Plan of treatment prepared (Type 3)	63a	17	43%
Procedures for performing check of dose calculations (Type 3)	63b	24	60%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	25	63%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	23	58%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	35	88%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	36	90%
Administration confirmed by person administering treatment (Type 3)	64b	6	15%
Recording of sources by authorized user (Type 3)	64c	15	38%
Missed any part of Objective 5 (Unintended Deviations)	obj5	25	63%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	21	53%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	15	38%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	14	35%
Missed any part of periodic review requirements	review	37	93%
Time intervals do not exceed 12 months (Type 1)	69	35	88%
Acceptable sample reviewed (Type 1)	70	19	48%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	4	10%
Procedures for evaluating effectiveness of QM program (Type 1)	72	22	55%
Records of each review and evaluation maintained for 3 years (Type 1)	74	14	35%

Other missed	other	39	98%
W.D. and records of each Brachytherapy maintained three years (Type 1)	66	8	20%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	4	10%
Commitment for all workers to seek guidance (Type 2)	65	31	78%

Table 31: I-125 and/or I-131 > 30μCi Responses - Region 4

I-125 and/or I-131 > 30μCi Responses - Region 4	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		135	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	126	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	1	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	123	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	94	76%
Missed any part of Objective 1 (Written Directive)	obj1	111	90%
Prepared a written directive (Type 3)	77	117	95%
Written directive complete (Type 3)	77a	80	65%
W.D. includes order for specific patient (Type 3)	77b	85	69%
W.D. includes authorized user signature and date(Type 3)	77c	104	85%
W.D. includes dosage to be administered (Type 3)	77d	91	74%
Policy for oral revision to written directive (Type 1)	78a	37	30%
Policy for oral directive (Type 1)	78b	36	29%
Policy for written revision to written directive (Type 2)	79	39	32%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	11	9%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	53	43%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	104	85%
Administration confirmed by person administering treatment (Type 3)	81b	73	59%
Missed any part of Objective 5 (Unintended Deviations)	obj5	84	68%

Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	59	48%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	53	43%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	61	50%
Missed any part of periodic review requirements	review	110	89%
Time intervals do not exceed 12 months (Type 1)	86	104	85%
Acceptable sample reviewed (Type 1)	87	52	42%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	15	12%
Procedures for evaluating effectiveness of QM program (Type 1)	89	71	58%
Records of each review and evaluation maintained for 3 years (Type 1)	91	63	51%
Missed any of Other (see below)	other	93	76%
W.D. and records of each I-125 and/or I-131 > 30μCi maintained three years (Type 1)	83	53	43%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	42	34%
Commitment for all workers to seek guidance (Type 2)	82	88	72%

Table 32: Therapeutic Radiopharmaceutical Responses - Region 4

Therapeutic Radiopharmaceutical Responses - Region 4	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		135	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	84	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	0	
Licensees which provided a QMP for Therapeutic Radio-pharmaceuticals (Type 3)	92	77	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	61	79%
Missed any part of Objective 1 (Written Directive)	obj1	68	88%
Prepared a written directive (Type 3)	94	75	97%
Written directive complete (Type 3)	94a	38	49%
W.D. includes radiopharmaceutical (Type 3)	94b	53	69%
W.D. includes dosage (Type 3)	94c	55	71%
W.D. includes route of administration (Type 3)	94d	48	62%
W.D. includes order for specific patient (Type 3)	94e	51	66%
W.D. includes authorized user signature and date(Type 3)	94f	67	87%
Policy for oral revision to written directive (Type 1)	95a	23	30%
Policy for oral directive (Type 1)	95b	23	30%
Policy for written revision to written directive (Type 2)	96	23	30%
Missed Objective 2 (Patient Verification) (Type 3)	97	7	9%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	30	39%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	69	90%

Administration confirmed by person administering treatment (Type 3)	98b	48	62%
Missed any part of Objective 5 (Unintended Deviations)	obj5	53	69%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	39	51%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	28	36%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	38	49%
Missed any part of periodic review requirements	review	73	95%
Time intervals do not exceed 12 months (Type 1)	103	63	82%
Acceptable sample reviewed (Type 1)	104	31	40%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	6	8%
Procedures for evaluating effectiveness of QM program (Type 1)	106	44	57%
Records of each review and evaluation maintained for 3 years (Type 1)	108	37	48%
Missed any of Other (see below)	other	57	74%
W.D. and records of each Therapeutic Radiopharmaceutical maintained three years (Type 1)	100	31	40%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	28	36%
Commitment for all workers to seek guidance (Type 2)	99	64	83%

Table 33: Teletherapy Responses - Region 5

Teletherapy Responses - Region 5	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		43	
Letters sent to facilities with Teletherapy authorized on license	tot	1	
Negative declarations for Teletherapy	neg	0	
Licensees which provided a QMP for Teletherapy (Type 3)	3	1	
Licensees which certified implementation of the QMP for Teletherapy (Type 3)	4	1	100%
Missed any part of Objective 1 (Written Directive)	obj1	1	100%
Prepared a written directive (Type 3)	5	1	100%
Written directive complete (Type 3)	5a	0	0%
W.D. includes total dose (Type 3)	5b	1	100%
W.D. includes dose per fraction (Type 3)	5c	1	100%
W.D. includes treatment site (Type 3)	5d	1	100%
W.D. includes overall treatment period (Type 3)	5e	1	100%
W.D. includes order for specific patient (Type 3)	5f	0	0%
W.D. includes authorized user signature and date(Type 3)	5g	1	100%
Policy for oral revision to written directive (Type 1)	6a	1	100%
Policy for oral directive (Type 1)	6b	1	100%
Policy for written revision to written directive (Type 2)	7	1	100%
Missed Objective 2 (Patient ID Verification) (Type 3)	8	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	0	0%
Plan of treatment prepared (Type 3)	9a	1	100%
Procedures for performing check of dose calculations (Type 3)	9b	1	100%
Independent check of full calibration measurements (Type 3)	9c	1	100%

Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	9d	1	100%
Determination of transmission factors before first use and after source replacement for beam -modifying devices (Type 3)	9e	1	100%
Physical measurements of the teletherapy output for treatment parameters not addressed in calibration measurements (Type 3)	9f	1	100%
For prescribed doses that are administered in fractions, procedure for checking dose calculations prior to administration of total dose (Type 3)	9g	1	100%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	0	0%
Policy to ensure administration in accordance with W.D. (Type 3)	10a	1	100%
Administration confirmed by person administering treatment (Type 3)	10b	1	100%
Missed any part of Objective 5 (Unintended Deviations)	obj5	0	0%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	13	1	100%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	14a	1	100%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	14b	0	0%
Missed any part of periodic review requirements	review	0	0%
Time intervals do not exceed 12 months (Type 1)	15	1	100%
Acceptable sample reviewed (Type 1)	16	1	100%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	17	1	100%
Procedures for evaluating effectiveness of QM program (Type 1)	18	1	100%
Records of each review and evaluation maintained for 3 years (Type 1)	20	0	0%
Missed any of Other (see below)	other	1	100%
W.D. and records of each teletherapy maintained three years (Type 1)	12	0	0%

Modifications to QM Program submitted to NRC within 30 days (Type 1)	19	0	0%
Commitment for all workers to seek guidance (Type 2)	11	1	100%

Table 34: HDR Brachytherapy Responses - Region 5

HDR Brachytherapy Responses - Region 5	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		43	
Letters sent to facilities with HDR Brachytherapy authorized on license	tot	0	0%
Negative declarations for HDR Brachytherapy	neg	0	0%
Licensees which provided a QMP for HDR Brachytherapy (Type 3)	39	0	0%
Licensees which certified implementation of the QMP for HDR Brachytherapy (Type 3)	40	0	0%
Missed any part of Objective 1 (Written Directive)	obj1	0	0%
Prepared a written directive (Type 3)	41	0	0%
Written directive complete (Type 3)	41a	0	0%
W.D. includes total dose (Type 3)	41b	0	0%
W.D. includes dose per fraction (Type 3)	41c	0	0%
W.D. includes treatment site (Type 3)	41d	0	0%
W.D. includes overall treatment period (Type 3)	41e	0	0%
W.D. includes order for specific patient (Type 3)	41f	0	0%
W.D. includes authorized user signature and date(Type 3)	41g	0	0%
Policy for oral revision to written directive (Type 1)	42a	0	0%
Policy for oral directive (Type 1)	42b	0	0%
Policy for written revision to written directive (Type 2)	43	0	0%
Missed Objective 2 (Patient ID Verification) (Type 3)	44	0	0%
Missed any part of Objective 3 (Treatment Plans Verification)	obj3	0	0%
Plan of treatment prepared (Type 3)	45a	0	0%
Procedures for performing check of dose calculations (Type 3)	45b	0	0%

Verification of position of dummy sources or fixed geometry applicators (Type 3)	45c	0	0%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	45d	0	0%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	0	0%
Policy to ensure administration in accordance with W.D. (Type 3)	46	0	0%
Administration confirmed by person administering treatment (Type 3)	47a	0	0%
Recording of sources by authorized user (Type 3)	47b	0	0%
Missed any part of Objective 5 (Unintended Deviations)	obj5	0	0%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	49	0	0%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	50a	0	0%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	50b	0	0%
Missed any part of periodic review requirements	review	0	0%
Time intervals do not exceed 12 months (Type 1)	51	0	0%
Acceptable sample reviewed (Type 1)	52	0	0%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	53	0	0%
Procedures for evaluating effectiveness of QM program (Type 1)	54	0	0%
Records of each review and evaluation maintained for 3 years (Type 1)	56	0	0%
Missed any of Other (see below)	other	0	0%
W.D. and records of each HDR Brachytherapy maintained three years (Type 1)	48	0	0%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	55	0	0%
Commitment for all workers to seek guidance (Type 2)	47c	0	0%

Table 35: Brachytherapy Responses - Region 5

Brachytherapy Responses - Region 5	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		43	
Letters sent to facilities with Brachytherapy authorized on license	tot	15	
Negative declarations for Brachytherapy	neg	0	
Licensees which provided a QMP for Brachytherapy (Type 3)	57	10	
Licensees which certified implementation of the QMP for Brachytherapy (Type 3)	58	10	100%
Missed any part of Objective 1 (Written Directive)	obj1	7	70%
Prepared a written directive (Type 3)	59	9	90%
Written directive complete (Type 3)	59a	5	50%
W.D. includes order for a specific patient (Type 3)	59b	9	90%
W.D. includes authorized user signature and date (Type 3)	59c	8	80%
W.D. includes the radioisotope prior to implantation (Type 3)	59e	10	100%
W.D. includes number of sources prior to implantation (Type 3)	59f	9	90%
W.D. includes source strengths prior to implantation (Type 3)	59g	9	90%
W.D. includes the radioisotope after implantation (Type 3)	59i	5	50%
W.D. includes treatment site after implantation (Type 3)	59j	6	60%
W.D. includes total dose after implantation (Type 3)	59k	8	80%
Policy for oral revision to written directive (Type 1)	60a	3	30%
Policy for oral directive (Type 1)	60b	4	40%
Policy for written revision to written directive (Type 2)	61	4	40%
Missed Objective 2 (Patient ID Verification) (Type 3)	62	0	0%

Missed any part of Objective 3 (Treatment Plans Verification)	63	5	50%
Plan of treatment prepared (Type 3)	63a	7	70%
Procedures for performing check of dose calculations (Type 3)	63b	7	70%
Verification of position of dummy sources or fixed geometry applicators (Type 3)	63c	8	80%
Acceptance testing on computer program used for treatment planning or dose calculations (Type 3)	63d	7	70%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	7	70%
Policy to ensure administration in accordance with W.D. (Type 3)	64a	6	60%
Administration confirmed by person administering treatment (Type 3)	64b	3	30%
Recording of sources by authorized user (Type 3)	64c	8	80%
Missed any part of Objective 5 (Unintended Deviations)	obj5	5	50%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	67	7	70%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	68a	5	50%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	68b	5	50%
Missed any part of periodic review requirements	review	9	90%
Time intervals do not exceed 12 months (Type 1)	69	10	100%
Acceptable sample reviewed (Type 1)	70	6	60%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	71	1	10%
Procedures for evaluating effectiveness of QM program (Type 1)	72	7	70%
Records of each review and evaluation maintained for 3 years (Type 1)	74	5	50%

Other missed	other	9	90%
W.D. and records of each Brachytherapy maintained three years (Type 1)	66	4	40%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	73	2	20%
Commitment for all workers to seek guidance (Type 2)	65	8	80%

Table 36: I-125 and/or I-131 > 30μCi Responses - Region 5

I-125 and/or I-131 > 30μCi Responses - Region 5	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		43	
Letters sent to facilities with I-125 and/or I-131 > 30μCi authorized on license	tot	42	
Negative declarations for I-125 and/or I-131 > 30μCi	neg	1	
Licensees which provided a QMP for I-125 and/or I-131 > 30μCi (Type 3)	75	38	
Licensees which certified implementation of the QMP for I-125 and/or I-131 > 30μCi (Type 3)	76	38	100%
Missed any part of Objective 1 (Written Directive)	obj1	30	79%
Prepared a written directive (Type 3)	77	37	97%
Written directive complete (Type 3)	77a	30	79%
W.D. includes order for specific patient (Type 3)	77b	32	84%
W.D. includes authorized user signature and date(Type 3)	77c	34	89%
W.D. includes dosage to be administered (Type 3)	77d	33	87%
Policy for oral revision to written directive (Type 1)	78a	15	39%
Policy for oral directive (Type 1)	78b	15	39%
Policy for written revision to written directive (Type 2)	79	10	26%
Missed Objective 2 (Patient ID Verification) (Type 3)	80	0	0%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	11	29%
Policy to ensure administration in accordance with W.D. (Type 3)	81a	34	89%
Administration confirmed by person administering treatment (Type 3)	81b	28	74%
Missed any part of Objective 5 (Unintended Deviations)	obj5	15	39%

Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	84	27	71%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	85a	25	66%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	85b	25	66%
Missed any part of periodic review requirements	review	26	68%
Time intervals do not exceed 12 months (Type 1)	86	38	100%
Acceptable sample reviewed (Type 1)	87	21	55%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	88	12	32%
Procedures for evaluating effectiveness of QM program (Type 1)	89	23	61%
Records of each review and evaluation maintained for 3 years (Type 1)	91	23	61%
Missed any of Other (see below)	other	36	95%
W.D. and records of each I-125 and/or I-131 > 30μCi maintained three years (Type 1)	83	20	53%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	90	3	8%
Commitment for all workers to seek guidance (Type 2)	82	28	74%

Table 37: Therapeutic Radiopharmaceutical Responses - Region 5

Therapeutic Radiopharmaceutical Responses - Region 5	Question #	# Responses	Percentage
Letters sent out to date, included in this summary		43	
Letters sent to facilities with Therapeutic Radiopharmaceuticals authorized on license	tot	35	
Negative declarations for Therapeutic Radiopharmaceuticals	neg	0	
Licensees which provided a QMP for Therapeutic Radio-pharmaceuticals (Type 3)	92	31	
Licensees which certified implementation of the QMP for Therapeutic Radiopharmaceuticals (Type 3)	93	29	100%
Missed any part of Objective 1 (Written Directive)	obj1	24	83%
Prepared a written directive (Type 3)	94	28	97%
Written directive complete (Type 3)	94a	24	83%
W.D. includes radiopharmaceutical (Type 3)	94b	26	90%
W.D. includes dosage (Type 3)	94c	27	93%
W.D. includes route of administration (Type 3)	94d	25	86%
W.D. includes order for specific patient (Type 3)	94e	26	90%
W.D. includes authorized user signature and date(Type 3)	94f	27	93%
Policy for oral revision to written directive (Type 1)	95a	11	38%
Policy for oral directive (Type 1)	95b	12	41%
Policy for written revision to written directive (Type 2)	96	7	24%
Missed Objective 2 (Patient Verification) (Type 3)	97	0	0%
Missed any part of Objective 4 (Each administration in accordance with W.D.)	obj4	11	38%
Policy to ensure administration in accordance with W.D. (Type 3)	98a	26	90%

Administration confirmed by person administering treatment (Type 3)	98b	20	69%
Missed any part of Objective 5 (Unintended Deviations)	obj5	11	38%
Policies for identification and evaluation of unintended deviations from W.D. (Type 2)	101	20	69%
Institution of corrective actions in event of unintended deviation form W.D. (Type 2)	102a	20	69%
Evaluation and response to recordable events (Policy to evaluate and respond) (Type 2)	102b	19	66%
Missed any part of periodic review requirements	review	21	72%
Time intervals do not exceed 12 months (Type 1)	103	28	97%
Acceptable sample reviewed (Type 1)	104	13	45%
Procedure to expand if recordable event or misadministration uncovered (Type 1)	105	8	28%
Procedures for evaluating effectiveness of QM program (Type 1)	106	17	59%
Records of each review and evaluation maintained for 3 years (Type 1)	108	17	59%
Missed any of Other (see below)	other	29	100%
W.D. and records of each Therapeutic three years (Type 1)	100	13	45%
Modifications to QM Program submitted to NRC within 30 days (Type 1)	107	0	0%
Commitment for all workers to seek guidance (Type 2)	99	21	72%

APPENDIX A: Quality Management (QM) Program Checklist

QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST

1. *NAME OF LICENSEE:_____

Date QM Plan submitted to NRC_____

*License No.:_____

*Docket No.:_____

Telephone No.: (___)_____

LLNL Authorization Reviewer#_____

Reviewer#_____Reviewer Loc (UCSF or other)_____

2nd Reviewer#_____Reviewer Loc (UCSF or other)_____

LLNL Reviewer#_____

Reviewer's Notes:

Reviewers: Cross out comments which are no longer relevant. Date and initial comments. This information will not be stored in database. These are comments to the tracking office.

*R.S.O._____(include title ,e.g. Dr., Mr., Ms., etc.)

*Department_____(e.g., Nuclear Med., Radiation Oncology, etc.)

*Street or P.O. Box_____

*City_____ State_____Zip Code_____

*Reviewer: Take this information from license only.

2a. Authorized user for Teletherapy (35.600)..... ❑ YES ❑ NO ❑ U

2b. Authorized user for Gamma Stereotactic Radiosurgery..... ❑ YES ❑ NO ❑ U

2c. Authorized user for High-Dose-Rate Remote Afterloading Brachytherapy (HDR)..... ❑ YES ❑ NO ❑ U

2d. Authorized user for Brachytherapy (35.400)..... ❑ YES ❑ NO ❑ U

2e. Authorized user for I-125 and/or I-131> 30 uCi

Any or all of 35.100, 35.200, 35.300, unless both I-125 and I-131 are excluded or not included in section 6 of license ..... ❑ YES ❑ NO ❑ U

2f. Authorized user for Radiopharmaceutical Therapy other than I-125 and/or I-131 (35.300)..... ❑ YES ❑ NO ❑ U

Reviewer: U means that the licensee is authorized for this modality but has stated in a letter that the facility will not be using this modality in practice.

Quality Management Program for Teletherapy

3. A written QMP for teletherapy was provided. _ YES _ NO (3a) Type 3

A written QMP must be established and maintained for each teletherapy use as required in 10CFR 35.32(f)(1). Please submit your QMP for your teletherapy program.

4. Written certification that QM program for teletherapy has been implemented _ YES _ NO (4) Type 3

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

5a. A written directive is prepared for teletherapy: _ YES _ NO (14) Type 3

The preparation of written directives prior to administration of any teletherapy dose, is required by 10 CFR 35.32(a)(1). Your QMP must include a written policy that requires that such a written directive be prepared for each patient and that written directives for teletherapy doses will include all treatment parameters prior to administration.

5b. The QMP provides procedures to require that the written directive:

Contains the total dose	_ YES _ NO (14a)	Type 3
Contains the dose per fraction	_ YES _ NO (14b)	
Contains the treatment site	_ YES _ NO (14c)	
Contains the overall treatment period	_ YES _ NO (14d)	
Is an order for a specific patient	_ YES _ NO (14e)	
Is dated and signed by authorized user	_ YES _ NO (14f)	

Your QMP is missing procedures to require that the written directive include:

(a)the total dose
(b)the dose per fraction
(c)the treatment site
(d)the overall treatment period
(e)an order for a specific patient
(f)Is dated and signed by authorized user

6. Documentation of oral revisions and oral directives:

a. Policies and procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. <u>within 48 hours of the oral revision</u> _ YES _ NO (18a) Type 1

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user <u>within 48 hours of the oral revision</u>. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP. _ YES _ NO (18b) Type 1

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a policy in your QMP.

7. Revisions to written directives dated and signed by a.u. prior to administration of teletherapy dose or next fraction of teletherapy dose. _ YES _ NO (21) Type 2

Revisions to written directives for teletherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the teletherapy dose or the next teletherapy fractional dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration of the teletherapy dose or next teletherapy fractional dose.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

8. Procedure to verify patient's identity by more than one method prior to administration _ YES _ NO (23a) Type 3

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each teletherapy administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

9. **For Teletherapy:** (25)

a. a plan of treatment will be prepared in accordance with the respective written directive. _ YES _ NO (a) Type 3

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculation _ YES _ NO (b) Type 3

c. An independent check of full calibration measurements that resulted from source replacement, or when spot check measurement indicates that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay, _ YES _ NO (c) Type 3

d. Acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, _ YES _ NO (d) Type 3

e. determination of transmission factors for beam modifying devices before the first medical use of the beam-modifying device and after replacement of the source, _ YES _ NO (e) Type 3

f. physical measurements of the teletherapy output for treatment parameters not addressed in the most recent full calibration measurement _ YES _ NO (f) Type 3

g. for prescribed doses that are to be administered in fractions, describe your procedure for checking the dose calculations prior to administration of the total dose. An authorized user or qualified individual under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible, did not make the original calculations, should check the dose calculations. Your procedures should include both a consideration of the number of fractions and a specified time within which the check should be performed. _ YES _ NO (g) Type 3

Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for teletherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include:

a. a plan of treatment will be prepared in accordance with the respective written directive.

b. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations,

c. an independent check of full calibration measurements that resulted from source replacement, or when spot check measurement indicates that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay,

d. determination of transmission factors for beam modifying devices before the first medical use of the beam-modifying device and after replacement of the source,

e. physical measurements of the teletherapy output for treatment parameters not addressed in the most recent full calibration measurement,

f. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations)

g for prescribed doses that are to be administered in fractions, describe your procedure for checking the dose calculations prior to administration of the total dose. An authorized user or qualified individual under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible, did not make the original calculations, should check the dose calculations. Your procedures should include both a consideration of the number of fractions and a specified time within which the check should be performed.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

10a. Policies/Procedures to ensure, before administration, that each administration is in accordance with the written directive _ YES _ NO (28a) Type 3

Your submittal for teletherapy does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Please include such a provision in your QMP.

10b. Administration is confirmed by the person administering the teletherapy treatment to verify agreement with the written directive and plan of treatment. _ YES _ NO (28b) Type 3

- verification of the treatment site
- verification of the dose per fraction.

(*Reviewer, either item is missing, mark "no")

Your QMP, according to guidance provided in Reg. Guide 8.33, should ensure that before administering each teletherapy dose or dose fraction, that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to verify agreement with the written directive and plan of treatment.

11. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive _ YES _ NO (31) Type 2

Your QMP should include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP

12. A written directive and records of each administered teletherapy must be maintained for three years _ YES _ NO (33) Type 1

Your QMP must include a commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

13. Policies and procedures for identification and evaluation of unintended deviations from the written directive _ YES _ NO (34a) Type 2

Your QMP for teletherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

14a. Institution of corrective actions to be taken after the deviation has been identified _ YES _ NO (35) Type 2

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

14b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. _ YES _ NO (1) Type 2

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

15. Time intervals (intervals not to exceed 12 months) _ YES _ NO (36a) Type 1

Your submittal for teletherapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

16. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations _ YES _ NO (37) Type 1

Your QMP review procedure does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

17. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _ NO (38) Type 1

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

18. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _ NO (39) Type 1

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

19. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES _ NO (40) — Type 1

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e).

20. Records of each review and evaluation to be maintained for 3 years — _ YES _ NO (41) — Type 1

Please provide assurance that records of each QMP review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS:_____

Quality Management Program for Gamma Stereotactic Radiosurgery

21. Written QMP for Gamma Stereotactic Radiosurgery _ YES _ NO (3b) **Type 3**

A written QMP must be established and maintained for each Gamma Stereotactic use as required in 10 CFR 35.32((f)(1). Please submit your QMP for your **Gamma Stereotactic Radiosurgery** program.

22. Written certification that QM program for Gamma Stereotactic Radiosurgery has been implemented _ YES _ NO (4) **Type 3**

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

23a. A written directive is prepared for Gamma Stereotactic Radiosurgery _ YES _ NO (16) **Type 3**

The preparation of written directives for gamma stereotactic radiosurgery are required by 10 CFR 35.32(a)(1). Your QMP must include a written policy that requires that such a written directive be prepared for each patient administration, and that written directives for gamma stereotactic radiosurgery will include all treatment parameters prior to administration.

23. The QMP provides procedures to require that the written directive include:

23b.	Target coordinates	_ YES _ NO (16a)	**Type 3**
23c.	Collimator size	_ YES _ NO (16b)	
23d.	Plug pattern	_ YES _ NO (16c)	
23e.	Total dose	_ YES _ NO (16d)	
23f.	Order for a specific patient	_ YES _ NO (16e)	
23g.	Dated and signed by authorized user	_ YES _ NO (16f)	

Your QMP is missing procedures to require that the written directive include:

(a)Target coordinates
(b)Collimator size
(c)Plug pattern
(d)Total dose
(e)Order for a specific patient
(f)Dated and signed by authorized user

24. Documentation of oral revisions and oral directives:

a. Policies and procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

_ YES _ NO (18a) Type 1

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP.

_ YES _ NO (18b) Type 1

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

25. Revisions to written directives dated and signed by an a.u. prior to administration of gamma stereotactic radiosurgery dose administration

_ YES _ NO (20) Type 2

Revisions to written directives for gamma stereotactic radiosurgery may be made provided that the revision is dated and signed by an authorized user prior to the administration of the gamma stereotactic radiosurgery dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

26. Procedure to verify patient's identity by more than one method prior to administration

_ YES _ NO (23b) Type 3

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each **Gamma Stereotactic Radiosurgery**, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

27. For Gamma stereotactic radiosurgery: (26)

a. a plan of treatment will be prepared in accordance with the respective written directive. _ YES _ NO (26a) Type 3

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). The verification should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physicist, or radiation therapy technologist) other than the individuals who dated and signed the written directive. _ YES _ NO (26b)

c. verification that computer generated dose calculations were correctly input to the gamma stereotactic radiosurgery unit and that the computer print-out to verifies that the correct data for the patient were used in the calculations. _ YES _ NO (26c) Type 3

d. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations. _ YES _ NO (26d) Type 3

Your policies/procedures for gamma stereotactic radiosurgery do not provide assurance that final plans of treatment and related calculations will be in accordance with the respective written directive. Your procedures should include:

a. a plan of treatment will be prepared in accordance with the respective written directive.

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Verification should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physicist, or radiation therapy technologist) other than the individuals who dated and signed the written directive and plan of treatment.

c. verification that computer generated dose calculations were correctly input to the gamma stereotactic radiosurgery unit and that the computer print-out to verifies that the correct data for the patient were used in the calculations.

d. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

28a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. _ YES _ NO (30a) Type 3

Your submittal for stereotactic radiosurgery does not include policies/ procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR35.32(a)(4). Please include such a provision in your QMP.

28b. Verification that, prior to administration, the specific details of the administration are in accordance with the written directive and plan of treatment. _ YES _ NO (30b) Type 3

Please include in the QMP a procedure to verify, before administering each treatment, that the specific details of the administration are in accordance with the guidance provided in Reg. Guide 8.33

29. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive _ YES _ NO (31) Type 2

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP. Please include such a provision in your QMP.

30. A written directive and records of each administered Gamma Stereotactic Radio Surgery are maintained for three years. _ YES _ NO (33) Type 1

Your QMP must include a commitment to retain each written directive an a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

31. Policies/Procedures for identification and evaluation of unintended deviations from the written directive _ YES _ NO (34b) Type 2

Your QMP for **Gamma Stereotactic Radiosurgery** must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

32a. Institution of corrective actions to be taken after the deviation has been identified _ YES _ NO (35) Type 2

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

32b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. _ YES _ NO (1) Type 2

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

33. Time intervals (intervals not to exceed 12 months) _ YES _ NO (36b) **Type 1**

Your submittal for Gamma Stereotactic Radiosurgery does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

34. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations _ YES _ NO (37) **Type 1**

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

35. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _ NO (38) **Type 1**

According to guidance provided by Regulatory Guide 8.33, your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

36. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _ NO (39) **Type 1**

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

37. Modifications to QM program submitted to NRC within 30 days after modification has been made _ YES _ NO (40) **Type 1**

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e).

38. Records of each review and evaluation to be maintained for 3 years _ YES _ NO (41) **Type 1**

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS:_____

Quality Management Program for High-Dose-Rate Remote Afterloading Brachytherapy

39. Written QMP for High-Dose-Rate Remote Afterloading Brachytherapy — _ YES _ NO (3c) — Type 3

A written QMP must be established and maintained for each High-Dose -Rate Remote Afterloading Brachytherapy use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your High-Dose-Rate Remote Afterloading Brachytherapy program.

40. Written certification that QM program has been implemented — _ YES _ NO (4) — Type 3

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

41a. A written directive is prepared for administration of High-Dose-Rate Remote Afterloading Brachytherapy — _ YES _ NO (13) — Type 3

The preparation of written directives prior to administration of high dose rate afterloaders is required by 10CFR35.32(a)(1). Please provide such a policy in your QMP.

41. The QMP provides procedures to require that the written directive include:

41b.	The total dose	_ YES _ NO (16a)	Type 3
41c.	dose per fraction	_ YES _ NO (16b)	
41d.	treatment site	_ YES _ NO (16c)	
41e.	overall treatment period	_ YES _ NO (16d)	
41f.	Order for a specific patient	_ YES _ NO (16e)	
41g.	Dated and signed by authorized user	_ YES _ NO (16f)	

Your QMP is missing procedures to require that the written directive include:

The total dose,
dose per fraction
treatment site
overall treatment period
Order for a specific patient
Dated and signed by authorized user

42. Documentation of oral revisions and oral directives: _ YES _ NO (18a) Type 1

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP _ YES _ NO (18b) Type 1

if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

43. Revisions to written directives dated and signed by a.u. prior to administration of brachytherapy dose or next fraction of brachytherapy dose _ YES _ NO (22) Type 2

Revisions to written directives for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose or next fractional brachytherapy dose.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

44. Procedure to verify patient's identity by more than one method prior to administration _ YES _ NO (23c) Type 3

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each high-dose-rate remote afterloading bracytherapy administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

45. For High Dose Rate Remote Afterloading Brachytherapy: (24)

a. a plan of treatment will be prepared in accordance with the respective written directive. _ YES _ NO (24a) Type 3

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Dose calculations checked by an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations. _ YES _ NO (24b) Type 3

c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources _ YES _ NO (24c) Type 3

d. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations _ YES _ NO (24d) Type 3

Your submittal does not include policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should require that:

a. a plan of treatment will be prepared in accordance with the respective written directive.

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations.

c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources, is accomplished

d. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations is performed.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

46. Procedures to ensure, before administration, that each administration is in accordance with the written directive. __YES __NO (29a) Type 3

Your submittal for high dose rate remote afterloading brachytherapy does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Please provide such a provision in your QMP.

47a. The person administering the high-dose-rate remote brachytherapy treatment should confirm the prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, total dose.
(*Reviewer, if any one item is missing, mark "no")

__YES __NO (29b) **Type 3**

Your procedures should require: verification, before administering each high-dose-rate remote brachytherapy, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the treatment to verify agreement with the written directive and treatment plan.

47b. Prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record.

__YES __ NO (29c) **Type 3**

Your procedures should require: prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record.

47c. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive.

_ YES _ NO (31) **Type 2**

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

48. A written directive and records of each administered High-Dose-Rate Remote Afterloading Brachytherapy are retained for three years.

_ YES _ NO (33) **Type 1**

A commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

49. Policies/Procedures for identification and evaluation of unintended deviations from the written directive

_ YES _ NO (34c) **Type 2**

Your QMP for **High-Dose-Rate Remote Afterloading Brachytherapy** must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

50a. Institution of corrective actions to be taken after the deviation has been identified

_ YES _ NO (35) **Type 2**

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

50b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. _ YES _ NO (1) **Type 2**

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

51. Time intervals (intervals not to exceed 12 months) _ YES _ NO (36c) **Type 1**

Your submittal for **High-Dose-Rate Remote Afterloading Brachytherapy** does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

52. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations _ YES _ NO (37) **Type 1**

Your QMP review does not provide an evaluation of (i) adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

53. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _ NO (38) **Type 1**

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

54. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _ NO (39) **Type 1**

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

55. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES _ NO (40) — Type 1

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32(e).

56. Records of each review and evaluation to be maintained for 3 years — _ YES _ NO (41) — Type 1

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS:_____

Quality Management Program for Brachytherapy

57. A written QMP for Brachytherapy was provided. _ YES _ NO (3d) Type 3

A written QMP must be established and maintained for each Brachytherapy use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your Brachytherapy program

58. Written certification that QM program has been implemented _ YES _ NO (4) Type 3

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented long with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

59a. A written directive is prepared for Brachytherapy, other than high-dose-rate: _ YES _ NO (11) Type 3

10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient.

The QMP provides procedures to require that the written directive : (12) Type 3

59b. Order for a specific patient..... _ YES _ NO (12a)
59c. Dated and signed by authorized user ..... _ YES _ NO (12b)

Prior to implantation: (12c)

59d. the radioisotope, ... _ YES _ NO (12d)
59e. number of sources,..... _ YES _ NO (12e)
59f. source strengths;..... _ YES _ NO (12f)

After implantation, but prior to completion of the procedure: (12g)

59g. the radioisotope, ... _ YES _ NO (12h)
59h. treatment site, ... _ YES _ NO (12i)
59i. total source strength and exposure time (or,equivalently, the total dose)..... _ YES _ NO (12j)

Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10CFR35.2, must include: the radioisotope, number of sources, and source strengths; and after implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose). Your QMP must include a written policy/procedure which requires that any written directives for brachytherapy doses will include all treatment parameters prior to administration. Your QMP is missing procedures to require that the written directive include:

(a)Order for a specific patient.
(b)Dated and signed by authorized user
(c)Prior to implantation:
(d)the radioisotope,
(e)number of sources,
(f)source strengths;.
(g)After implantation, but prior to completion of the procedure:
(h)the radioisotope,
(i)treatment site,
(j)total source strength and exposure time (or, equivalently, the total dose)

60. Documentation of oral revisions and oral directives: _ YES _ NO (18a) **Type 1**

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP _ YES _ NO (18b) **Type 1**

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

61. Revisions to written directives dated and signed by a.u. prior to administration of brachytherapy dose or next fraction of brachytherapy dose _ YES _ NO (22) **Type 2**

Revisions to written directives for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose or next fractional brachytherapy dose.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

62. Procedure to verify patient's identity by more than one method prior to administration — _ YES _ NO (23d) **Type 3**

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each **Brachytherapy** administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

63. For brachytherapy other than high-dose-rate remote afterloaders:

a. a plan of treatment will be prepared in accordance with the respective written directive. — _ YES _ NO (24a) **Type 3**

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Dose calculations checked by an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations. — _ YES _ NO (24b) **Type 3**

c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources — _ YES _ NO (24c) **Type 3**

d. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations — _ YES _ NO (24d) **Type 3**

Your submittal does not include policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should require that:

a. a plan of treatment will be prepared in accordance with the respective written directive.

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations) are prepared. Procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations.

c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources, is accomplished

d. acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations is performed.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

64a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. _ YES __ NO (29d) Type 3

Your submittal for brachytherapy does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10CFR35.32(a)(4). Please include such a provision in your QMP.

64b. The person administering the brachytherapy treatment should confirm the prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, total dose. **(*Reviewer, if any one item is missing, mark "no")** _ YES _ NO (29e) Type 3

Your procedures should include a requirement for verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

64c. Prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record. _ YES _ NO (29f) Type 3

Your procedures should include a requirement for prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record.

65. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive _ YES _ NO (31) Type 2

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

66. A written directive and records of each administered Brachytherapy must be maintained for three years. _ YES _ NO (33) Type 1

Your QMP must include a commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

67. Policies/Procedures for identification and evaluation of unintended deviations from the written directive — _ YES _ NO (34d) **Type 2**

Your QMP for **Brachytherapy** must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

68a. Institution of corrective actions to be taken after the deviation has been identified — _ YES _ NO (35) **Type 2**

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

68b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. — _ YES _ NO (1) **Type 2**

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

69. Time intervals (intervals not to exceed 12 months) — _ YES _ NO (36d) **Type 1**

Your submittal for **Brachytherapy** does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews These reviews should be conducted at intervals no greater than 12 months.

70. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations — _ YES _ NO (37) **Type 1**

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

71. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _ NO (38) Type 1

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include this provision in your QMP.

72. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _ NO (39) Type 1

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

73. Modifications to QM program submitted to NRC within 30 days after modification has been made _ YES _ NO (40) Type 1

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e).

74. Records of each review and evaluation to be maintained for 3 years _ YES _ NO (41) Type 1

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS: _____

Quality Management Program for I-125 and/or I-131 > 30uCi

75. A written QMP for I-125 and/or I-131>30 uCi was provided. _ YES _ NO (3e) **Type 3**

A written QMP must be established and maintained for each I-125 and/or I-131>uCi use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your NaI I-125 or I-131 >30 microCi

76. Written certification that QM program has been implemented _ YES _ NO (4) **Type 3**

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

77a. A written directive is prepared for administration of greater than 30 uci of I-125 and/or I-131 _ YES _ NO (7) **Type 3**

The preparation of written directives prior to the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 is required by 10 CFR 35.32(a)(1). Your QMP must include a written policy that requires that such a written directive be prepared prior to each patient administration.

The QMP provides procedures to require that the written directive :

77b. Is an order for a specific patient..... _ YES _ NO (8a) **Type 3**
77c. Is dated and signed by authorized user..... _ YES _ NO (8b)
77d. Contains dosage to be administered..... _ YES _ NO (8c)

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and , for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require:

(a) be an order for a specific patient
(b) is dated and signed by the authorized user
(c) contains the dosage to be administered.

78. Documentation of oral revisions and oral directives: _ YES _ NO (18a) **Type 1**

a. Documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP

_ YES _ NO (18b) Type 1

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

79. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage

_ YES _ NO (19) Type 2

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

80. Procedure to verify patient's identity by more than one method prior to administration

_ YES _ NO (23e) Type 3

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each **NaI I-125 or I-131 >30 microCi** administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

81a. Procedures to ensure, before administration, that each administration is in accordance with the written directive.

_ YES _ NO (27a) Type 3

Your submittal for I-125 and/or I-131 > 30uCi administration does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive.

81b. For I-125 and/or I-131 > 30uCi:

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive — _ YES _ NO (27b) Type 3

According to guidance provided by Regulatory Guide 8.33, the dosage, should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures in your QMP.

82. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive — _ YES _ NO (31) Type 2

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP

83. A written directive and records of each administered I-125 and/or I-131>30 uCi must be maintained for three years. — _ YES _ NO (32) Type 1

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

84. Policies/Procedures for identification and evaluation of unintended deviations from the written directive — _ YES _ NO (34e) Type 2

Your QMP for **NaI I-125 or I-131 >30 microCi** must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

85a. Institution of corrective actions to be taken after the deviation has been identified — _ YES _ NO (35) Type 2

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

85b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. — _ YES _ NO (1) Type 2

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

86. Time intervals (intervals not to exceed 12 months) _ YES _ NO (36e) Type 1

Your submittal for NaI I-125 or I-131 >30 microCi does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

87. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations _ YES _ NO (37) Type 1

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

88. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _ NO (38) Type 1

According to guidance provided by Regulatory Guide 8.33, your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

89. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _ NO (39) Type 1

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

90. Modifications to QM program submitted to NRC within 30 days after modification has been made _ YES _ NO (40) Type 1

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32(e).

91. Records of each review and evaluation to be maintained for 3 years _ YES _ NO (41) Type 1

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS: _____

Quality Management Program for Therapeutic Radiopharmaceutical other than I-125 or I-131

92. A written QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 was provided. _ YES _ NO (3f) Type 3

A written QMP must be established and maintained for Radiopharmaceutical use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

93. Written certification that QM program has been implemented _ YES _ NO (4) Type 3

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32.f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

94a. A written directive is prepared for administration of therapeutic radiopharmaceutical other than I-125 and/or I-131 _ YES _ NO (9) Type 3

10 CFR 35.32(a)(1) requires a QMP to include policies and procedures for the preparation of a written directive, prior to the administration of any therapeutic radiopharmaceutical, other than sodium iodide I-125 or I-131. Please provide such a policy in your QMP.

The QMP provides procedures to require that the written directive include:

94b.	Radiopharmaceutical.....	_ YES _ NO (10a)	Type 1
94c.	Dosage.....	_ YES _ NO (10b)	
94d.	Route of administration.....	_ YES _ NO (10c)	
94e.	Order for a specific patient.....	_ YES _ NO (10d)	
94f.	Dated and signed by authorized user.....	_ YES _ NO (10e)	

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for a therapeutic use of a radiopharmaceutical other than I-125 or I-131, the radiopharmaceutical, dosage, and route of administration. Your QMP is missing procedures to require that the written directive include:

(a) Radiopharmaceutical
(b) Dosage
(c) Route of administration
(d) Order for a specific patient
(e) Date and signed by authorized user

95. Documentation of oral revisions and oral directives:

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

_ YES _ NO (18a) **Type 1**

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a provision in your QMP.

_ YES _ NO (18b) **Type 1**

if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

96. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage

_ YES _ NO (19) **Type 2**

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

97. Procedure to verify patient's identity by more than one method prior to administration

_ YES _ NO (23f) **Type 3**

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each **Therapeutic Radiopharmaceutical** other than I-125 or I-131 administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

98a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. _ YES _ NO (27c) Type 3

Your submittal for administration of therapeutic radiopharmaceutical other than I-125 or I-131 does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive.

98b. Confirm the radiopharmaceutical, dosage and route of administration

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive _ YES _ NO (27d) Type 3

According to guidance provided by Regulatory Guide 8.33, the radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures in your QMP.

99. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive _ YES _ NO (31) Type 2

Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

100. A written directive and records of each administered Therapeutic Radiopharmaceutical other than I-125 or I-131 must be maintained for three years. _ YES _ NO (32) Type 1

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d)(2). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

101. Policies/Procedures for identification and evaluation of unintended deviations from the written directive _ YES _ NO (34f) Type 2

Your QMP for **Therapeutic Radiopharmaceutical other than I-125 or I-131** must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

102a. Institution of corrective actions to be taken after the deviation has been identified — _ YES _ NO (35) Type 2

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

102b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. — _ YES _ NO (1) Type 2

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

103. Time intervals (intervals not to exceed 12 months) — _ YES _ NO (36f) Type 1

Your submittal for **Therapeutic Radiopharmaceutical other than I-125 or I-131** does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

104. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations — _ YES _ NO (37) Type 1

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

105. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. — _ YES _ NO (38) Type 1

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

106. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program — _ YES _ NO (39) **Type 1**

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

107. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES _ NO (40) **Type 1**

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32 (e)

108. Records of each review and evaluation to be maintained for 3 years — _ YES _ NO (41) **Type 1**

Please provide assurance that records of each review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

COMMENTS:_____

APPENDIX B: Strontium-90 Checklist

QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST
Strontium-90 Eye Applicator

1. *NAME OF LICENSEE:_____

Date QM Plan submitted to NRC_____

*License No.:_____

*Docket No.:_____

Telephone No.: (___)_____

LLNL Authorization Reviewer#_____

Reviewer # _____ Reviewer Loc (UCSF or other) _____

2nd Reviewer # _____ Reviewer Loc (UCSF or other) ____

LLNL Reviewer#_____

Reviewer's Notes:

Reviewers: Cross out comments which are no longer relevant. Date and initial comments. This information will not be stored in database. These are comments to the tracking office.

*R.S.O._____(include title, e.g., Dr., Mr., Ms., etc.)

*Department_____(e.g., Nuclear Med., Radiation Oncology, etc.)

*Street or P.O. Box_____

*City_____State_____Zip Code_____

*Reviewer: Take this information from license only.

2a. Authorized user for Strontium-90 Eye Applicator..... o YES o NO o U

2b. Also, authorized user for other modalities?..... o YES o NO

Reviewer: U means that the licensee is authorized for this modality but has stated in a letter that the facility will not be using this modality in practice.

Quality Management Program for Strontium-90

3. Is a written QMP for Strontium-90 Eye Applicators provided? _ YES _ NO (1)

The Quality Management Rule, 10 CFR 35.32, requires that a Quality Management Program (QMP) be submitted for applicable modalities. Please provide a QMP that contains the policies and procedures for your Strontium-90 Eye Applicator program. Please provide certification that your program has been implemented.

In your QMP, also include your method and frequency for training/instruction of supervised individuals for implementation of your program as required in 10 CFR 35.25.

OBJECTIVE 1—Written Directive [10 CFR 35.32(a)(1)]

4a. Is a written directive prepared for Strontium-90 Eye Applicators? _ YES _ NO (3)

4b. Does this directive include: _ YES _ NO (4)

- radioisotope
- treatment site, and either:
- total dose?

or

- source strength and
- exposure time?

Strontium-90 Eye Applicators are listed under 10 CFR 35.400 as brachytherapy. 10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient.

Written directives for Strontium-90 Eye Applicators must include: the radioisotope, the treatment site and either the total dose, or source strength and treatment time.

5. Are revisions to written directives dated and signed by a.u. prior to administration? _ YES _ NO (6)

Revisions to written directives for Strontium-90 Eye Applicators may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dose. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration of the dose with the Strontium-90 Eye Applicator.

6. Oral Directives:

a. Policies and procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision. _ YES _ NO (5a)

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

b. If a delay—in order to provide a written directive—would jeopardize the patient's health, an oral directive will be acceptable, provided that information is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. _ YES _ NO (5b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

OBJECTIVE 2—Patient Identify Verification [10 CFR 35.32 (a) (2)]

7. Procedure to verify patient's identity by more than one method prior to administration of Sr-90 Eye Applicator _ YES _ NO (7)

Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2), have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each Strontium-90 Eye Applicator administration, the patient's identity will be verified by more than one method as the individual named in the written directive.

OBJECTIVE 3 —Final Plans of Treatment and related calculations are in accordance with the written directive [10 CFR 35.32 (a) (3)]

8. For SR-90 Eye Applicators:

a. A plan of treatment will be prepared in accordance with the respective written directive _ YES _ NO (8a)

b. Procedure for assessing the quantity of material left after decay (decay chart or other method) _ YES _ NO (8b)

c. Procedure for checking dose calculations _ YES _ NO (8c)

d. Procedure that describes the method used to time the administration _ YES _ NO (8d)

Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for Strontium-90 Eye Applicator treatments are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include:

a. a plan of treatment will be prepared in accordance with the respective written directive

b. procedures for performing a check of dose calculations

c. a procedure for assessing the quantity of material left after decay

d. a procedure that describes the method used to time the administration

OBJECTIVE 4 —**Verification prior to administration that each administration is in accordance with the written directive [10 CFR 35.32 (a) (4)]**

9a. A procedure to ensure the person administering the Sr-90 Eye Applicator treatment should confirm the prescribed treatment site and either the total dose, or the source strength and exposure time _ YES _ NO (9a)

9b. Prompt recording, by the authorized user, of the source strength and exposure time, or total dose and sign or initial the patient's chart or appropriate record _ YES _ NO (9b)

Your submittal for Strontium-90 Eye Applicator brachytherapy does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive. Your procedures should include:

a. verification, before administering the dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed treatment site, and either the total dose, or source strength and treatment time should be confirmed by the person administering the treatment to verify agreement with the written directive and treatment plan.

b. prompt recording, by the authorized user, of the source strength and exposure time, or the total dose, and sign or initial the patient's chart or appropriate record.

Comments:

OBJECTIVE 5—Unintended deviations from the written directive are identified and evaluated, and appropriate corrective action is taken [10 CFR 35.32 (a) (5)]

10. A procedure for identification and evaluation of unintended deviations from the written directive _ YES _ NO (10)

Your QMP for Strontium-90 Eye Applicator brachytherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5).

11. Institution of corrective actions to be taken after the deviation has been identified _ YES _ NO (11)

Please include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

Periodic Reviews of the QM Program [10 CFR 35.32 (b)]

12. Time intervals (intervals not to exceed 12 months): _ YES _ NO (12)

Your submittal does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). Your procedure should include the time intervals for your reviews (in months) and describe your representative sample. These reviews should be conducted at intervals no greater than 12 months. Program reviews must include an evaluation of a representative sample of all patient administrations, and should include all recordable events and misadministrations. Your QMP review should include provisions to expand the review in the event that unidentified reportable events or misadministrations are found. Your QMP should describe your procedure for evaluating each of these reviews, and for making modifications to meet the objective of the QMP. Regulatory Guide 8.33, Section 6 (enclosed) may be of help in developing procedures for review of your QMP.

13. Review includes an acceptable representative sample of all patient administrations including all recordable events and misadministrations _ YES _ NO (13)

Your QMP review does not provide for an adequate representative sample of patient administrations as required in 10 CFR 35.32(b)(1)(i). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110; or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.

14. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP _ YES _ NO (14)

In your QMP, please include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP.

15. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program — _ YES _ NO (15)

Your QMP must include procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

16. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES _ NO (16)

Please include a provision to submit modifications to your QMP to the NRC within 30 days after the modification has been made.

17. Records of each review and evaluation to be maintained for 3 years — _ YES _ NO (17)

Your QMP should include assurance that records of each review and evaluation must be maintained for three years.

COMMENTS: _____

_____

_____

_____

APPENDIX C: Sample Letters

Negative Declaration

Facility Name
Attn: Name
Address
City, State Zip

RE: License Number:
Docket Number:
Plan File Date:
NRC Region:

Dear Name:

We have received your statement that, although you are licensed for [Teletherapy, Gamma Stereotactic Radiosurgery, High-Dose-Rate Remote Afterloading Brachytherapy, Brachytherapy, I-125 and/or I-131 > 30 Microcuries, and/or other Radiopharmaceutical Therapy], you do not intend to use it. Please be aware that before using [Teletherapy, etc.] for human use, you must provide an applicable quality management program that meets the requirements in 10 CFR 35.32 to the NRC regional office. Use of this material without the submission of an applicable quality management program could result in enforcement action.

No reply is required in response to this letter. Use of this modality will be reviewed at the next regular inspection of your facility.

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the NRC contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management.

Thank you for your cooperation in this matter. If you have any questions, please call me at .

Sincerely yours,

Enclosures

Sample Letter Type 1

Facility Name
Attn: Name
Address
City, State Zip

RE: License Number:
Docket Number:
Plan File Date:
NRC Region:

Dear Name:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on your submission, your QMP appears to meet the requirements of 10 CFR 35.32. You are reminded that the training and/or instruction of supervised individuals for implementation of your QMP is required in 10 CFR 35.25.

Additionally, please review your QMP with respect to the following:

[individual paragraphs describe where QMP needs revision.]

No reply is required in response to this letter. We will review implementation of your QMP at the next regular inspection of your facility.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your Quality Management Program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this office within 30 days as required by 10 CFR 35.32 (e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the NRC contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management.

Thank you for your cooperation in this matter. If you have any questions, please call me at .

Sincerely yours,

Enclosures

Sample Letter Type 2

Facility Name
Attn: Name
Address
City, State Zip

RE: License Number:
Docket Number:
Plan File Date:
NRC Region:

Dear Name:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on your submission, it appears your QMP may not fully meet all objectives in 10 CFR 35.32. You should review the following comments to determine if your program requires additional modification.

[individual paragraphs describe where QMP needs revision.]

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements occurred. Enforcement action may be taken at that time. Therefore, you should take prompt corrective action to address any deficiency to ensure your QMP and how it is implemented meet the objectives in 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your Quality Management Program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this office within 30 days as required by 10 CFR 35.32 (e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the NRC contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management.

Thank you for your cooperation in this matter. If you have any questions, please call me at .

Sincerely yours,

Enclosures

Sample Letter Type 3

Facility Name
Attn: Name
Address
City, State Zip

RE: License Number:
Docket Number:
Plan File Date:
NRC Region:

Dear Name:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

[individual paragraphs describe where QMP needs revision.]

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will review these matters during your next routine inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be take at that time for failure to meet the requirements of 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your Quality Management Program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this office within 30 days as required by 10 CFR 35.32 (e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the NRC contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management.

Thank you for your cooperation in this matter. If you have any questions, please call me at .

Sincerely yours,

Enclosures

APPENDIX D: Quality Management Program Database

KEY TO ABBREVIATIONS

The following abbreviations appear throughout the QMP database.

B	Licensee is licensed for at least one of Teletherapy, Gamma Stereotactic Radiosurgery, Brachytherapy, HDR Brachytherapy, in addition to possible radiopharmaceuticals.
H	Licensee is licensed for HDR Brachytherapy, according to list received from NRC staff 3/15/94.
nQMPr	No QMP Required.
Pilot	Part of Pilot Study.
R	Licensee is licensed for radiopharmaceuticals only.
regsntlet	Region sent a letter to this facility detailing their shortcomings.
Retired	Region declares that license is "retired."
Rnegdec	Region sent us a copy of negative declaration stating that even though a license has been issued, the facility is not using the modality.
Rtnd 9/2	Documents returned on 9/2/94 to UCSF for further review.
S	Licensee is licensed for Strontium-90 Eye Applicator therapy, according to list received from NRC staff 3/15/94.
s	Licensee is licensed for Strontium-90 Eye Applicator therapy, according to license.
T	License terminated.
U	Letter type "negative declaration."
Y	Additional facility information received at LLNL on date noted has been included in review. (Note: if this column is blank, then any additional information has not been included in review.)

QMP Database

License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
01-00643-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
01-03042-02	R	2	5/25/94			1	8/5/94	x				S			
02-06186-01	R	5	1/18/94			2	5/13/94	x							6/7/94
02-10072-01	R	5	6/27/94			3	7/25/94	x							
02-12726-01	R	5	8/25/94			U	8/30/94	x							
03-01082-01	B	4	6/15/94	N/A	N/A	3	7/6/94	x							8/19/94
04-00181-04	B	5	7/11/94	7/15/94	8/25/94	3	8/30/94	x					5/31/94	Y	
04-00181-12	B	5	7/11/94	7/15/94	8/30/94	3	9/7/94	x							
04-00421-05	B	5	6/13/94	6/14/94	7/21/94	3	8/5/94	x				s			
04-00689-07	B	5	7/20/94	7/22/94	8/15/94	3	8/19/94	x							
04-00916-04	R	5	1/14/94			3	4/4/94	x							
04-01496-01	B	5	2/17/94	2/28/94	4/21/94		nQMPr	x							
04-01935-03	R	5	4/25/94			2	5/13/94	x							6/7/94
04-02956-02	R	5	6/27/94			3	7/25/94	x							
04-09450-02	R	5	3/14/94			2	4/4/94	x							
04-12727-02	R	5	2/17/94			2	4/4/94	x							
04-15030-01	B	5	1/4/94	1/7/94	2/16/94	3	5/13/94	x					5/31/94		6/7/94
04-17862-01	B	5	2/11/94	2/28/94	4/21/94	3	8/5/94	x							
04-23242-01	B	5	1/31/94	2/4/94	3/22/94	3	6/3/94	x							6/16/94
05-00046-13	B	4	6/13/94	6/14/94	7/21/94	3	8/5/94	x					4/19/94	Y	10/11/94
05-00046-15	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							
05-01401-02	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							6/30/94
05-26854-01	R	4	7/15/94			3	7/25/94	x							9/27/94
06-00092-05	R	1	1/4/94	1/7/94	2/16/94	2	5/13/94	x							
06-00200-03	B	1	1/4/94	1/7/94	2/16/94	3	8/5/94	x				H/S			
06-00253-04	B	1	2/17/94	2/28/94	4/21/94	3	5/13/94	x							
06-00649-03	B	1	4/22/94	7/15/94	8/15/94	3	8/19/94	x				S			
06-00679-01	B	1	5/25/94	6/14/94	8/15/94	3	8/19/94	x							
06-00819-03	B	1	7/11/94	7/15/94	8/5/94	3	8/19/94	x				H			
06-00843-03	B	1	7/22/94	8/3/94	8/25/94	3	8/30/94	x							
06-00854-03	B	1	3/14/94	7/15/94	8/15/94	3	8/19/94	x				H			
06-01060-01	B	1	5/20/94	6/14/94	8/5/94	3	8/19/94	x					3/7/94	Y	
06-02057-01	R	1	1/5/94			3	5/13/94	x							
06-02388-01	B	1	6/9/94	6/14/94	8/5/94	3	8/19/94	x							
06-02406-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x					7/19/94		
06-03413-01	R	1	5/20/94			3	6/3/94	x							
06-05686-02	B	1	2/11/94	2/28/94	4/21/94	3	5/13/94	x							
06-06697-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
06-06922-02	B	1	4/18/94	4/20/94	6/17/94	3	7/6/94	x					7/19/94		
06-06941-01	B	1	1/24/94	2/4/94	3/22/94	3	6/3/94	x							
06-07795-01	R	1	3/22/94			U	6/3/94	x							
06-08020-02	R	1	3/22/94			3	5/13/94	x							
06-08349-04	R	1	3/25/94			3	5/13/94	x							
06-08544-01	B	1	3/2/94	3/30/94	5/17/94	3	6/3/94	x							
06-09261-01	R	1	7/15/94			3	7/25/94	x							
06-09522-01	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x							
06-10957-01	R	1	5/31/94			U	6/3/94	x							

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
06-11222-01	R	1	3/14/94			3	4/4/94	x							
06-11734-02	B	1	1/31/94	2/4/94	3/22/94	3	5/13/94	x							
06-12276-02	B	1	6/9/94	7/15/94	8/5/94	3	8/19/94	x				S	6/6/94	Y	
06-12276-03	B	1	5/20/94	6/14/94	8/5/94	3	8/19/94	x							
06-13001-02	R	1	3/22/94			3	4/4/94	x							
06-13022-02	B	1	7/28/94	8/3/94	8/25/94	3	8/30/94	x							
06-13022-05	B	1	7/7/94	7/15/94	8/5/94	3	8/19/94	x							
06-13504-02	R	1	7/12/94			3	7/25/94	x							
06-13611-01	R	1	3/23/94			3	4/4/94	x							
06-13905-01	R	1	1/17/94			2	5/13/94	x							
06-14734-01	B	1	2/22/94	2/28/94	4/21/94	3	5/13/94	x							
06-14854-01	R	1	1/10/94			3	5/13/94	x							
06-15203-01	R	1	3/17/94			3	4/4/94	x							
06-16123-01	R	1	7/22/94			3	8/5/94	x							
06-16624-01	R	1	1/27/94			3	5/13/94	x							
06-16869-01	R	1	6/20/94			3	7/6/94	x							
06-16872-01	R	1	1/10/94			3	5/13/94	x							
06-17145-01	R	1	1/12/94			3	5/13/94	x					4/5/94		
06-17434-01	R	1	6/20/94			3	7/6/94	x							
06-17892-01	R	1	2/7/94			3	6/3/94	x							
06-18121-01	R	1	5/23/94			3	6/3/94	x							
06-19749-01	R	1	7/27/94			U	8/5/94	x							
06-20528-01	R	1	7/15/94			3	7/25/94	x							
06-20691-01	R	1	4/19/94			3	5/13/94	x							
06-20862-01	R	1	3/25/94			3	5/13/94	x							
06-20870-01	B	1	3/22/94	3/30/94	5/17/94	3	6/3/94	x							
06-20957-01	R	1	1/28/94			3	4/4/94	x							
06-21317-01	R	1	1/27/94			3	3/11/94	x							
06-23632-02	R	1	2/22/94			U	5/13/94	x							
06-27909-01	R	1	3/25/94			U	5/13/94	x							
06-28141-01	R	1	1/10/94			3	5/13/94	x							
06-28283-01	R	1	6/10/94			U	7/6/94	x							
06-28502-01	R	1	1/14/94			3	5/13/94	x							
06-28615-01	R	1	4/19/94			U	5/13/94	x							
06-28707-01	R	1	7/7/94			3	7/25/94	x							
06-28708-01	R	1	7/15/94			U	7/25/94	x							
06-28716-01	R	1	7/7/94			U	7/25/94	x							
06-28786-01	R	1	1/17/94			U	5/13/94	x							
07-09495-01	R	1	1/28/94			2	6/3/94	x							
07-12153-02	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x					6/6/94		
07-12153-03	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x					3/7/94		
07-14850-01	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
07-14900-01	R	1	1/27/94			2	3/11/94	x							
07-16167-01	R	1	1/10/94			3	5/13/94	x							
07-16199-02	R	1	3/25/94			U	5/13/94	x							
07-16529-01	R	1	6/15/94			3	7/6/94	x							
07-16862-01	R	1	4/25/94			3	5/13/94	x							

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
07-17618-01	R	1	4/19/94			U	5/13/94	x							
07-17792-01	R	1	1/5/94			U	5/13/94	x							
07-18391-01	R	1	1/31/94			3	4/4/94	x							
07-28154-01	R	1	4/25/94			U	5/13/94	x							
07-28190-01	R	1	4/25/94			2	5/13/94	x							
07-28657-01	R	1	1/28/94			3	6/3/94	x							
07-28689-01	R	1	7/7/94			U	7/25/94	x							
07-28780-01	R	1	4/22/94			U	5/13/94	x							
08-00216-22	B	1	1/4/94	1/7/94	2/28/94	3	8/5/94	x				S			
08-00942-04	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
08-00942-05	R	1	1/11/94	2/4/94	3/22/94	2	6/3/94	x							
08-01709-04	B	1	7/19/94	7/22/94	8/25/94	3	8/30/94	x				H			
08-01709-06	B	1	N/A				nQMPr	x							
08-01728-01	R	1	2/4/94			3	8/5/94	x				S			
08-01738-02	B	1	6/9/94	7/15/94	8/30/94	3	9/7/94	x				s			
08-03075-07	B	1	1/20/94	6/14/94	8/5/94	3	8/19/94	x							
08-03309-01	R	1	1/18/94			3	5/13/94	x							
08-03604-03	B	1	1/11/94	2/4/94	3/22/94	3	8/5/94	x				H	6/6/94		
08-04289-06	B	1	2/4/94	2/28/94	4/21/94	3	5/13/94	x							
08-07398-03	R	1	4/8/94			3	6/3/94	x				S			
08-11182-01	B	1	1/27/94	2/4/94	3/22/94	3	5/13/94	x							
08-15994-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
08-16752-01	R	1	1/31/94			U	5/13/94	x							
08-19624-01	R	1	5/31/94			3	6/3/94	x							
08-19630-01	R	1	7/11/94			2	7/25/94	x							
08-20702-01	R	1	3/17/94			3	5/13/94	x							
08-23376-01	R	1	3/25/94			U	5/13/94	x							
08-28277-01	R	1	1/5/94			3	5/13/94	x							
08-28675-01	R	1	4/18/94			U	5/13/94	x							
08-28752-01	R	1	8/2/94			3	8/19/94	x							
09-00239-06	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x				H			
09-04233-03	R	2	5/11/94			2	6/3/94	x					4/27/94	Y	
09-12467-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
09-15294-01	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
09-25129-01	R	2	4/20/94			3	5/13/94	x							
10-01169-01	R	2	8/1/94			2	8/5/94	x							
10-06493-02		2	N/A				regsntlet	x							
10-08389-03	B	2	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
10-12044-03	R	2	8/4/94			3	8/19/94	x							
11-18311-01	R	4	6/27/94			3	7/25/94	x							9/27/94
11-27072-01	R	4	6/15/94			3	7/6/94	x							8/19/94
11-27082-01	B	4	3/15/94	3/30/94	5/17/94	2	6/3/94	x							
11-27085-01	R	4	7/1/94			2	7/25/94	x							
11-27087-01	R	4	7/15/94			3	7/25/94	x							9/27/94
11-27089-01	R	4	4/1/94			3	5/13/94	x							6/13/94
11-27306-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/12/94
11-27307-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x					6/29/94		7/12/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
11-27312-01	B	4	6/20/94	7/15/94	8/25/94	3	8/30/94	x					4/19/94	Y	
11-27346-01	R	4	7/15/94			3	7/25/94	x							9/27/94
11-27371-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x					5/13/94		7/12/94
11-27384-01	B	4	4/18/94	4/20/94	6/17/94	3	7/6/94	x							8/19/94
11-27393-01	R	4	8/15/94			3	8/19/94	x							
12-01087-07	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/16/94
12-01087-09	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
12-01403-01	B	3	5/23/94			3	6/3/94	x							6/29/94
12-02642-06	B	3	7/7/94	5/3/94	7/21/94	3	7/25/94	x							
12-10057-04	R	3	1/31/94			2	4/4/94	x							6/17/94
12-13568-02	R	3	7/15/94			3	7/25/94	x							
12-16473-01	R	3	7/18/94			2	8/5/94	x							
13-00133-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/30/94
13-00142-02	B	3	4/29/94	5/3/94	7/21/94	3	8/5/94	x							
13-00418-02	B	3	1/4/94	1/7/94	2/16/94	2	5/13/94	x							6/16/94
13-00694-03	B	3	3/14/94	7/15/94	8/30/94	3	9/7/94	x							
13-00951-03	B	3	1/11/94	2/4/94	3/22/94	3	7/6/94	x							7/14/94
13-00951-04	B	3	5/9/94	6/14/94	8/5/94	3	8/19/94	x							
13-01148-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x					4/14/94		6/17/94
13-01284-02	B	3	5/25/94	6/14/94	8/5/94	3	8/19/94	x				H			
13-01535-01	B	3	6/17/94	7/15/94	8/25/94	3	8/30/94	x							
13-01629-03	R	3	3/17/94			3	5/13/94	x							7/13/94
13-01629-04	B	3	4/26/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
13-01631-05	B	3	5/31/94	6/14/94	8/5/94	3	8/19/94	x							
13-01674-01	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
13-01674-02	B	3	7/15/94	7/15/94	8/15/94	3	8/19/94	x							
13-01719-02	R	3	7/15/94			3	7/25/94	x							
13-01787-01	B	3	6/24/94	7/15/94	8/15/94	3	8/19/94	x							
13-01787-04	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x							
13-02047-02	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x				H			
13-02063-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/22/94
13-02128-02	B	3	3/14/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
13-02128-03	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x				H			
13-02650-02	B	3	3/25/94	4/20/94	8/25/94	3	8/30/94	x				S			
13-02752-03	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x				H			6/23/94
13-02752-08	B	3	5/13/94	6/13/94	6/14/94	3	7/6/94	x							
13-03226-03	B	3	3/22/94	3/30/94	5/17/94	2	6/3/94	x							7/8/94
13-03226-04	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x				H			7/8/94
13-03284-02	B	3	6/13/94	6/14/94	7/21/94	3	8/5/94	x					5/31/94		
13-03284-03	B	3	8/9/94	8/9/94	8/25/94	3	8/30/94	x							
13-03459-02	B	3	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
13-03459-03	B	3	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
13-05605-01	R	3	4/13/94			3	6/3/94	x							6/17/94
13-06009-01	B	3	1/4/94	1/7/94	2/16/94	3	6/3/94	x				H			6/29/94
13-06652-01	B	3	2/22/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
13-08615-04	B	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x				S	5/11/94	Y	
13-08615-05	B	3	1/4/94	2/4/94	3/22/94	2	5/13/94	x							6/24/94

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								Complete	No File	QMP Only	Lic Only				
13-09274-03	R	3	4/29/94			2	6/3/94	x							7/8/94
13-09649-01	B	3	6/17/94	7/15/94	8/15/94	3	8/19/94	x							
13-09649-02	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
13-09788-01	R	3	6/17/94			2	7/6/94	x					4/5/94		7/14/94
13-10205-01	R	3	3/17/94			3	5/13/94	x							7/13/94
13-10408-02	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							7/13/94
13-11385-01	B	3	2/11/94	2/28/94	4/21/94	3	7/6/94	x							7/17/94
13-11983-01	R	3	7/22/94			2	8/5/94	x							
13-12367-01	R	3	3/23/94			3	4/4/94	x							6/9/94
13-12371-01	R	3	2/17/94			3	5/13/94	x							7/6/94
13-12914-01	B	3	2/11/94	2/28/94	4/21/94	3	6/3/94	x							6/17/94
13-13028-01	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
13-13028-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/22/94
13-13144-02	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x							
13-14817-01	R	3	2/17/94			2	5/13/94	x							7/13/94
13-14823-01	R	3	5/25/94			3	6/3/94	x							6/29/94
13-14877-01	R	3	2/17/94			3	5/13/94	x							7/6/94
13-15151-01	B	3	2/17/94	2/28/94	4/21/94	3	8/5/94	x				S			
13-15399-01	R	3	1/17/94			3	4/4/94	x					5/17/94		6/9/94
13-15882-01	B	3	1/4/94	1/7/94	2/28/94	3	7/6/94	x				H			7/14/94
13-15933-01	B	3	1/4/94	1/7/94	2/16/94	2	5/13/94	x					5/31/94		6/17/94
13-16286-01	R	3	3/14/94			3	4/4/94	x							6/8/94
13-16404-01	R	3	4/19/94			3	5/13/94	x							6/16/94
13-16457-01	B	3	2/11/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
13-16518-01	R	3	5/31/94			2	6/3/94	x							6/17/94
13-16558-01	B	3	5/25/94	6/14/94	8/5/94	3	8/19/94	x							
13-16680-01	R	3	5/13/94			3	6/3/94	x							7/8/94
13-16730-01	R	3	8/2/94			3	8/19/94	x							
13-17073-01	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x					4/14/94		6/22/94
13-17076-01	R	3	5/20/94			U	6/3/94	x							6/28/94
13-17082-01	R	3	2/17/94			2	5/13/94	x							7/13/94
13-17129-01	R	3	8/22/94			U	8/30/94	x							
13-17327-01	R	3	7/18/94			2	7/25/94	x					4/14/94	Y	
13-17449-01	R	3	2/22/94			3	5/13/94	x							7/6/94
13-17793-01	B	3	3/22/94	3/30/94	5/17/94	3	8/19/94	x				H			
13-17793-02	B	3	3/22/94	3/30/94	8/5/94	3	6/3/94	x							7/8/94
13-17841-01	R	3	7/29/94			U	8/5/94	x							
13-17943-01	R	3	7/26/94			3	8/5/94	x							
13-17956-01	R	3	3/22/94			3	5/13/94	x							6/24/94
13-17958-01	R	3	2/4/94			2	5/13/94	x							6/22/94
13-18506-01	R	3	3/17/94			3	5/13/94	x							7/13/94
13-18543-01	R	3	4/25/94			2	5/13/94	x							6/28/94
13-18570-01	R	3	7/7/94			U	7/25/94	x							
13-18677-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
13-18692-01	R	3	1/27/94			3	5/13/94	x							6/28/94
13-18703-01	R	3	1/17/94			3	5/13/94	x							6/30/94
13-18845-01	R	3	1/27/94			3	5/13/94	x							7/6/94

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								Complete	No File	QMP Only	Lic Only				
13-18847-01	R	3	2/17/94			3	5/13/94	x							7/13/94
13-18879-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							7/13/94
13-18880-01	R	3	7/26/94			3	8/5/94	x							
13-18881-01	B	3	3/2/94	3/30/94	5/17/94	3	6/3/94	x				H			6/17/94
13-18881-02	B	3	2/17/94	2/28/94	4/21/94	3	6/3/94	x							6/17/94
13-18992-01	R	3	1/10/94			2	5/13/94	x							6/30/94
13-20329-01	R	3	8/1/94			3	8/5/94	x							
13-20352-01	R	3	7/12/94			3	7/25/94	x							
13-20449-01	R	3	7/15/94			2	7/25/94	x							
13-23331-01	R	3	7/12/94			2	7/25/94	x							
13-23543-01	R	3	8/1/94			3	8/5/94	x							
13-23665-01	R	3	5/20/94			3	6/3/94	x							6/29/94
13-24433-01	R	3	1/14/94			2	5/13/94	x							6/30/94
13-24760-01	B	3	5/9/94	6/14/94	7/21/94	2	8/5/94	x							
13-24760-02	B	3	3/22/94	3/30/94	5/17/94	2	6/3/94	x							7/8/94
13-24834-01	R	3	4/8/94			U	5/13/94	x							6/24/94
13-24861-01	B	3	5/25/94	6/14/94	8/5/94	3	8/19/94	x							
13-25945-01	B	3	5/20/94	6/14/94	8/5/94	3	8/19/94	x				H			
13-26028-02	R	3	5/20/94			3	6/3/94	x							6/29/94
13-26043-01	R	3	3/14/94			3	4/4/94	x							6/17/94
13-26065-01	R	3	1/31/94		8/5/94	2	4/4/94	x							6/17/94
13-26133-01	R	3	1/14/94			3	5/13/94	x							6/30/94
13-26245-01	R	3	3/17/94			3	5/13/94	x							7/13/94
13-26371-01	R	3	4/19/94			3	5/13/94	x							6/16/94
13-26401-01	R	3	4/22/94			2	5/13/94	x							6/22/94
13-26497-01	R	3	7/15/94			3	7/25/94	x							
13-26500-01	R	3	5/13/94			3	7/25/94	x							
14-00822-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/17/94
14-03523-02	R	3	8/1/94			3	8/19/94	x							
15-08114-01	R	4	7/15/94			3	7/25/94	x							10/4/94
15-10940-01	R	4	6/10/94			3	4/4/94	x							6/3/94
15-26381-01	R	3	3/25/94			3	5/13/94	x							7/13/94
16-03121-02	R	2	4/20/94			3	5/13/94	x							
16-03657-01	R	2	4/1/94			2	7/6/94	x							
16-08896-04	B	2	7/15/94	7/22/94	8/15/94	3	8/19/94	x							
17-01322-07	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x					5/20/94&6/14/		7/12/94
17-09273-01	R	4	1/14/94			3	4/4/94	x							6/3/94
17-12273-01	B	4	6/27/94	7/15/94	8/25/94	3	8/30/94	x				s	6/7/94	Y	
18-07561-01	R	1	1/17/94			2	4/4/94	x							
19-00296-10	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			
19-00975-01	R	1	7/15/94			3	7/25/94	x							
19-01058-01	R	1	3/14/94			2	4/4/94	x							
19-07187-01	R	1	4/14/94			3	5/13/94	x							
20-00083-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
20-00096-02	R	1	7/7/94			3	8/5/94	x				S			
20-00275-08	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x					4/5/94	Y	
20-00289-07	B	1	4/28/94	6/14/94	7/21/94	3	8/5/94	x					3/7/94		

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
20-00506-03	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
20-00634-03	B	1	4/19/94	4/20/94	6/17/94	3	7/6/94	x							
20-00671-02	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
20-00713-03	R	1	7/15/94			3	7/25/94	x							
20-00742-18	B	1	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
20-01412-03	B	1	7/19/94	7/22/94	8/25/94	3	8/30/94	x							
20-01412-05	B	1	7/19/94	7/22/94	8/25/94	2	8/30/94	x							
20-02039-01	R	1	1/14/94			3	5/13/94	x							
20-02215-01	B	1	4/26/94	7/15/94	8/25/94	3	8/30/94	x				S			
20-02399-01	R	1	1/17/94			3	5/13/94	x							
20-02452-01	B	1	1/10/94	2/28/94	4/21/94	3	5/13/94	x							
20-02452-03	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
20-02615-01	R	1	1/12/94			3	7/6/94	x							
20-02829-01	R	1	1/14/94			U	6/3/94	x							
20-03333-02	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
20-03502-01	R	1	3/23/94			3	4/4/94	x							
20-03814-14	B	1	2/17/94	2/28/94	4/21/94	3	5/13/94	x							
20-03814-80	B	1	2/17/94	2/28/94	4/21/94	3	8/5/94	x				H/S			
20-03857-06	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
20-05258-02	R	1	2/4/94			3	6/3/94	x							
20-05271-01	R	1	1/27/94			3	5/13/94	x							
20-05655-01	R	1	1/27/94			3	3/11/94	x							
20-05691-01	R	1	3/25/94			3	5/13/94	x							
20-05696-02	B	1	1/4/94	1/7/94	2/28/94	2	5/13/94	x							
20-05766-02	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x				H	6/6/94		
20-06006-02	R	1	1/18/94			3	3/11/94	x							
20-06296-01	R	1	6/15/94			3	7/6/94	x					4/5/94		
20-06579-02	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
20-06900-01	R	1	7/12/94			3	7/25/94	x							
20-07347-01	R	1	5/31/94			3	6/3/94	x							
20-07590-02	R	1	3/22/94			3	5/13/94	x							
20-08551-01	B	1	7/14/94	7/15/94	8/25/94	3	8/30/94	x							
20-09021-03	R	1	6/20/94			U	7/6/94	x							
20-09214-02	R	1	1/14/94			U	5/13/94	x							
20-09496-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
20-09568-17	B	1	7/8/94	7/15/94	8/30/94	3	9/7/94	x							
20-10184-01	R	1	1/18/94			U	5/13/94	x							
20-10621-01	R	1	1/27/94			3	6/3/94	x							
20-10784-02	B	1	5/20/94	6/14/94	8/15/94	3	8/19/94	x							
20-11013-02	R	1	7/12/94			3	7/25/94	x							
20-11973-01	R	1	3/17/94			3	4/4/94	x							
20-12009-01	R	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
20-12009-03	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
20-12063-01	R	1	2/22/94			2	6/3/94	x							
20-12063-02	B	1	2/22/94			3	6/3/94	x							
20-12498-01	R	1	6/20/94			3	7/25/94	x							
20-12560-01	R	1	2/7/94			3	5/13/94	x							

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								Complete	No File	QMP Only	Lic Only				
20-12561-01	R	1	1/27/94			3	5/13/94	x							
20-12828-01	R	1	1/17/94			3	5/13/94	x							
20-12869-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x					3/7/94	Y	
20-13162-02	R	1	1/5/94			3	5/13/94	x							
20-13254-01	R	1	3/22/94			3	4/4/94	x							
20-13391-01	R	1	1/5/94			3	5/13/94	x							
20-13404-01	R	1	1/14/94			U	6/3/94	x							
20-13448-01	R	1	5/20/94			3	6/3/94	x							
20-13486-01	R	1	8/22/94			3	8/30/94	x							
20-13486-02	B	1	6/13/94	6/14/94	7/21/94	3	8/5/94	x							
20-13515-01	R	1	2/7/94			U	5/13/94	x							
20-13556-01	R	1	1/27/94			3	6/3/94	x							
20-13682-01	R	1	1/17/94			U	5/13/94	x							
20-13758-01	B	1	1/11/94	2/4/94	3/22/94	3	7/6/94	x				H			
20-13758-03		1	N/A				T								
20-13864-01	R	1	1/10/94			1	5/13/94	x							
20-13916-02	B	1	3/2/94	3/30/94	5/17/94	3	6/3/94	x							
20-14009-01	R	1	1/17/94			U	5/13/94	x							
20-14767-01	R	1	6/20/94			3	7/6/94	x							
20-14816-01	R	1	6/21/94			3	7/6/94	x							
20-14868-01	R	1	1/31/94			3	5/13/94	x							
20-15007-01	R	1	6/15/94			3	7/6/94	x							
20-15240-01	R	1	2/17/94			U	5/13/94	x							
20-15280-01	R	1	1/31/94			U	5/13/94	x							
20-15295-01	R	1	1/10/94			U	5/13/94	x							
20-15373-01	R	1	5/31/94			U	6/3/94	x							
20-15385-01	R	1	1/17/94			3	5/13/94	x							
20-15522-01	R	1	1/17/94			3	5/13/94	x					6/6/94		
20-15613-01	R	1	1/27/94			U	5/13/94	x							
20-15614-01	R	1	7/15/94			3	7/25/94	x							
20-15761-01	R	1	7/29/94			3	8/5/94	x							
20-15906-01	R	1	1/5/94			3	5/13/94	x							
20-16181-01	R	1	2/22/94			U	5/13/94	x							
20-16389-01	R	1	7/15/94			U	7/25/94	x							
20-16392-01	R	1	1/14/94			3	6/3/94	x							
20-16804-01	R	1	2/17/94			U	5/13/94	x							
20-16970-01	R	1	1/27/94			U	5/13/94	x							
20-17131-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
20-18110-01	R	1	3/17/94			U	5/13/94	x							
20-18133-01	R	1	1/17/94			U	6/3/94	x							
20-18449-01	R	1	7/15/94			3	7/25/94	x							
20-18449-02	R	1	7/15/94			3	7/25/94	x							
20-19039-01	R	1	1/5/94			3	5/13/94	x							
20-19761-02	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
20-20554-01	B	1	6/9/94	6/14/94	7/21/94	3	8/5/94	x							
20-20615-01	R	1	3/22/94			3	4/4/94	x							
20-20621-01	R	1	1/31/94			2	4/4/94	x							

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								Complete	No File	QMP Only	Lic Only				
20-20799-01	R	1	2/7/94			3	4/4/94	x							
20-28032-01	R	1	4/19/94			3	5/13/94	x							
20-28078-01	R	1	6/29/94			3	7/25/94	x							
20-28078-02	R	1	2/17/94			3	5/13/94	x							
20-28172-01	R	1	2/17/94			U	5/13/94	x							
20-28429-01	R	1	3/25/94			U	5/13/94	x							
20-28558-01	R	1	6/20/94			3	7/6/94	x							
20-28676-01	R	1	7/15/94			3	7/25/94	x							
20-28729-01	R	1	1/31/94			U	5/13/94	x							
21-00159-04	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/22/94
21-00215-04	B	3	1/4/94	1/7/94	2/16/94	2	6/3/94	x							
21-00243-06	B	3	4/26/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
21-00258-06	R	3	1/14/94			2	4/4/94	x							6/8/94
21-00299-04	B	3	5/13/94	7/15/94	8/5/94	3	8/19/94	x							
21-00299-06	B	3	1/11/94	2/4/94	3/22/94	3	6/3/94	x							6/17/94
21-00338-02	B	3	1/31/94	2/4/94	3/22/94	3	4/4/94	x				H			
21-00607-04	R	3	3/14/94			2	4/4/94	x							6/8/94
21-00943-03	B	3	6/17/94	7/15/94	8/15/94	3	8/19/94	x							
21-00943-04	B	3	6/17/94	7/15/94	8/15/94	2	8/19/94	x							
21-00998-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x					4/5/94		6/22/94
21-01078-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/17/94
21-01103-04	B	3	1/4/94	1/7/94	2/28/94	3	6/3/94	x							6/29/94
21-01190-05	B	3	5/11/94	6/14/94	7/21/94	3	8/5/94	x							
21-01333-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H/S			6/30/94
21-01354-04	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
21-01424-03	B	3	2/7/94	2/28/94	4/21/94	3	6/3/94	x				H			6/29/94
21-01430-01	B	3	2/7/94	2/28/94	4/21/94	2	5/13/94	x							6/22/94
21-01430-02	B	3	7/15/94	7/15/94	8/5/94	3	8/19/94	x							
21-01492-02	R	3	7/15/94			2	8/5/94	x				S			
21-01549-02	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
21-02037-03	R	3	5/20/94			3	6/3/94	x							6/29/94
21-02187-01	R	3	2/22/94			3	5/13/94	x							7/6/94
21-02802-03	B	3	1/4/94	1/7/94	2/28/94	3	8/5/94	x				S			
21-03001-01	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
21-03194-01	R	3	1/14/94			2	5/13/94	x							6/21/94
21-03210-01	B	3	3/2/94	4/20/94	6/17/94	3	7/6/94	x					4/27/94		7/14/94
21-03298-05	B	3	5/13/94	6/14/94	8/15/94	3	8/19/94	x							
21-03429-04	R	3	1/17/94			3	5/13/94	x							6/30/94
21-03646-03	B	3	1/4/94	1/7/94	2/28/94	3	8/5/94	x				H/S			
21-03835-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-04072-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/17/94
21-04073-01	R	3	1/18/94			2	6/3/94	x							6/17/94
21-04080-01	R	3	2/7/94			2	5/13/94	x							6/28/94
21-04081-03	R	3	5/25/94			3	6/3/94	x					4/5/94		6/29/94
21-04082-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x					4/27/94		6/22/94
21-04109-08	B	3	8/17/94	9/2/94				x							
21-04109-16	B	3	1/4/94	1/7/94	2/16/94	3	7/6/94	x				H			7/14/94

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								Complete	No File	QMP Only	Lic Only				
21-04125-01	B	3	2/17/94	2/28/94	4/21/94	3	8/5/94	x					4/5/94		
21-04127-02	B	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x				H			
21-04127-06	B	3	2/17/94	2/28/94	4/21/94	2	5/13/94	x							6/22/94
21-04171-04	B	3	1/31/94	2/4/94	3/22/94	3	7/6/94	x				H			7/14/94
21-04177-01	B	3	7/15/94	7/22/94	8/25/94	3	8/30/94	x							
21-04234-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
21-04515-01	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x				H/S			
21-05432-04	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
21-06217-02	B	3	4/22/94	5/3/94	6/17/94	3	7/6/94	x					5/17/94		7/14/94
21-07437-01	R	3	6/15/94			2	7/6/94	x							7/14/94
21-08317-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
21-08892-01	R	3	1/14/94			3	5/13/94	x							6/30/94
21-08966-01	B	3	8/1/94	N/A	N/A	3	8/19/94	x							
21-10140-01	R	3	1/14/94			2	5/13/94	x					5/17/94		6/30/94
21-10578-02	R	3	7/26/94			3	8/5/94	x							
21-10717-01	R	3	8/17/94			3	8/30/94	x							
21-10983-01	R	3	7/19/94			3	8/5/94	x							
21-11457-02	R	3	1/5/94			2	5/13/94	x					4/5/94		
21-11475-01	R	3	1/14/94			2	5/13/94	x					5/11/94		6/30/94
21-11494-01	B	3	1/31/94	2/4/94	3/22/94	3	5/13/94	x					6/24/94		6/24/94
21-11553-01	R	3	7/19/94			3	8/5/94	x							
21-11651-01	B	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x				H	8/16/94		
21-11850-01	B	3	5/20/94	6/14/94	7/21/94	3	8/5/94	x					4/5/94		
21-12275-01	B	3	5/23/94	6/14/94	7/21/94	3	8/5/94	x							
21-12275-02	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
21-12424-01	R	3	1/27/94			2	5/13/94	x					5/17/94		7/6/94
21-12826-01	R	3	1/27/94			2	5/13/94	x							6/28/94
21-12829-01	R	3	5/13/94			3	6/3/94	x							7/8/94
21-12916-01	R	3	3/14/94			3	4/4/94	x							6/17/94
21-12930-01	R	3	7/12/94			2	7/25/94	x							
21-13125-01	B	3	1/5/94	2/4/94	3/22/94	3	5/13/94	x							7/13/94
21-13255-01	R	3	1/31/94			2	4/4/94	x							6/21/94
21-13562-01	R	3	1/14/94			3	5/13/94	x							6/30/94
21-13717-02	R	3	7/19/94			3	8/5/94	x							
21-13963-01	R	3	1/14/94			3	5/13/94	x							7/8/94
21-13973-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-14844-01	R	3	1/18/94			2	5/13/94	x							
21-14849-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							7/13/94
21-15147-01	R	3	2/11/94			2	5/13/94	x							6/22/94
21-15166-01	R	3	2/11/94			3	5/13/94	x							6/22/94
21-15462-01	R	3	4/25/94			2	5/13/94	x							6/22/94
21-15638-01	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
21-15652-01	R	3	4/19/94			2	5/13/94	x							6/16/94
21-15723-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-15910-01	R	3	5/31/94			U	6/3/94	x							6/17/94
21-15940-02	R	3	5/20/94			2	6/3/94	x							6/29/94
21-16277-01	R	3	3/17/94			2	4/4/94	x							6/17/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
21-16317-01	R	3	1/14/94			2	4/4/94	x							6/9/94
21-16327-01	R	3	3/14/94			3	4/4/94	x							6/17/94
21-16339-01	R	3	2/17/94			2	5/13/94	x							7/8/94
21-16394-01	R	3	7/15/94			3	7/25/94	x							
21-16425-01	R	3	6/29/94			3	7/25/94	x							
21-16475-01	R	3	2/7/94			3	4/4/94	x							6/9/94
21-16481-01	R	3	3/14/94			3	4/4/94	x							6/9/94
21-16489-01	R	3	7/26/94			3	8/5/94	x							
21-16542-03	R	3	1/17/94			2	4/4/94	x							6/9/94
21-16656-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-16672-01	R	3	4/25/94			3	5/13/94	x							6/22/94
21-16732-01	B	3	5/13/94	6/14/94	7/21/94	3	8/5/94	x							
21-16737-01	R	3	1/27/94			3	5/13/94	x							7/13/94
21-16754-01	R	3	1/28/94			2	5/13/94	x							6/23/94
21-16868-01	R	3	1/14/94			2	5/13/94	x							6/21/94
21-16891-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-17068-01	R	3	1/28/94			U	5/13/94	x							6/23/94
21-17093-01	R	3	1/27/94			2	5/13/94	x							7/8/94
21-17360-01	R	3	1/17/94			2	5/13/94	x							6/30/94
21-17754-01	R	3	7/29/94			3	8/5/94	x							
21-17789-01	R	3	1/14/94			2	5/13/94	x					4/27/94		6/30/94
21-17830-01	R	3	5/24/94			3	6/3/94	x					5/31/94		6/29/94
21-17971-01	R	3	2/22/94			3	5/13/94	x							7/8/94
21-17974-01	R	3	7/27/94			2	8/19/94	x					5/17/94	Y	
21-18502-01	R	3	7/15/94			2	7/25/94	x							
21-18525-01	R	3	2/22/94			3	4/4/94	x							6/9/94
21-18566-01	R	3	7/15/94			3	7/25/94	x							
21-18585-01	R	3	4/13/94			3	5/13/94	x							6/16/94
21-18586-01	R	3	1/17/94			3	5/13/94	x							6/30/94
21-18621-01	R	3	2/7/94			3	4/4/94	x							6/8/94
21-18659-01	R	3	2/17/94			3	5/13/94	x							7/8/94
21-18667-01	R	3	4/25/94			3	5/13/94	x							6/24/94
21-18752-01	R	3	1/14/94			2	5/13/94	x							6/30/94
21-18816-01	R	3	1/27/94			2	5/13/94	x							7/15/94
21-18889-01	R	3	1/17/94			3	5/13/94	x							6/30/94
21-18892-01	R	3	7/26/94			3	8/5/94	x							
21-18912-01	R	3	1/27/94			2	5/13/94	x							7/8/94
21-18979-01	R	3	2/7/94			2	4/4/94	x							6/9/94
21-19572-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/17/94
21-20093-01	R	3	7/1/94			2	7/25/94	x							
21-20104-01	R	3	1/17/94			2	5/13/94	x							6/28/94
21-20137-01	R	3	6/17/94			3	7/6/94	x							7/14/94
21-20152-01	R	3	5/23/94			2	6/3/94	x							6/29/94
21-20242-01	R	3	4/13/94			2	7/25/94	x							
21-20318-01	R	3	8/4/94			2	8/19/94	x							
21-20320-01	R	3	7/29/94			3	8/5/94	x							
21-20355-01	R	3	2/22/94			2	5/13/94	x					5/31/94		6/23/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
21-20416-01	R	3	1/28/94			3	6/3/94	x							7/8/94
21-20487-01	R	3	6/21/94			3	7/9/94	x							7/14/94
21-21265-01	R	3	2/7/94			2	4/4/94	x							6/17/94
21-23633-01	R	3	1/10/94			2	5/13/94	x							6/30/94
21-24363-01	R	3	1/17/94			2	5/13/94	x							6/30/94
21-24368-01	R	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x							
21-24562-01	R	3	6/15/94			2	7/6/94	x							7/14/94
21-24652-01	R	3	5/20/94			2	6/3/94	x							6/29/94
21-24748-01	R	3	1/10/94			2	5/13/94	x							
21-24820-01	R	3	3/22/94			2	4/4/94	x					11/29/93		
21-24843-01	R	3	7/15/94			2	7/25/94	x							
21-24901-01	R	3	8/1/94			2	8/5/94	x							
21-25815-01	R	3	3/25/94			3	5/13/94	x							7/13/94
21-25921-01	R	3	2/17/94			2	5/13/94	x							7/8/94
21-25934-01	R	3	4/19/94			2	5/13/94	x							6/16/94
21-25967-01	R	3	5/20/94			2	6/3/94	x							6/29/94
21-25968-01	R	3	4/22/94			2	6/3/94	x							7/8/94
21-25972-01	R	3	1/17/94			2	4/4/94	x							6/9/94
21-25980-01	R	3	7/15/94			2	8/5/94	x					4/14/94		
21-25987-01	R	3	7/26/94			1	8/5/94	x							
21-25987-02		3	N/A				nQMPr	x							
21-26029-01	R	3	2/4/94			2	5/13/94	x							6/21/94
21-26050-01	R	3	6/20/94			2	7/6/94	x							7/14/94
21-26076-01	R	3	3/14/94			3	4/4/94	x							6/17/94
21-26196-01	R	3	1/14/94			2	5/13/94	x					6/30/94		6/30/94
21-26202-01	R	3	1/27/94			2	5/13/94	x							7/13/94
21-26213-01	R	3	3/22/94			2	5/13/94	x							6/22/94
21-26255-01	R	3	1/5/94			2	5/13/94	x							6/30/94
21-26259-01		3	N/A				Rnegdec	x							
21-26263-01	R	3	6/15/94			2	7/6/94	x							7/14/94
21-26266-01	R	3	3/14/94			3	4/4/94	x							6/17/94
21-26287-01	R	3	8/1/94			2	8/5/94	x							
21-26306-01	R	3	5/31/94			2	6/3/94	x							6/17/94
21-26313-01	R	3	5/13/94			2	6/3/94	x							7/8/94
21-26338-01	R	3	5/31/94			2	6/3/94	x							6/17/94
21-26346-01	R	3	4/8/94			3	5/13/94	x							6/24/94
21-26488-01	B	3	4/26/94	6/14/94	7/21/94	3	8/5/94	x				H			
21-26498-01		3	N/A				Rnegdec	x							
22-00015-02	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
22-00519-03	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x					8/16/94		
22-01448-01	B	3	6/29/94	7/15/94	8/5/94	3	8/19/94	x							
22-01519-02	B	3	1/4/94	1/7/94	2/16/94	3	7/25/94	x							
22-01717-01	R	3	2/7/94			3	4/4/94	x							7/8/94
22-01859-01	B	3	1/4/94	1/7/94	2/16/94	3	8/5/94	x				S			
22-01914-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
22-02003-04	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							7/13/94
22-02396-03	R	3	2/7/94			3	4/4/94	x							6/9/94

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								Complete	No File	QMP Only	Lic Only				
22-02403-01	R	3	2/22/94			3	5/13/94	x							7/8/94
22-02491-03	R	3	1/14/94			2	5/13/94	x							6/28/94
22-03251-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
22-03364-02	R	3	1/14/94			1	5/13/94	x							6/30/94
22-04178-02	R	3	3/25/94			3	5/13/94	x							7/13/94
22-04588-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x				H			
22-05792-01	B	3	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
22-09562-01	B	3	6/29/94	7/15/94	8/5/94	3	8/19/94	x							
22-10236-01	R	3	2/7/94			3	5/13/94	x							6/30/94
22-10258-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x					5/11/94		6/17/94
22-11070-01	B	3	7/28/94	8/3/94	8/25/94	2	8/30/94	x							
22-12614-01	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
22-13487-01	R	3	2/7/94			3	4/4/94	x							6/9/94
22-13859-02	B	3	6/13/94	6/14/94	7/21/94	2	8/5/94	x							
22-13867-01	R	3	3/17/94			3	4/4/94	x							6/17/94
22-15169-01	R	3	7/12/94			U	7/25/94	x							
22-15252-01	R	3	5/9/94			2	6/3/94	x							7/8/94
22-15538-01	R	3	3/14/94			3	4/4/94	x							6/8/94
22-16390-01	B	3	1/4/94	1/7/94	2/28/94	3	7/25/94	x							
22-16390-02	B	3	1/4/94	1/7/94	2/28/94	3	6/3/94	x							6/29/94
22-16543-01	R	3	1/27/94			U	5/13/94	x							7/8/94
22-16550-01	R	3	1/18/94			2	5/13/94	x							6/23/94
22-16766-01	R	3	1/14/94			3	5/13/94	x							6/30/94
22-16966-01	R	3	2/7/94			3	4/4/94	x							6/8/94
22-17053-01	R	3	1/14/94			3	5/13/94	x							6/30/94
22-17557-02	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x					4/5/94		7/13/94
22-17994-01	R	3	1/27/94			3	8/5/94	x				S			
22-18027-01	R	3	1/10/94			2	5/13/94	x							6/30/94
22-18652-01	R	3	3/18/94			3	5/13/94	x							6/23/94
22-18838-01	R	3	3/14/94			2	4/4/94	x							6/8/94
22-18989-01	R	3	5/20/94			2	6/3/94	x							6/29/94
22-20034-01	R	3	2/7/94			3	4/4/94	x							
22-20451-01	R	3	3/22/94			3	5/13/94	x							6/21/94
22-20499-01	R	3	1/14/94			3	5/13/94	x							6/28/94
22-24306-01	R	3	1/10/94			2	5/13/94	x							6/30/94
22-24441-01	R	3	1/17/94			3	5/13/94	x							6/28/94
22-26031-01	B	3	7/28/94			3	8/5/94	x				G	8/16/94		
22-26244-01	R	3	1/14/94			3	6/3/94	x							
23-08786-01	R	2	7/15/94			2	8/5/94	x							
23-12255-02	R	2	4/25/94			2	5/13/94	x					4/27/94		
24-00063-10	B	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x							
24-00128-03	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
24-00144-05	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/17/94
24-00158-03	R	3	1/4/94			2	5/13/94	x							6/24/94
24-00167-11	B	3	7/11/94	7/15/94	8/25/94	3	8/30/94	x				H	5/17/94	Y	
24-00196-07	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x				H			7/8/94
24-00496-06	B	3	1/4/94	1/7/94	2/16/94	3	7/6/94	x					4/5/94	Y	7/14/94

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								Complete	No File	QMP Only	Lic Only				
24-00513-32	B	3	4/5/94	6/14/94	7/21/94	3	8/5/94	x							
24-00624-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/21/94
24-00752-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/23/94
24-00752-03	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/23/94
24-00794-03	B	3	3/22/94	3/30/94	5/17/94	2	6/3/94	x					4/5/94		7/8/94
24-00866-02	B	3	3/2/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
24-00889-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/17/94
24-00889-02	B	3	7/28/94	8/3/94	8/25/94	3	8/30/94	x							
24-01041-04	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
24-01090-02	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
24-01090-03	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							7/13/94
24-01143-06	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							
24-01239-01	B	3	6/27/94	7/15/94	8/30/94	3	9/7/94	x							
24-01381-01	R	3	2/17/94			2	5/13/94	x							7/8/94
24-01565-01	B	3	6/29/94	7/15/94	8/5/94	3	8/19/94	x				H			
24-01565-02	B	3	6/29/94	7/15/94	8/15/94	3	8/19/94	x							
24-01570-03	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/30/94
24-02490-03	B	3	4/29/94	5/3/94	7/21/94	3	8/5/94	x				H			
24-02704-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
24-04010-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/21/94
24-04581-19	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							7/8/94
24-04584-01	R	3	5/20/94			2	6/3/94	x							6/29/94
24-05245-01	R	3	2/4/94			3	5/13/94	x							6/30/94
24-06806-01	B	3	1/4/94	1/7/94	2/28/94	1	5/13/94	x							6/22/94
24-08960-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H	4/5/94		6/30/94
24-11128-02	B	3	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
24-11858-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
24-12699-01	B	3	3/2/94	3/30/94	5/17/94	3	6/3/94	x							
24-12876-02	R	3	3/23/94			3	4/4/94	x							
24-13246-02	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
24-13383-01	B	3	1/5/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
24-13975-01	R	3	1/17/94			2	5/13/94	x							6/30/94
24-15095-01	R	3	2/17/94			3	5/13/94	x							7/8/94
24-15122-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
24-15159-01	R	3	2/4/94			3	6/3/94	x							7/8/94
24-15235-03	B	3	3/2/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
24-15513-01	R	3	3/17/94			3	5/13/94	x							7/13/94
24-16178-01	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
24-16275-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/22/94
24-16275-02	B	3	6/13/94	6/14/94	7/21/94	3	8/5/94	x							
24-16281-01	B	3	1/4/94	1/7/94	2/28/94	2	5/13/94	x							6/16/94
24-16597-01	R	3	5/31/94			3	7/6/94	x							7/14/94
24-16612-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
24-16616-01	R	3	2/17/94			3	5/13/94	x							7/8/94
24-16652-01	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							6/22/94
24-16652-02	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
24-16714-01	R	3	1/12/94			3	5/13/94	x							6/28/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
24-17037-02	R	3	2/22/94			3	4/4/94	x							6/9/94
24-17205-01	R	3	1/10/94			3	5/13/94	x							6/30/94
24-17477-01	B	3	3/2/94	3/30/94	5/17/94	3	6/3/94	x					5/17/94		6/29/94
24-17554-01	R	3	1/27/94			3	5/13/94	x							7/8/94
24-17561-01	R	3	7/27/94			3	8/5/94	x							
24-17628-01	R	3	1/28/94			3	6/3/94	x							7/8/94
24-17680-02	B	3	7/19/94			3	8/5/94	x							
24-18020-01	R	3	1/31/94			3	4/4/94	x							6/9/94
24-18040-01	R	3	5/25/94			2	6/3/94	x							6/29/94
24-18095-01	R	3	3/18/94			2	5/13/94	x							6/23/94
24-18279-01	R	3	4/25/94			2	5/13/94	x							6/23/94
24-18287-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/23/94
24-18295-01	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x					4/5/94		6/23/94
24-18315-01	R	3	2/17/94			3	5/13/94	x							7/13/94
24-18625-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/16/94
24-18627-01	R	3	1/14/94			2	5/13/94	x							6/30/94
24-18628-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
24-18631-01	R	3	2/7/94			3	4/4/94	x							6/9/94
24-18655-01	B	3	1/20/94	6/14/94	7/21/94	3	8/5/94	x							
24-18678-01	R	3	1/27/94			3	5/13/94	x							7/8/94
24-18689-01	R	3	4/19/94			3	5/13/94	x							6/16/94
24-18695-01	R	3	1/31/94			2	5/13/94	x							6/28/94
24-18732-01	R	3	1/31/94			2	5/13/94	x							6/28/94
24-18733-01	R	3	1/12/94			3	5/13/94	x							6/28/94
24-18733-02	B	3	5/13/94	6/14/94	8/15/94	3	8/19/94	x							
24-18740-01	R	3	1/5/94			3	5/13/94	x							6/30/94
24-18818-01	B	3	1/20/94	2/4/94	3/22/94	3	6/3/94	x							6/17/94
24-18891-01	R	3	3/14/94			2	4/4/94	x							6/9/94
24-18968-01	R	3	9/6/94					x							
24-19486-01	B	3	6/9/94	6/14/94	8/5/94	3	8/19/94	x							
24-20047-01	R	3	2/22/94			2	4/4/94	x					10/22/93	Y	6/8/94
24-20234-02	R	3	1/5/94			3	5/13/94	x							6/30/94
24-20274-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
24-20330-01	R	3	4/25/94			3	5/13/94	x							
24-20335-01	B	3	1/31/94	2/4/94	3/22/94	3	6/3/94	x							6/17/94
24-24332-01	R	3	1/14/94			3	5/13/94	x							6/28/94
24-24405-01	R	3	1/31/94			1	4/4/94	x							6/8/94
24-24423-01	R	3	1/14/94			2	5/13/94	x							6/30/94
24-24518-01	R	3	2/11/94			3	6/3/94	x							7/8/94
24-24660-01	R	3	1/17/94			3	5/13/94	x							6/30/94
24-24859-01	R	3	1/28/94			3	6/3/94	x							7/8/94
24-25816-01	R	3	1/14/94			1	4/4/94	x							6/17/94
24-25867-01	R	3	1/5/94			3	5/13/94	x							7/6/94
24-25979-01	B	3	6/29/94	7/15/94	8/30/94	3	9/7/94	x							
24-26051-01	R	3	5/25/94			U	7/25/94	x							
24-26183-01	R	3	1/27/94			2	5/13/94	x							7/8/94
24-26243-01	R	3	2/17/94			1	5/13/94	x							7/13/94

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								Complete	No File	QMP Only	Lic Only				
24-26297-01	R	3	3/14/94			3	4/4/94	x							6/9/94
24-26424-01	R	3	4/22/94			3	5/13/94	x							6/23/94
24-26475-01	R	3	2/22/94			3	5/13/94	x							7/8/94
24-26477-01	R	3	2/17/94			3	5/13/94	x							7/8/94
25-01051-01	B	4	4/18/94	4/20/94	6/17/94	2	7/6/94	x					7/6/94		
25-02337-03	B	4	4/18/94	4/20/94	7/21/94	3	8/5/94	x							10/11/94
25-07553-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/12/94
25-12453-02	R	4	7/15/94			3	7/25/94	x					6/7/94		10/4/94
25-12710-01	R	4	7/29/94			3	8/5/94	x							10/11/94
25-13173-02	B	4	6/29/94	7/15/94	8/5/94	3	8/19/94	x							
25-15463-01	B	4	7/14/94	N/A		3	7/25/94	x					4/6/94		9/27/94
25-16773-02	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/12/94
25-17163-02	R	4	3/15/94			S	8/5/94	x				S	5/11/94		
25-17265-01	R	4	5/31/94			3	6/3/94	x							7/29/94
25-17441-01	R	4	4/1/94			3	5/13/94	x					4/18/94		6/15/94
25-18307-01	R	4	5/31/94			3	6/3/94	x							7/29/94
25-18361-01	R	4	4/1/94			2	5/13/94	x					4/27/94		
25-19824-01	R	4	5/31/94			3	6/3/94	x							7/29/94
25-21258-01	R	4	4/1/94			3	5/13/94	x							6/13/94
25-26847-02		4	N/A				nQMPr	x							
26-00138-10	B	4	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
26-16293-01	R	4	1/14/94			2	4/4/94	x							
27-15192-01	B	5	1/4/94	1/7/94	2/16/94	2	5/13/94	x							6/7/94
28-27885-01	R	1	7/26/94			3	8/5/94	x							
29-00102-07	B	1	4/28/94	5/3/94	7/21/94	3	8/5/94	x							
29-00232-08	B	1	6/9/94	6/14/94	7/21/94	3	8/5/94	x				S			
29-01024-01	R	1	7/15/94			2	7/25/94	x					6/8/94	Y	
29-01040-03	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
29-01101-03	R	1	1/14/94			3	6/3/94	x							
29-01423-01	B	1	4/18/94	4/20/94	7/21/94	3	8/5/94	x				H			
29-01600-02	B	1	2/17/94	2/28/94	4/21/94	3	5/13/94	x				H			
29-01608-03	B	1	3/22/94	3/30/94	5/17/94	3	6/3/94	x				H			
29-01663-01	R	1	1/27/94			1	5/13/94	x							
29-01698-02	B	1	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
29-01862-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
29-02023-05	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
29-02023-06	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x				H	7/19/94		
29-02114-03	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
29-02234-02	B	1	6/13/94	6/14/94	7/21/94	3	8/5/94	x							
29-02234-03	B	1	2/17/94	2/28/94	4/21/94	3	5/13/94	x							
29-02575-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
29-02575-03	B	1	1/4/94	1/7/94	2/16/94	1	5/13/94	x							
29-02641-03	B	1	6/9/94	6/14/94	8/5/94	3	8/19/94	x							
29-02641-04	B	1	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
29-02957-13	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x					4/5/94		
29-03038-01	B	1	1/27/94	2/4/94	3/22/94	3	5/13/94	x							
29-03038-02	B	1	6/13/94	6/14/94	7/21/94	3	8/5/94	x							

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								Complete	No File	QMP Only	Lic Only				
29-03047-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x					6/6/94		
29-03089-01	R	1	7/22/94			3	8/5/94	x							
29-03163-03	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
29-03217-01	R	1	1/12/94			3	5/13/94	x							
29-03217-03	B	1	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
29-03297-02	B	1	4/28/94	5/3/94	6/17/94	3	7/6/94	x				H			
29-03308-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x					3/7/94		
29-03382-01	R	1	2/17/94			3	5/13/94	x							
29-03438-01	R	1	2/7/94			3	6/3/94	x							
29-03845-01	B	1	9/16/94	9/16/94				x				H			
29-04333-01	B	1	1/4/94	1/7/94	2/28/94	3	6/3/94	x							
29-04481-01	B	1	6/13/94	6/14/94	7/21/94	3	8/5/94	x							
29-05084-02	R	1	1/27/94			3	5/13/94	x							
29-05139-03	B	1	7/13/94	7/15/94	8/5/94	3	8/19/94	x				S			
29-06134-01	R	1	1/27/94			3	5/13/94	x					4/5/94		
29-06431-01	R	1	4/13/94			3	5/13/94	x							
29-06750-01	B	1	4/19/94	4/20/94	7/21/94	3	8/5/94	x							
29-06759-01	R	1	1/17/94			3	4/4/94	x							
29-06760-08	R	1	7/22/94			3	8/5/94	x							
29-07213-03	R	1	1/10/94			2	5/13/94	x					4/5/94		
29-07470-03	B	1	4/19/94	4/20/94	6/17/94	3	7/6/94	x							
29-07566-01	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
29-07566-02	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
29-07758-01	R	1	2/7/94			U	5/13/94	x							
29-07868-01	R	1	1/18/94			1	3/11/94	x							
29-07892-01	R	1	7/22/94			3	8/5/94	x							
29-07987-02	R	1	1/27/94			U	5/13/94	x							
29-08113-03	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x					6/6/94		
29-08285-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x				H			
29-08519-01	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
29-08519-02	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
29-08532-01	R	1	1/17/94			3	4/4/94	x					6/6/94		
29-08622-04	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
29-09701-01	B	1	6/9/94	6/14/94	7/21/94	3	8/5/94	x							
29-09701-02	B	1	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
29-09806-03	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
29-10173-02	R	1	8/1/94			3	8/5/94	x							
29-10191-02	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x				H			
29-10245-02	B	1	1/24/94	2/4/94	3/22/94	3	6/3/94	x							
29-10313-01	R	1	3/14/94			3	4/4/94	x					4/27/94		
29-11187-01	R	1	6/7/94			3	7/6/94	x							
29-11642-01	R	1	4/25/94			2	5/13/94	x							
29-11935-01	B	1	1/24/94	2/4/94	3/22/94	3	5/13/94	x							
29-11982-01	R	1	7/26/94			U	8/5/94	x							
29-12109-01	B	1	6/15/94	8/9/94	8/25/94	3	8/30/94	x					6/6/94	Y	
29-12167-01	R	1	6/15/94			2	7/6/94	x							
29-12224-01	R	1	5/31/94			U	6/3/94	x							

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								Complete	No File	QMP Only	Lic Only				
29-12253-01	B	1	1/12/94	7/15/94	8/30/94			x				H	3/7/94	Y	
29-12611-01	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x				H	6/6/94		
29-12664-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x					3/7/94		
29-12745-01	R	1	5/23/94			3	6/3/94	x							
29-12855-01	R	1	2/7/94			3	4/4/94	x					4/5/94		
29-12907-01	B	1	1/4/94	1/7/94	2/28/94	1	5/13/94	x							
29-12907-02	R	1	7/7/94			3	7/25/94	x							
29-12997-01	R	1	2/7/94			3	4/4/94	x							
29-13453-01	B	1	1/24/94	2/4/94	3/22/94	3	6/3/94	x					4/5/94		
29-13746-01	B	1	1/14/94	2/4/94	3/22/94	3	5/13/94	x							
29-13746-02	B	1	1/4/94	1/7/94	2/28/94	3	6/3/94	x				H			
29-13911-01	B	1	1/4/94	1/7/94	2/28/94	3	6/3/94	x							
29-14017-01	R	1	5/25/94			3	6/3/94	x							
29-14859-01	R	1	5/31/94			3	6/3/94	x							
29-14966-01	B	1	4/29/94	5/3/94	7/21/94	3	8/5/94	x							
29-15035-01	R	1	4/22/94			U	5/13/94	x							
29-15175-01	R	1	4/1/94			2	5/13/94	x							
29-15459-01	R	1	1/27/94			U	5/13/94	x							
29-15615-01	R	1	7/11/94			3	7/25/94	x							
29-15739-01	R	1	1/31/94			3	4/4/94	x							
29-15749-01	R	1	3/25/94			U	5/13/94	x							
29-16145-01	R	1	1/18/94			3	3/11/94	x							
29-16384-01	R	1	1/10/94			3	3/11/94	x							
29-16511-01	R	1	1/31/94			3	5/13/94	x							
29-16585-01	R	1	5/31/94			U	6/3/94	x							
29-16796-02	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
29-16857-01	B	1	3/22/94	3/30/94	5/17/94	3	6/3/94	x							
29-17045-01	R	1	7/15/94			3	7/25/94	x							
29-17064-01	R	1	3/22/94			3	5/13/94	x							
29-17234-01	B	1	6/29/94	7/15/94	8/5/94	3	8/19/94	x							
29-17475-01	R	1	4/18/94	4/20/94	6/17/94	3	7/6/94	x							
29-17610-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
29-17623-01	R	1	1/18/94			U	6/3/94	x							
29-17736-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x					7/19/94		
29-17855-01	R	1	3/17/94			U	5/13/94	x					10/12/94		
29-17874-01	R	1	4/18/94	4/20/94	6/17/94	3	7/6/94	x							
29-17895-01	R	1	1/14/94			3	6/3/94	x							
29-17925-01	R	1	1/27/94			3	5/13/94	x							
29-18129-01	R	1	6/20/94			3	7/6/94	x							
29-18190-01	R	1	1/10/94			3	5/13/94	x							
29-18266-01	R	1	7/22/94			3	8/5/94	x							
29-18334-01	B	1	4/5/94	6/14/94	7/21/94	3	8/5/94	x							
29-18346-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
29-18376-01	R	1	3/25/94			3	5/13/94	x							
29-18434-01	B	1	1/11/94	2/4/94	3/22/94	1	5/13/94	x							
29-20527-01	R	1	7/22/94			3	8/5/94	x							
29-20597-01	R	1	7/22/94			3	8/5/94	x							

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
29-20690-01	B	1	1/4/94	1/7/94	2/16/94	3	6/3/94	x							
29-20709-01	R	1	4/28/94			U	5/13/94	x							
29-20798-01	R	1	1/27/94			3	5/13/94	x							
29-20863-01	R	1	3/22/94			U	6/3/94	x							
29-20974-01	R	1	1/27/94			2	5/13/94	x							
29-20977-01	R	1	1/10/94			U	5/13/94	x							
29-21382-01	R	1	3/25/94			3	6/3/94	x							
29-23540-01	R	1	1/27/94			3	5/13/94	x							
29-27832-01	R	1	4/19/94			U	5/13/94	x							
29-28019-01	R	1	4/28/94			U	5/13/94	x							
29-28049-01	R	1	2/17/94			U	5/13/94	x							
29-28089-01	R	1	4/18/94			U	5/13/94	x							
29-28164-01	R	1	4/13/94			U	5/13/94	x							
29-28186-01	R	1	3/25/94			3	5/13/94	x							
29-28223-01	R	1	1/14/94			3	5/13/94	x							
29-28231-01	R	1	1/31/94			U	5/13/94	x							
29-28273-01	R	1	1/31/94			3	4/4/94	x							
29-28330-01	R	1	1/31/94			U	5/13/94	x							
29-28395-01	R	1	4/13/94			U	5/13/94	x							
29-28408-01	R	1	5/31/94			U	6/3/94	x							
29-28428-01	R	1	2/7/94			U	8/5/94	x							
29-28460-01	R	1	5/20/94			3	6/3/94	x							
29-28554-01	R	1	2/17/94			3	3/11/94	x							
29-28557-01	R	1	1/12/94			U	5/13/94	x							
29-28593-01	R	1	4/19/94			3	5/13/94	x							
29-28616-01	R	1	4/19/94			U	5/13/94	x							
29-28619-01	R	1	7/14/94			U	7/25/94	x							
29-28685-01		1	N/A				inactive				x	H	10/12/94		
29-28728-01	R	1	3/22/94			U	6/3/94	x							
29-28747-01	R	1	1/14/94			3	6/3/94	x							
29-28777-01	R	1	5/23/94			U	6/3/94	x							
29-28784-01	R	1	2/17/94			U	5/13/94	x							
29-30001-01		1	N/A				T								
29-30019-01	R	1	3/14/94			U	6/3/94	x							
29-30032-01	R	1	2/22/94			3	4/4/94	x							
31-00032-04	B	1	7/1/94	N/A		3	8/19/94	x							
31-00636-07	R	1	7/15/94			3	7/25/94	x							
31-00786-02	R	1	7/19/94			3	8/5/94	x					6/6/94	Y	
31-00845-01	R	1	3/17/94			2	4/4/94	x							
31-02755-05	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
31-02892-03	R	1	7/14/94			3	7/25/94	x							
31-02892-05	B	1	5/23/94	6/14/94	8/5/94	3	8/30/94	x							
31-08946-02	R	1	7/7/94			3	7/25/94	x							
31-11399-01	R	1	7/15/94			U	7/25/94	x							
31-13511-04	R	1	7/19/94			1	8/5/94	x							
31-13511-05	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
31-17455-01	R	1	1/17/94			U	4/4/94	x							

QMP Database

License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
32-01134-01	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
32-04054-04	R	2	4/20/94			3	5/13/94	x							
32-05830-01	R	2	5/11/94			2	6/3/94	x							
32-13654-01	R	2	5/20/94			3	6/3/94	x							
32-15483-01	R	2	7/15/94			U	7/25/94	x							
33-15145-03	R	4	7/15/94			2	7/25/94	x							10/4/94
34-00179-02	R	3	5/11/94			3	6/3/94	x							6/29/94
34-00203-03	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-00293-02	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
34-00305-03	R	3	4/28/94			2	5/13/94	x							7/8/94
34-00341-06	B	3	4/28/94	5/3/94	7/21/94	3	8/5/94	x				H	5/17/94		
34-00398-08	B	3	5/25/94	6/14/94	8/5/94	3	8/19/94	x							
34-00398-10	R	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
34-00466-01	B	3	Pilot			3	4/29/94	x							6/17/94
34-00746-02	B	3	5/25/94	6/14/94	8/15/94	3	8/19/94	x							
34-00746-03	B	3	6/17/94	7/15/94	8/5/94	3	8/19/94	x							
34-00774-04	B	3	1/31/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
34-00774-07	B	3	1/31/94	2/4/94	3/22/94	3	5/13/94	x							6/24/94
34-00789-01	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
34-00799-03	B	3	1/11/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
34-00852-02	B	3	5/25/94	6/14/94	8/15/94	3	8/30/94	x							
34-00852-03	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-00855-07	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
34-00991-02	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
34-01026-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			6/30/94
34-01055-01	B	3	4/28/94	5/3/94	7/21/94	3	8/5/94	x				H			
34-01131-01	B	3	6/9/94	6/14/94	8/5/94	3	8/19/94	x				H			
34-01131-03	B	3	3/14/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
34-01197-01	R	3	3/14/94			3	6/3/94	x							7/13/94
34-01216-03	B	3	4/18/94	4/20/94	6/17/94	1	7/6/94	x							7/14/94
34-01311-01	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
34-01312-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/22/94
34-01334-02	R	3	2/7/94			3	4/4/94	x							6/8/94
34-01386-01	R	3	2/17/94			2	5/13/94	x							7/13/94
34-01505-01	R	3	1/14/94			3	5/13/94	x							6/30/94
34-01654-02	B	3	4/22/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-01710-05	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
34-01833-01	R	3	7/19/94			3	8/5/94	x							
34-01856-01	B	3	2/11/94	2/28/94	4/21/94	3	5/13/94	x				H			6/23/94
34-01869-01	B	3	Pilot			3	4/29/94	x							6/9/94
34-01869-02	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
34-01922-02	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x							
34-01932-01	B	3	1/4/94	1/7/94	2/28/94	2	5/13/94	x							6/9/94
34-01954-01	B	3	1/11/94	2/4/94	3/22/94	2	5/13/94	x					5/11/94		6/17/94
34-02007-01	B	3	1/20/94	6/14/94	7/21/94	3	8/5/94	x							
34-02007-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-02091-03	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x					5/24/94		6/23/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
34-02121-02	B	3	5/25/94	6/14/94	7/21/94	2	8/5/94	x							
34-02162-01	R	3	1/28/94			3	5/13/94	x							6/16/94
34-02176-01	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/17/94
34-02400-02	R	3	3/14/94			3	4/4/94	x							6/17/94
34-02867-01	R	3	1/12/94			3	5/13/94	x							6/24/94
34-03111-02	R	3	7/12/94			3	7/25/94	x							
34-03329-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-03362-02	B	3	Pilot			3	4/29/94	x					5/11/94		
34-03362-03	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
34-03424-02	B	3	1/31/94	2/4/94	3/22/94	3	6/3/94	x							6/17/94
34-03424-03	B	3	2/17/94	2/28/94	4/21/94	3	6/3/94	x							
34-03509-02	B	3	4/29/94	5/3/94	7/21/94	3	8/5/94	x							
34-03749-07	B	3	5/20/94	6/14/94	7/21/94	3	8/5/94	x							
34-03749-10	B	3	Pilot			3	4/29/94	x				H			
34-03831-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-04307-02	R	3	8/17/94			3	8/30/94	x							
34-04474-01	B	3	Pilot			3	4/29/94	x							6/17/94
34-04474-02	B	3	8/1/94	8/3/94	8/25/94	3	8/30/94	x					11/16/93	Y	
34-04492-02	R	3	3/23/94			3	4/4/94	x							6/8/94
34-05015-01	R	3	4/25/94			3	5/13/94	x							6/23/94
34-05124-01	R	3	1/14/94			3	5/13/94	x							6/30/94
34-05382-01	R	3	2/17/94			3	5/13/94	x							7/8/94
34-05422-01	R	3	1/14/94			3	6/3/94	x							7/13/94
34-05469-01	B	3	Pilot			3	4/29/94	x				S			6/9/94
34-05488-01	B	3	4/29/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-05488-02	B	3	4/29/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-05582-01	R	3	1/18/94			2	5/13/94	x							6/23/94
34-06002-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
34-06123-01	R	3	6/29/94			3	7/25/94	x							
34-06295-02	R	3	1/12/94			3	5/13/94	x							6/24/94
34-06578-01	B	3	5/9/94	6/14/94	8/5/94	3	8/19/94	x							
34-06578-02	R	3	1/14/94			3	4/4/94	x							6/8/94
34-06662-01	R	3	2/17/94			3	5/13/94	x							7/8/94
34-06903-05	B	3	4/5/94	4/20/94	6/17/94	3	7/6/94	x							7/14/94
34-06904-01	R	3	1/17/94			2	5/13/94	x							6/28/94
34-07455-01	R	3	1/14/94			3	5/13/94	x							6/28/94
34-08051-01	R	3	7/27/94			3	8/5/94	x							
34-08279-02	B	3	4/22/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-09133-01	R	3	1/17/94			3	5/13/94	x							6/30/94
34-09457-02	R	3	2/17/94			3	5/13/94	x							7/8/94
34-09621-01	B	3	1/4/94	1/7/94	2/28/94	3	8/5/94	x							
34-09739-01	R	3	5/20/94			3	6/3/94	x							6/17/94
34-09846-02	R	3	3/17/94			2	5/13/94	x							7/13/94
34-10802-02	R	3	1/31/94			2	5/13/94	x							6/28/94
34-10802-03	B	3	2/17/94	3/30/94	4/21/94	3	5/13/94	x							6/22/94
34-10921-03	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x				H			6/23/94
34-11155-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
34-11202-02	R	3	1/27/94			3	5/13/94	x							7/8/94
34-11232-02	R	3	7/29/94			2	8/5/94	x							
34-11852-01	R	3	1/27/94			3	5/13/94	x							7/8/94
34-11852-02	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
34-11908-02	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/23/94
34-12100-01	B	3	9/16/94	N/A	N/A					x	I				
34-12100-03	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x					5/11/94		6/22/94
34-12165-01	R	3	2/17/94			3	5/13/94	x							7/8/94
34-12541-01	R	3	7/13/94			3	8/5/94	x				S			
34-12685-01	R	3	6/27/94			3	7/25/94	x							
34-13011-04	B	3	1/11/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
34-13100-02	R	3	1/14/94			3	4/4/94	x							6/17/94
34-13234-01	R	3	1/14/94			3	4/4/94	x							6/8/94
34-13273-01	R	3	3/18/94			2	5/13/94	x							6/24/94
34-13317-02	B	3	4/13/94	4/20/94	6/17/94	3	7/6/94	x							7/14/94
34-13381-01	R	3	1/14/94			2	5/13/94	x							6/30/94
34-13394-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							
34-13394-02	R	3	6/29/94			3	7/25/94	x							
34-13663-01	B	3	6/10/94	6/14/94	7/21/94	3	8/5/94	x							
34-13832-01	R	3	1/28/94			2	5/13/94	x					6/24/94		6/24/94
34-13857-01	B	3	4/26/94	6/14/94	8/15/94	3	8/19/94	x				H/S			
34-13929-02	R	3	5/31/94			3	6/3/94	x							6/17/94
34-13995-01	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
34-14016-01	B	3	4/28/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-14016-02	R	3	1/31/94			2	4/4/94	x							6/9/94
34-14146-01	R	3	2/17/94			2	5/13/94	x							7/13/94
34-14164-01	R	3	5/13/94			3	6/3/94	x							7/8/94
34-15046-01	B	3	6/29/94	7/15/94	8/30/94	3	9/7/94	x							
34-15072-01	B	3	1/24/94	2/4/94	3/22/94	3	5/13/94	x							6/22/94
34-15184-01	B	3	2/17/94	2/28/94	4/21/94	2	5/13/94	x							6/24/94
34-15236-01	R	3	5/9/94			3	6/3/94	x							6/17/94
34-15317-01	R	3	5/20/94			U	6/3/94	x							6/17/94
34-15388-01	R	3	2/11/94			3	6/3/94	x							7/13/94
34-15389-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
34-15469-01	R	3	1/17/94			3	5/13/94	x							6/30/94
34-15549-01	R	3	5/9/94			3	6/3/94	x							6/17/94
34-15649-01	R	3	2/7/94			3	5/13/94	x							7/8/94
34-15653-02	R	3	5/13/94			U	6/3/94	x							7/8/94
34-15654-01	R	3	1/10/94			3	5/13/94	x							7/6/94
34-15661-01	R	3	7/15/94			3	7/25/94	x							
34-15938-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-16032-01	R	3	7/15/94			3	7/25/94	x							
34-16241-01	R	3	7/15/94			3	7/25/94	x							
34-16411-01	R	3	2/22/94			3	5/13/94	x							7/8/94
34-16581-01	R	3	1/14/94			3	5/13/94	x							6/28/94
34-16588-01	R	3	5/31/94			3	6/3/94	x					3/7/94	Y	6/17/94
34-16621-01	R	3	7/12/94			3	7/25/94	x					5/11/94	Y	

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								Complete	No File	QMP Only	Lic Only				
34-16710-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
34-16725-02	B	3	7/14/94	7/15/94	8/5/94	3	8/19/94	x							
34-16739-01	R	3	5/25/94			3	6/3/94	x							6/17/94
34-16830-01	R	3	7/15/94			3	7/25/94	x							
34-16885-01	R	3	2/4/94			3	5/13/94	x							6/22/94
34-16919-01	R	3	2/17/94			3	5/13/94	x							7/8/94
34-17013-01	R	3	4/19/94			3	5/13/94	x							6/22/94
34-17013-02	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-17025-01	R	3	3/17/94			3	4/4/94	x							6/17/94
34-17056-01	R	3	2/7/94			2	4/4/94	x							7/8/94
34-17339-01	R	3	2/4/94			3	5/13/94	x							6/22/94
34-17355-01	R	3	3/14/94			3	4/4/94	x							7/8/94
34-17386-01	R	3	1/14/94			3	5/13/94	x							7/1/94
34-17397-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
34-17397-02	B	3	4/29/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-17575-01	R	3	7/12/94			3	7/25/94	x							
34-17774-01	R	3	1/31/94			2	4/4/94	x							6/8/94
34-17796-01	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/24/94
34-17807-02	B	3	5/25/94	6/14/94	7/21/94	3	8/5/94	x							
34-17809-01	R	3	1/14/94			2	5/13/94	x							6/30/94
34-17835-01	R	3	1/28/94			2	5/13/94	x							6/24/94
34-17932-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-17967-01	R	3	3/17/94			3	5/13/94	x							7/13/94
34-17975-01	R	3	1/27/94			3	5/13/94	x							7/8/94
34-18120-01	R	3	3/14/94			3	6/3/94	x							7/8/94
34-18241-01	B	3	4/5/94	4/20/94	6/17/94	3	7/6/94	x							7/14/94
34-18514-01	R	3	1/28/94			2	5/13/94	x							6/24/94
34-18541-01	R	3	1/17/94			1	4/4/94	x							6/9/94
34-18591-01	R	3	6/17/94			3	7/6/94	x							7/14/94
34-18610-01	R	3	4/5/94			3	6/3/94	x							7/8/94
34-18674-02	R	3	1/17/94			3	4/4/94	x							6/9/94
34-18728-01	R	3	2/22/94			3	5/13/94	x							7/8/94
34-18731-01	R	3	7/19/94			3	8/5/94	x							
34-18796-01	R	3	2/11/94			U	5/13/94	x							
34-18797-01	B	3	7/13/94	7/15/94	8/5/94	3	8/19/94	x							
34-18808-01	R	3	2/17/94			3	5/13/94	x							7/13/94
34-18868-01	R	3	1/27/94			3	5/13/94	x							6/30/94
34-18884-01	R	3	1/14/94			2	5/13/94	x							6/30/94
34-18896-01	R	3	1/27/94			3	5/13/94	x							7/8/94
34-18954-01	R	3	1/14/94			3	5/13/94	x							6/30/94
34-18980-01	R	3	4/25/94			3	5/13/94	x							6/24/94
34-19119-01	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/24/94
34-20036-01	R	3	1/14/94			3	5/13/94	x							6/30/94
34-20342-01	R	3	4/22/94			1	5/13/94	x							6/24/94
34-20465-01	R	3	8/1/94			3	8/5/94	x							
34-21422-01	B	3	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/16/94
34-23399-01	R	3	2/22/94			U	6/3/94	x							7/8/94

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								Complete	No File	QMP Only	Lic Only				
34-23475-01	B	3	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/16/94
34-24358-01	R	3	4/8/94			3	5/13/94	x							6/17/94
34-24377-01	R	3	7/29/94			2	8/5/94	x							
34-24664-01	R	3	4/19/94			3	5/13/94	x							6/22/94
34-24802-01	R	3	1/14/94			3	5/13/94	x							6/16/94
34-25877-01	R	3	7/15/94			3	7/25/94	x							
34-25951-01	R	3	7/15/94			3	7/25/94	x							
34-25962-01	R	3	3/17/94			2	5/13/94	x							7/13/94
34-25976-01	R	3	1/14/94			2	5/13/94	x							
34-25978-01	B	3	4/26/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
34-26014-01	B	3	1/31/94	2/4/94	3/22/94	3	6/3/94	x							6/17/94
34-26053-01	R	3	4/22/94			U	5/13/94	x							6/24/94
34-26066-01	R	3	1/27/94			3	5/13/94	x							7/8/94
34-26092-01	R	3	2/17/94			3	5/13/94	x							7/13/94
34-26164-01	R	3	7/19/94			3	8/5/94	x							
34-26265-01	R	3	4/19/94			2	5/13/94	x							6/22/94
34-26267-01	R	3	7/15/94			3	7/25/94	x							
34-26273-01	R	3	6/20/94			3	7/6/94	x							7/14/94
34-26286-01	R	3	1/14/94			3	5/13/94	x							6/30/94
34-26314-01	R	3	1/14/94			3	6/3/94	x							7/8/94
34-26383-01	R	3	3/14/94			3	6/3/94	x							7/8/94
34-26388-01	R	3	8/1/94			3	8/5/94	x							
34-26390-01	R	3	4/20/94			3	5/13/94	x							6/22/94
34-26427-01		3	N/A				Rnegdec	x							
34-26443-01		3	N/A				Rnegdec	x							
34-26463-01	B	3	9/16/94	N/A	N/A						x				
34-26521-01		3	N/A				Rnegdec	x							
35-00376-02	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x					4/5/94		7/13/94
35-00526-04	R	4	4/1/94			2	5/13/94	x							
35-00957-02	R	4	4/1/94			1	5/13/94	x							
35-01164-02	R	4	6/21/94			2	7/6/94	x					6/14/94		
35-01164-03	B	4	4/19/94	4/20/94	6/17/94	3	7/6/94	x							8/22/94
35-01332-06	R	4	2/8/94			3	5/13/94	x							6/3/94
35-01428-03	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/13/94
35-05860-01	B	4	2/8/94	2/28/94	4/21/94	3	8/5/94	x							
35-05860-03	B	4	2/8/94	2/28/94	4/21/94	3	8/19/94	x							
35-07018-02	B	4	7/13/94	7/15/94	8/25/94	3	8/30/94	x				S	5/11/94	Y	
35-07163-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/13/94
35-09206-02	B	4	3/15/94	4/20/94	6/17/94	3	7/6/94	x							8/22/94
35-09206-03	B	4	3/15/94	4/20/94	6/17/94	3	7/6/94	x							8/22/94
35-10202-01	R	4	4/1/94			2	5/13/94	x							
35-10669-01	B	4	4/18/94	4/20/94	6/17/94	3	7/6/94	x							
35-10669-02	B	4	4/18/94	4/20/94	6/17/94	3	7/6/94	x					5/11/94	Y	9/8/94
35-11022-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/13/94
35-12091-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x				H			7/13/94
35-13058-01	B	4	3/15/94	4/20/94	6/17/94	3	7/25/94	x							9/27/94
35-13058-02	B	4	3/15/94	4/20/94	6/17/94	3	7/25/94	x					5/31/94		9/27/94

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								Complete	No File	QMP Only	Lic Only				
35-13127-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/13/94
35-13157-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							6/30/94
35-13157-02	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							6/30/94
35-13184-01	R	4	4/1/94			2	5/13/94	x							
35-13341-01	R	4	7/29/94			3	8/5/94	x							10/11/94
35-13435-01	R	4	4/1/94			3	5/13/94	x							6/3/94
35-13539-01	R	4	7/15/94			3	7/25/94	x							10/4/94
35-13821-02	B	4	6/13/94	6/14/94	8/5/94	2	8/19/94	x							
35-14042-01	R	4	7/1/94			3	8/5/94	x				S			10/11/94
35-14046-01	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							9/8/94
35-14046-02	R	4	7/15/94			3	7/25/94	x					11/22/93		10/4/94
35-14145-01	B	4	7/14/94	7/15/94	8/15/94		rtnd9/2	x				S			
35-14990-01	R	4	4/1/94			3	8/19/94	x							
35-15500-01	R	4	4/1/94			2	5/13/94	x							
35-16149-01	R	4	7/15/94			3	7/25/94	x							10/4/94
35-16189-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-16233-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-16298-01	R	4	4/1/94			3	5/13/94	x							6/13/94
35-16494-01	R	4	4/1/94			3	6/3/94	x							7/29/94
35-16700-01	R	4	1/14/94			3	5/13/94	x							6/3/94
35-17087-01	R	4	4/1/94			1	5/13/94	x							
35-17144-01	B	4	5/31/94	6/14/94	7/21/94	3	8/5/94	x							
35-17213-01		4	N/A				T	x							
35-17414-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-17598-01	R	4	4/1/94			1	5/13/94	x							
35-17654-01	R	4	7/15/94			3	7/25/94	x							10/11/94
35-17723-01	R	4	7/15/94			2	7/25/94	x							
35-17756-01	R	4	4/1/94			2	5/13/94	x							
35-17926-02	R	4	1/14/94			2	5/13/94	x							
35-18025-01	R	4	4/1/94			U	6/3/94	x							
35-18284-01	R	4	4/1/94			3	6/3/94	x					7/7/94		
35-19227-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-21011-02	R	4	6/14/94			3	7/25/94				x				9/27/94
35-21035-01	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							9/8/94
35-21106-01	R	4	4/1/94			3	8/5/94	x				S			
35-21269-01	R	4	4/1/94			2	5/13/94	x							
35-23125-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-23159-01	R	4	4/1/94			3	7/6/94	x							8/19/94
35-23180-01	R	4	7/22/94			3	8/19/94	x				S			
35-23461-01	R	4	4/1/94			2	5/13/94	x							
35-27041-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x				H			7/27/94
35-27053-01	R	4	4/1/94			3	5/13/94	x							6/15/94
35-27406-01	R	4	7/1/94			3	7/25/94	x							9/27/94
36-01395-01	B	5	2/11/94	2/28/94	4/21/94	3	5/13/94	x							6/7/94
36-21137-01	R	5	3/17/94			2	4/4/94	x							
37-00051-03	R	1	3/25/94			U	5/13/94	x							
37-00062-07	R	1	3/22/94	3/30/94	5/17/94	2	6/3/94	x							

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								Complete	No File	QMP Only	Lic Only				
37-00118-07	B	1	Pilot			3	4/29/94	x							
37-00148-06	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x				H			
37-00168-06	R	1	3/18/94			3	5/13/94	x							
37-00245-02	B	1	6/15/94	7/15/94	8/15/94	3	8/19/94	x				H/S			
37-00245-09	B	1	7/28/94			3	8/5/94	x				G			
37-00266-03	B	1	1/31/94	2/4/94	3/22/94	3	8/5/94	x				S			
37-00358-04	B	1	1/14/94	2/4/94	3/22/94	3	5/13/94	x							
37-00358-05	B	1	1/14/94	2/4/94	3/22/94	3	5/13/94	x							
37-00432-02	B	1	6/14/94	N/A		3	7/6/94	x							
37-00444-02	B	1	1/27/94	2/4/94	3/22/94	3	5/13/94	x							
37-00448-19	B	1	1/4/94	1/7/94	2/16/94	3	8/5/94	x				S			
37-00467-34	B	1	Pilot			3	4/29/94	x							
37-00485-04	B	1	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
37-00554-03	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x							
37-00697-02	B	1	6/27/94	7/15/94	8/15/94	3	8/19/94	x					6/8/94		
37-00697-31	B	1	6/17/94	7/15/94	8/15/94		rtnd9/2	x				H			
37-00783-04	R	1	7/14/94			U	7/25/94	x				S			
37-00865-11	B	1	4/28/94	5/3/94	6/17/94	3	7/6/94	x							
37-00896-03	B	1	6/27/94	7/15/94	8/25/94	3	8/30/94	x							
37-00897-01	R	1	2/22/94			3	5/13/94	x							
37-00993-05	B	1	4/19/94	4/20/94	6/17/94	3	7/6/94	x				H	4/27/94		
37-01033-02	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
37-01072-01	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
37-01146-03	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-01230-03	R	1	7/18/94			2	8/5/94	x							
37-01317-01	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
37-01321-02	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x					4/5/94		
37-01374-03	B	1	1/4/94	1/7/94	2/16/94	3	8/5/94	x				H			
37-01421-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x				H			
37-01421-04	B	1	5/31/94	6/14/94	8/15/94	3	8/19/94	x							
37-01548-01	B	1	1/31/94	2/4/94	3/22/94	3	7/25/94	x							
37-01548-03	B	1	1/31/94	2/4/94	3/22/94	3	7/25/94	x							
37-01553-01	R	1	7/15/94			3	7/25/94	x							
37-01553-04	B	1	1/11/94	2/4/94	3/22/94	3	6/3/94	x							
37-01563-03	R	1	4/22/94			U	5/13/94	x							
37-01580-04	B	1	Pilot			3	4/29/94	x							
37-01626-04	R	1	3/14/94			2	4/4/94	x							
37-01758-05	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
37-01873-01	B	1	4/18/94	4/20/94	6/17/94	3	7/6/94	x							
37-01893-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x				H	7/19/94		
37-02136-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-02218-02	R	1	3/22/94			3	5/13/94	x							
37-02385-01	B	1	4/13/94	5/3/94	6/17/94	3	7/6/94	x							
37-02385-02	R	1	4/13/94			3	5/13/94	x							
37-02476-01	R	1	1/14/94			3	5/13/94	x							
37-02523-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x				H			
37-02562-01	B	1	1/27/94	2/4/94	3/22/94	3	5/13/94	x							

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								Complete	No File	QMP Only	Lic Only				
37-02569-01	B	1	2/17/94	2/28/94	2/25/94	3	6/3/94	x							
37-02584-01	B	1	1/4/94	1/7/94	2/28/94	3	7/6/94	x							
37-02763-01	B	1	2/8/94	2/28/94	4/21/94	1	5/13/94	x							
37-02763-02	B	1	7/20/94	7/22/94	8/25/94	2	8/30/94	x							
37-02766-01	B	1	3/2/94	3/30/94	5/17/94	3	6/3/94	x				H			
37-02847-01	R	1	2/22/94			2	5/13/94	x							
37-02894-02	B	1	2/11/94	2/28/94	4/21/94	3	5/13/94	x							
37-03387-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			
37-03390-03	B	1	1/4/94	1/7/94	2/28/94	3	6/3/94	x					4/5/94		
37-03420-01	R	1	1/17/94			3	5/13/94	x							
37-03552-02	R	1	6/20/94			U	7/6/94	x							
37-03906-01	B	1	4/18/94	4/20/94	6/17/94	3	7/6/94	x					4/27/94		
37-04172-01	R	1	4/19/94			3	5/13/94	x							
37-04185-01	B	1	2/11/94	2/28/94	4/21/94	3	5/13/94	x					3/7/94	Y	
37-04871-01	R	1	1/10/94			2	5/13/94	x							
37-05089-01	R	1	1/27/94			3	5/13/94	x							
37-05125-01	B	1	2/11/94	2/28/94	4/21/94	3	7/25/94	x				H			
37-05272-02	R	1	4/19/94			2	5/13/94	x							
37-05371-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-05433-01	R	1	1/18/94			3	3/11/94	x							
37-05453-02	B	1	1/31/94	2/4/94	3/22/94	3	5/13/94	x							
37-05453-03	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x				H			
37-05501-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-05811-02	R	1	6/15/94			3	7/6/94	x							
37-06064-02	R	1	2/17/94			3	3/11/94	x					4/5/94		
37-06185-01	R	1	1/14/94			2	5/13/94	x							
37-06572-02	R	1	4/19/94			2	5/13/94	x							
37-06575-03	B	1	4/19/94	4/20/94	6/17/94	3	7/6/94	x							
37-06621-01	R	1	4/19/94			3	5/13/94	x							
37-06717-04	R	1	1/10/94			3	5/13/94	x							
37-06784-01	R	1	4/19/94			3	5/13/94	x							
37-06855-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x					6/6/94		
37-06864-06	B	1	1/24/94	2/4/94	3/22/94	3	5/13/94	x							
37-07161-01	B	1	7/7/94	7/15/94	8/5/94	3	8/19/94	x							
37-07722-04	B	1	Pilot			3	4/29/94	x							
37-07739-01	R	1	2/7/94			3	4/4/94	x							
37-07854-01	R	1	3/17/94			3	5/13/94	x							
37-07905-04	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-07939-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-07942-01	R	1	2/22/94			3	5/13/94	x							
37-08336-02	R	1	4/25/94			U	5/13/94	x							
37-08975-01	R	1	1/14/94			U	5/13/94	x							
37-09016-01	B	1	3/25/94	4/20/94	6/17/94	3	7/6/94	x					6/6/94		
37-09463-01	R	1	1/27/94			3	5/13/94	x							
37-09938-01	B	1	5/25/94	6/14/94	8/5/94	1	8/19/94	x							
37-09995-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
37-10237-01	R	1	1/14/94			3	4/4/94	x							

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add Info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
37-10284-02	R	1	3/17/94			3	4/4/94	x							
37-10363-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x					6/6/94		
37-10599-01	B	1	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
37-11079-01	R	1	1/14/94			3	4/4/94	x					4/5/94		
37-11144-01	R	1	2/22/94			3	5/13/94	x							
37-11258-01	R	1	4/19/94			3	5/13/94	x							
37-11272-02	R	1	1/14/94			U	6/3/94	x							
37-11507-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-11562-01	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x				H	4/5/94		
37-11658-01	R	1	7/1/94			2	7/25/94	x							
37-11704-01	R	1	4/18/94			U	5/13/94	x							
37-11826-01	B	1	1/5/94	2/4/94	8/5/94	3	8/19/94	x				H			
37-11866-01	B	1	1/20/94	2/4/94	3/22/94	3	5/13/94	x				H	6/6/94		
37-11887-02	R	1	4/19/94			3	5/13/94	x							
37-11887-03	B	1	7/7/94	7/15/94	8/15/94	3	8/19/94	x							
37-12110-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-12141-01	R	1	5/31/94			2	6/3/94	x							
37-12240-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
37-12486-01	R	1	1/10/94			3	5/13/94	x							
37-12495-01	R	1	4/13/94			3	5/13/94	x							
37-12771-01	R	1	7/19/94			2	8/5/94	x							
37-12808-02	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
37-12890-01	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
37-12893-01	R	1	1/10/94			3	5/13/94	x							
37-12915-01	R	1	4/13/94			3	5/13/94	x							
37-13181-01	R	1	1/5/94			3	5/13/94	x							
37-13187-02	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x					4/5/94		
37-13232-01	R	1	6/7/94			3	7/6/94	x							
37-13464-02	R	1	1/18/94			3	6/3/94	x							
37-13483-01	R	1	1/14/94			2	5/13/94	x							
37-13499-01	R	1	2/7/94			3	6/3/94	x							
37-13509-01	R	1	2/7/94			3	4/4/94	x							
37-13548-01	R	1	1/5/94			U	5/13/94	x							
37-13551-02	R	1	1/5/94			2	5/13/94	x							
37-13651-01	R	1	7/22/94			3	8/5/94	x							
37-13666-01	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
37-13681-01	B	1	1/4/94	1/7/94	2/16/94	3	6/3/94	x				H	4/5/94		
37-13798-01	R	1	3/25/94			3	5/13/94	x					4/27/94		
37-13831-01	B	1	7/13/94	7/15/94	8/15/94		rtnd9/2	x				s	6/6/94		
37-13919-01	R	1	1/5/94			3	5/13/94	x							
37-13952-01	R	1	1/14/94			3	4/4/94	x							
37-14013-01	R	1	7/22/94			3	8/5/94	x					4/5/94	Y	
37-14014-01	R	1	2/7/94			3	4/4/94	x							
37-14041-01	R	1	6/15/94			U	7/6/94	x							
37-14802-01	R	1	1/17/94			U	5/13/94	x							
37-14805-01	R	1	3/17/94			3	5/13/94	x							
37-14870-01	R	1	2/7/94			3	5/13/94	x							

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								Complete	No File	QMP Only	Lic Only				
37-14987-01	R	1	7/15/94			3	7/25/94	x							
37-15068-01	R	1	7/29/94			3	8/5/94	x					6/6/94		
37-15121-01	R	1	1/14/94			3	5/13/94	x					4/5/94		
37-15128-01	R	1	5/23/94			3	6/3/94	x							
37-15217-01	R	1	7/26/94			U	8/5/94	x							
37-15221-01	B	1	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
37-15350-01	R	1	3/14/94			3	4/4/94	x					3/7/94	Y	
37-15400-01	B	1	Pilot			3	4/29/94	x							
37-15456-01	R	1	2/7/94			3	5/13/94	x							
37-15471-01	R	1	3/23/94			3	4/4/94	x							
37-15480-01	B	1	3/2/94	3/30/94	5/17/94	3	6/3/94	x							
37-15567-01	R	1	1/17/94			3	6/3/94	x							
37-15857-01	R	1	2/17/94			U	5/13/94	x							
37-15960-01	R	1	3/18/94			3	5/13/94	x							
37-16031-01	R	1	2/22/94			U	5/13/94	x							
37-16101-02	B	1	1/4/94	1/7/94	2/28/94	3	5/13/94	x							
37-16170-01	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x				H			
37-16245-01	R	1	3/14/94			2	4/4/94	x							
37-16335-01	R	1	3/25/94			3	5/13/94	x							
37-16435-01	B	1	1/24/94	2/4/94	3/22/94	3	5/13/94	x							
37-16507-02	R	1	7/15/94			U	7/25/94	x							
37-16554-01	R	1	6/20/94			3	7/6/94	x					3/7/94	Y	
37-16602-01	R	1	4/25/94			U	5/13/94	x							
37-16826-01	R	1	5/31/94			U	6/3/94	x							
37-17066-01	R	1	1/14/94			U	5/13/94	x							
37-17080-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
37-17125-01	R	1	1/18/94			3	6/3/94	x							
37-17164-01	R	1	1/14/94			U	5/13/94	x							
37-17215-01	R	1	1/10/94			3	5/13/94	x							
37-17222-01	R	1	1/28/94			U	6/3/94	x							
37-17331-01	R	1	2/11/94			3	5/13/94	x							
37-17377-01	R	1	1/17/94			3	5/13/94	x							
37-17379-01	R	1	1/17/94			3	5/13/94	x							
37-17502-01	R	1	2/11/94			U	5/13/94	x							
37-17522-01	R	1	2/7/94			3	5/13/94	x							
37-17643-01	R	1	7/27/94			2	8/5/94	x							
37-17688-01	R	1	1/4/94			U	5/13/94	x					3/7/94		
37-17755-01	R	1	1/28/94			U	6/3/94	x							
37-17817-01	R	1	7/15/94			3	7/25/94	x							
37-17818-01	R	1	2/17/94			3	5/13/94	x							
37-17863-01	B	1	6/27/94	7/15/94	8/15/94	3	8/19/94	x							
37-17886-01	R	1	7/19/94			2	8/5/94	x					3/7/94	Y	
37-17979-01	R	1	1/31/94			2	4/4/94	x							
37-18104-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
37-18146-01	R	1	3/18/94			2	5/13/94	x							
37-18169-01	R	1	1/17/94			3	5/13/94	x							
37-18201-01	R	1	4/20/94			U	5/13/94	x							

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								Complete	No File	QMP Only	Lic Only				
37-18239-01	R	1	2/7/94			U	7/6/94	x							
37-18253-01	B	1	7/19/94			U	8/5/94	x							
37-18263-01	R	1	4/19/94			3	5/13/94	x							
37-18286-01	R	1	3/18/94			1	5/13/94	x							
37-18404-01	R	1	2/17/94			3	5/13/94	x							
37-18445-01	R	1	1/12/94			U	5/13/94	x							
37-19220-01	R	1	4/25/94			U	5/13/94	x							
37-19272-01	R	1	4/19/94			U	5/13/94	x							
37-19448-01	R	1	1/14/94			2	6/3/94	x							
37-19497-01	R	1	3/25/94			3	5/13/94	x							
37-19568-01	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
37-19570-01	R	1	7/19/94			3	8/5/94	x					3/7/94	Y	
37-19657-01	R	1	1/14/94			U	6/3/94	x							
37-19766-01	R	1	2/7/94			U	5/13/94	x							
37-19800-01	R	1	4/19/94			U	6/3/94	x							
37-20518-01	R	1	2/7/94			3	5/13/94	x							
37-20548-01	R	1	1/17/94			U	5/13/94	x							
37-20622-01	R	1	1/28/94			U	6/3/94	x							
37-20624-01	R	1	4/13/94			U	5/13/94	x							
37-20727-01	R	1	7/7/94			U	7/25/94	x							
37-20753-01	R	1	4/18/94			U	5/13/94	x							
37-20758-01	B	1	1/11/94	2/4/94	3/22/94	3	5/13/94	x							
37-20820-01	R	1	1/31/94			2	4/4/94	x							
37-20919-01	R	1	7/26/94			U	8/5/94	x							
37-20920-01	R	1	1/27/94			3	5/13/94	x							
37-21012-01	R	1	4/19/94			U	5/13/94	x							
37-21441-01	R	1	6/20/94			U	7/6/94	x							
37-23451-01	R	1	5/31/94			U	6/3/94	x							
37-23537-01	R	1	3/14/94			U	7/6/94	x							
37-23544-01	R	1	1/14/94			U	7/6/94	x							
37-23560-01	B	1	1/24/94	2/4/94	3/22/94	3	5/13/94	x				H			
37-27825-01	R	1	7/7/94			U	7/25/94	x							
37-27899-01	R	1	1/31/94			3	5/13/94	x					6/6/94		
37-27960-01	R	1	4/19/94			U	5/13/94	x							
37-27998-01	R	1	7/19/94			2	8/5/94	x							
37-28023-01	R	1	4/25/94			U	5/13/94	x							
37-28074-01	R	1	2/17/94			U	5/13/94	x							
37-28179-01	R	1	8/1/94			S	8/5/94	x				S			
37-28196-01	R	1	1/5/94			U	5/13/94	x							
37-28240-01		1	N/A				T			x					
37-28266-01	R	1	1/14/94			3	6/3/94	x							
37-28336-01	R	1	2/7/94			U	5/13/94	x							
37-28349-01	R	1	4/13/94			2	5/13/94	x							
37-28354-01	R	1	7/29/94			U	8/5/94	x							
37-28359-01	B	1	2/7/94	2/28/94	4/21/94	3	5/13/94	x							
37-28388-01	B	1	4/19/94	N/A	N/A	3	5/13/94	x							
37-28414-01	R	1	4/26/94			U	5/13/94	x							

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								Complete	No File	QMP Only	Lic Only				
37-28424-01	R	1	1/27/94			U	5/13/94	x							
37-28453-01	R	1	1/27/94			U	5/13/94	x							
37-28466-01	R	1	2/17/94			3	5/13/94	x							
37-28520-01	R	1	1/17/94			U	5/13/94	x							
37-28540-01	B	1	6/9/94	6/14/94	8/5/94	3	8/19/94	x				H			
37-28563-01	R	1	7/15/94			3	7/25/94	x							
37-28638-01	R	1	1/14/94			3	5/13/94	x							
37-28653-01	R	1	3/25/94			U	5/13/94	x							
37-28677-01	R	1	6/15/94			U	7/6/94	x							
37-28715-01	R	1	3/25/94			U	5/13/94	x							
37-28723-01	R	1	7/19/94			3	8/5/94	x							
37-28742-01	B	1	2/11/94	2/28/94	4/21/94	3	5/13/94	x				H			
37-28749-01	R	1	7/11/94			U	7/25/94	x							
37-28757-01	R	1	7/11/94			U	7/25/94	x							
37-28804-01	R	1	7/7/94			U	7/25/94	x							
37-30026-01	R	1	2/22/94			U	5/13/94	x							
37-30034-01	R	1	2/17/94			3	5/13/94	x							
38-04946-01	R	1	7/18/94			3	8/5/94	x					3/7/94	Y	
39-09703-01	R	2	5/9/94			2	6/3/94	x							
39-12130-02	R	2	7/15/94			2	7/25/94	x							
39-14873-01	R	2	1/5/94			3	6/3/94	x							
40-00238-04	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/27/94
40-01683-01	R	4	7/15/94			3	7/25/94	x					7/6/94		10/11/94
40-07328-03	R	4	1/14/94			3	4/4/94	x					7/1/94		6/3/94
40-12378-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/27/94
40-16087-01	R	4	7/22/94			2	8/5/94	x							
40-16336-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							6/27/94
40-16571-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/27/94
40-16775-01	R	4	7/7/94			3	7/25/94	x							9/26/94
40-18000-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/27/94
40-26865-01	R	4	7/15/94			3	7/25/94	x							10/11/94
40-26908-01	R	4	4/26/94			3	6/3/94	x					5/31/94	Y	6/30/94
40-27013-01	R	4	4/1/94			2	5/13/94	x							
41-00104-04	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
41-00119-08	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x				s			
41-16374-01		2	N/A				regsntlet	x							
41-19792-01	B	2	4/22/94	5/3/94	6/17/94	3	7/25/94	x							
42-00084-06	B	4	4/18/94	4/20/94	6/17/94	3	7/25/94	x					6/7/94	Y	9/27/94
42-00220-06	R	4	4/20/94			2	5/13/94	x							
42-00220-08	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							9/8/94
42-01368-01	B	4	7/14/94	7/15/94	8/30/94	3	9/7/94	x				H			
42-01368-02	B	4	4/19/94	4/20/94	6/17/94	3	7/6/94	x							9/8/94
42-05255-07	B	4	4/19/94	4/20/94	6/17/94	3	7/6/94	x							9/8/94
42-10739-03	B	4	4/22/94	5/3/94	6/17/94	3	7/6/94	x							9/27/94
42-15881-01	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							9/27/94
42-17691-01	R	4	4/1/94			2	5/13/94	x							
42-19113-01	R	4	7/15/94			3	7/25/94	x							10/11/94

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								Complete	No File	QMP Only	Lic Only				
42-26941-01		4	N/A				T	x							
43-03299-01	B	4	4/20/94	4/20/94	6/17/94	3	7/6/94	x							9/27/94
44-05123-01	R	1	3/17/94			3	4/4/94	x							
44-10187-02	B	1	1/4/94	1/7/94	2/16/94	3	5/13/94	x							
44-10187-03	B	1	5/11/94	7/15/94	8/25/94	3	8/30/94	x							
44-11345-02	R	1	5/11/94			2	6/3/94	x							
44-13353-01	R	1	7/28/94			U	8/5/94	x							
44-13760-01	R	1	6/20/94			3	7/6/94	x							
44-13976-01	R	1	1/27/94			U	5/13/94	x							
44-14121-01	R	1	3/22/94			3	5/13/94	x							
44-16262-01	R	1	6/30/94			3	8/5/94	x				s			
44-16669-01	R	1	2/7/94			3	5/13/94	x							
44-19050-01	R	1	3/18/94			U	5/13/94	x							
44-19107-01	R	1	2/7/94			U	5/13/94	x							
44-19196-01	R	1	1/10/94			3	5/13/94	x							
44-19518-01	R	1	7/22/94			3	8/5/94	x							
44-25147-01	R	1	1/10/94			U	5/13/94	x							
44-28802-01	R	1	1/17/94			3	4/4/94	x							
45-00034-09	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
45-00034-26	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
45-00034-30	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x				G			
45-00048-17	B	2	4/22/94	5/3/94	8/5/94	3	8/19/94	x				H			
45-00131-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x				H			
45-00317-02	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x							
45-00935-02	R	2	4/8/94			3	5/13/94	x							
45-00986-01	B	2	8/1/94	8/3/94	8/25/94	3	8/30/94	x				H			
45-00986-02	B	2	4/25/94	5/3/94	5/17/94	3	7/25/94	x							
45-01099-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
45-01291-02	B	2	4/8/94	4/20/94	6/17/94	1	7/6/94	x							
45-01589-01	B	2	4/8/94	7/15/94	8/15/94	3	8/19/94	x							
45-02207-01	B	2	5/11/94	7/15/94	8/5/94	3	8/19/94	x				s			
45-02888-01	B	2	5/11/94	7/15/94	8/15/94	3	8/19/94	x							6/15/94
45-03550-01	R	2	7/29/94			3	8/5/94	x							
45-03654-01	R	2	7/12/94			2	7/25/94	x							
45-04263-02	R	2	4/8/94			2	5/13/94	x							
45-05594-01	B	2	4/8/94	4/20/94	6/17/94	3	7/25/94	x							
45-05594-02	B	2	4/8/94	4/20/94	6/17/94	3	7/25/94	x							
45-06082-01	R	2	7/11/94			1	8/5/94	x				S			
45-07569-01	R	2	3/23/94			2	4/4/94	x							
45-07950-01	R	2	4/25/94			2	5/13/94	x							
45-08482-01	B	2	7/7/94	7/15/94	8/15/94	3	8/19/94	x							
45-09001-01	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x				H			
45-09001-03	B	2	4/22/94	5/3/94	6/17/94	1	7/6/94	x							
45-09087-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
45-09207-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x					2/10/94		
45-09358-02	B	2	4/5/94	4/20/94	6/17/94	3	7/25/94	x				H	4/5/94		
45-09413-06	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							

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License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
45-09669-02	R	2	5/11/94			3	6/3/94	x					4/24/94	Y	
45-10542-01	B	2	8/1/94	8/3/94	8/25/94	3	8/30/94	x							
45-10542-02	B	2	7/15/94	7/15/94	8/5/94	3	8/19/94	x							
45-10831-02	B	2	6/13/94	6/14/94	8/5/94	2	8/19/94	x							
45-11035-01	B	2	4/8/94	7/15/94	8/25/94	3	8/30/94	x				S			
45-11367-02	B	2	6/10/94	6/14/94	8/5/94	3	8/19/94	x							
45-12706-01	B	2	4/22/94	5/3/94	6/17/94	3	7/25/94	x							
45-12768-01	R	2	1/14/94			3	5/13/94	x							
45-13692-01	B	2	4/8/94	4/20/94	6/17/94	3	7/6/94	x					4/27/94		
45-15048-01	R	2	6/15/94			2	7/6/94	x							
45-15154-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
45-15154-03	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
45-15249-01	R	2	1/5/94			2	7/25/94	x							
45-15367-01	R	2	7/29/94			3	8/5/94	x							
45-16209-02	R	2	3/23/94			2	4/4/94	x							
45-16222-01	B	2	4/8/94	7/15/94	8/25/94	3	8/30/94	x				S			
45-16231-01	B	2	4/19/94	4/20/94	6/17/94	3	7/6/94	x				H			
45-16231-02	B	2	4/19/94	4/20/94	6/17/94	3	7/6/94	x							
45-16391-01	R	2	7/12/94			2	7/25/94	x							
45-16618-01	R	2	5/11/94			2	6/3/94	x							
45-16806-01	B	2	4/8/94	4/20/94	6/17/94	3	7/6/94	x							
45-16909-01	B	2	5/11/94	6/14/94	8/5/94	2	8/19/94	x							
45-16973-01	R	2	8/15/94			3	8/19/94	x							
45-17123-01	R	2	4/8/94			3	5/13/94	x							
45-17128-01	B	2	5/11/94	6/14/94	8/15/94	3	8/19/94	x							
45-17187-01	R	2	4/8/94			3	5/13/94	x							
45-17395-01	R	2	8/15/94			1	8/19/94	x							
45-17606-01	R	2	7/14/94			U	7/25/94	x							
45-17898-01	R	2	7/12/94			3	7/25/94	x							
45-18103-01	R	2	6/15/94			U	7/6/94	x							
45-18195-01	B	2	4/8/94	4/20/94	6/17/94	3	7/6/94	x							
45-18332-01	R	2	4/8/94			3	5/13/94	x							
45-18349-01		2	N/A				Retired	x			R				
45-18398-01	R	2	3/23/94			3	4/4/94	x							
45-18401-01	R	2	5/11/94			3	6/3/94	x							
45-18488-01	R	2	4/8/94			2	5/13/94	x							
45-19057-01	R	2	4/8/94			3	5/13/94	x							
45-19273-01		2	N/A				regsntlet	x							
45-19382-01	R	2	7/29/94			U	8/5/94	x							
45-19485-01	R	2	7/12/94			3	7/25/94	x							
45-21121-01	R	2	4/25/94			3	5/13/94	x							
45-21209-01	R	2	4/25/94			3	5/13/94	x							
45-23001-01	R	2	7/15/94			3	8/5/94	x							
45-23003-01	R	2	1/27/94			3	5/13/94	x							
45-23040-01	R	2	8/15/94			3	8/19/94	x							
45-23046-01	R	2	5/11/94			U	6/3/94	x							
45-23073-01	R	2	8/4/94			1	8/19/94	x							

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								Complete	No File	QMP Only	Lic Only				
45-23447-01	R	2	6/15/94			1	7/6/94	x							
45-24876-01	R	2	5/11/94			1	6/3/94	x							
45-25031-01	R	2	4/20/94			3	5/13/94	x							
45-25110-01	R	2	7/22/94			3	8/5/94	x							
45-25118-01	B	2	5/20/94	N/A		3	7/25/94	x							
45-25136-01	R	2	4/1/94			U	6/3/94	x							
45-25177-01	R	2	4/25/94			3	5/13/94	x							
45-25182-01	R	2	6/21/94			3	7/6/94	x							
45-25187-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x				H			
45-25216-01	R	2	8/15/94			3	8/19/94	x							
45-25240-01	R	2	7/15/94			3	7/25/94	x							
46-00990-01	R	5	1/18/94			1	5/13/94	x							6/7/94
46-02645-03	B	5	1/4/94	1/7/94	2/28/94	3	6/3/94	x							6/16/94
47-00404-02	R	2	7/12/94			2	7/25/94	x							
47-00714-02	R	2	5/11/94			3	6/3/94	x							
47-01458-01	B	2	4/22/94	5/3/94	7/21/94	3	8/5/94	x				H			
47-01458-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
47-03630-02	R	2	4/1/94			1	6/3/94	x					4/27/94	Y	
47-05322-02	B	2	4/22/94	5/3/94	6/17/94	2	7/6/94	x							
47-08019-01	R	2	5/25/94			2	6/3/94	x							
47-09576-01	B	2	7/7/94	7/15/94	8/15/94	3	8/19/94	x				S			
47-09576-02	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
47-09772-02	B	2	4/8/94	4/20/94	6/17/94	3	7/6/94	x							
47-11709-01	R	2	4/8/94			3	5/13/94	x							
47-15473-01	B	2	4/8/94	4/20/94	6/17/94	3	7/6/94	x							
47-15717-01	B	2	5/25/94	6/14/94	8/5/94	3	8/19/94	x							
47-15717-03	B	2	7/15/94	7/15/94	8/5/94	3	8/19/94	x							
47-16156-01	R	2	4/8/94			3	5/13/94	x							
47-16259-01	R	2	4/19/94			3	5/13/94	x							
47-16307-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
47-16720-01	R	2	6/15/94			3	7/6/94	x							
47-17058-01	R	2	5/11/94			U	6/3/94	x							
47-17282-01	B	2	4/8/94	7/15/94	8/25/94	3	8/30/94	x				S			
47-17567-01	R	2	7/12/94			3	7/25/94	x							
47-17745-01	R	2	4/8/94			3	5/13/94	x							
47-17746-01	R	2	5/25/94			2	7/25/94	x							
47-17929-01	R	2	8/15/94			3	8/19/94	x							
47-18046-01	R	2	7/15/94			3	7/25/94	x							
47-18080-01	R	2	4/8/94			3	5/13/94	x							
47-19142-01	B	2	4/5/94	4/20/94	6/17/94	3	7/6/94	x				H			
47-19142-02	B	2	4/5/94	4/20/94	6/17/94	3	7/6/94	x							
47-19919-01	R	2	8/4/94			2	8/19/94	x							
47-23066-02	B	2	8/1/94	8/3/94	8/25/94	3	8/30/94	x							
47-23070-01	R	2	6/15/94			2	7/6/94	x							
47-24864-01	R	2	8/15/94			1	8/19/94	x							
47-25152-01	R	2	7/12/94			U	7/25/94	x							
47-25188-01	R	2	7/29/94			3	8/5/94	x							

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								Complete	No File	QMP Only	Lic Only				
48-00056-02	R	3	3/25/94			3	5/13/94	x							6/22/94
48-00395-02	B	3	1/20/94	2/4/94	3/22/94	3	5/13/94	x							6/23/94
48-00537-03	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
48-00810-02	B	3	3/14/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
48-00919-03	B	3	3/22/94	3/30/94	5/17/94	2	6/3/94	x							6/29/94
48-01032-01	B	3	2/11/94	2/28/94	4/21/94	3	5/13/94	x					4/5/94		6/22/94
48-01165-01	R	3	3/14/94			3	4/4/94	x					5/17/94		6/9/94
48-01183-01	B	3	3/14/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
48-01277-02	B	3	5/20/94	6/14/94	7/21/94	3	8/5/94	x							
48-01338-01	B	3	6/27/94	7/15/94	8/25/94	3	8/30/94	x					5/31/94	Y	
48-01670-01	R	3	2/7/94			3	4/4/94	x							6/8/94
48-01828-01	B	3	5/9/94	N/A		3	7/25/94	x							
48-02096-01	R	3	2/7/94			2	4/4/94	x							7/9/94
48-02122-05	B	3	2/17/94	2/28/94	4/21/94	3	5/13/94	x							6/22/94
48-02130-02	B	3	1/4/94	1/7/94	2/16/94	2	5/13/94	x							6/16/94
48-02411-01	R	3	4/28/94			3	6/3/94	x							7/8/94
48-02417-01	B	3	2/7/94	2/28/94	4/21/94	3	5/13/94	x							6/24/94
48-02419-02	B	3	5/13/94	6/14/94	8/15/94	3	8/19/94	x							
48-02419-03	B	3	7/19/94	7/22/94	8/15/94	3	8/19/94	x							
48-02435-01	R	3	2/7/94			3	4/4/94	x							6/9/94
48-03116-01	B	3	4/22/94	5/3/94	6/17/94	3	7/6/94	x							7/14/94
48-03220-03	B	3	1/14/94	2/4/94	3/22/94	3	5/13/94	x							6/16/94
48-03280-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x							6/29/94
48-03374-02	R	3	2/7/94			3	4/4/94	x							6/8/94
48-03411-02	R	3	5/23/94			2	6/3/94	x							6/17/94
48-04193-01	B	3	4/22/94	5/3/94	6/17/94	3	7/25/94	x				H			
48-04193-03	B	3	5/13/94	4/22/94	6/17/94	2	7/25/94	x							
48-04585-01	R	3	1/17/94			3	6/3/94	x							7/8/94
48-05006-03	R	3	4/13/94			2	5/13/94	x							6/22/94
48-05470-01	B	3	7/15/94	7/22/94	8/25/94	3	8/30/94	x					5/31/94	Y	
48-06239-01	B	3	7/15/94			3	7/25/94	x							
48-07957-01	R	3	5/20/94			2	6/3/94	x							6/17/94
48-09494-01	R	3	3/14/94			3	4/4/94	x							6/9/94
48-09843-18	B	3	2/17/94	4/21/94	5/17/94	3	6/3/94	x				H			7/8/94
48-10219-01	B	3	3/22/94	3/30/94	5/17/94	3	6/3/94	x				H			6/29/94
48-10251-01	R	3	2/17/94			3	5/13/94	x							7/13/94
48-10966-03	B	3	6/13/94	6/14/94	7/21/94	3	8/5/94	x							
48-11281-02	R	3	1/5/94			2	5/13/94	x							7/6/94
48-12272-01	R	3	7/29/94			U	8/5/94	x							
48-12786-01	R	3	2/7/94			3	4/4/94	x							6/9/94
48-12878-01	R	3	5/13/94			3	6/3/94	x							7/8/94
48-13249-02	B	3	2/11/94	2/28/94	4/21/94	3	5/13/94	x					5/31/94		6/22/94
48-13463-01	R	3	2/17/94			3	5/13/94	x							7/13/94
48-15519-01	R	3	5/25/94			2	6/3/94	x							6/17/94
48-15909-01	R	3	2/17/94			3	5/13/94	x							
48-15939-01	R	3	2/22/94			3	5/13/94	x							7/13/94
48-16117-01	R	3	7/15/94			3	7/25/94	x							

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								Complete	No File	QMP Only	Lic Only				
48-16485-01	B	3	5/9/94	N/A		3	7/25/94	x							
48-16593-01	R	3	5/24/94			3	7/6/94	x							7/14/94
48-16749-01	R	3	2/7/94			3	5/13/94	x							7/8/94
48-16772-01	R	3	1/31/94			3	4/4/94	x							6/8/94
48-16838-01	R	3	4/25/94			3	5/13/94	x							6/24/94
48-17367-01	R	3	7/29/94			3	8/5/94	x							
48-17393-01	R	3	3/14/94			2	4/4/94	x							6/9/94
48-17481-01	R	3	1/31/94			3	5/13/94	x							6/28/94
48-17543-01	R	3	8/15/94			3	8/19/94	x							
48-17547-01	R	3	3/14/94			3	4/4/94	x							6/9/94
48-17700-01	R	3	1/17/94			3	5/13/94	x							6/30/94
48-17740-01	R	3	3/17/94			2	5/13/94	x							7/13/94
48-18037-01	R	3	2/17/94			3	5/13/94	x							7/13/94
48-18578-01	R	3	7/13/94			3	7/25/94	x							
48-18643-01	R	3	4/22/94			3	5/13/94	x							6/24/94
48-18654-01	R	3	3/14/94			2	6/3/94	x							7/8/94
48-18679-01	R	3	5/9/94			2	6/3/94	x					4/14/94		6/17/94
48-18803-01	R	3	2/22/94			3	5/13/94	x							7/13/94
48-18864-01	R	3	1/31/94			3	5/13/94	x							6/28/94
48-20303-01	R	3	8/15/94			2	8/19/94	x							
48-24325-01	R	3	2/7/94			3	5/13/94	x							6/30/94
48-24379-01	R	3	7/11/94			3	7/25/94	x							
48-24533-01	R	3	4/25/94			3	5/13/94	x							6/24/94
48-24610-01	R	3	1/31/94			3	5/13/94	x							6/28/94
48-25969-01	R	3	5/20/94			3	6/3/94	x							6/17/94
48-26035-01	R	3	7/26/94			3	8/5/94	x							
48-26090-01	R	3	5/31/94			U	6/3/94	x							6/17/94
48-26123-01	R	3	1/10/94			3	5/13/94	x							7/6/94
48-26378-01	R	3	6/17/94			3	8/5/94	x							
48-26418-02	R	3	5/31/94			3	6/3/94	x							
48-26493-01		3	N/A				Rnegdec	x							
49-00152-02	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/29/94
49-01380-01	B	4	3/15/94	3/30/94	5/17/94	3	6/3/94	x							7/29/94
49-10982-02	R	4	4/1/94			2	5/13/94	x							
49-15978-01	R	4	4/1/94			3	5/13/94	x							6/13/94
49-17940-01	R	4	4/1/94			3	5/13/94	x							6/13/94
49-18030-01	R	4	7/15/94			3	7/25/94	x							10/11/94
49-18230-01	R	4	7/7/94			3	8/5/94	x				S			
49-18276-01	R	4	4/1/94			1	6/3/94	x							
49-19237-01	R	4	7/15/94			2	7/25/94	x							
49-21004-01	R	4	7/15/94			3	7/25/94	x							10/11/94
49-23121-01	R	4	4/1/94			3	5/13/94	x							6/21/94
49-23163-01	R	4	1/14/94			3	4/4/94	x							6/3/94
49-26949-01	R	4	7/15/94			3	7/25/94	x							10/11/94
50-13648-01	R	5	1/10/94			2	8/5/94	x				S			
50-17838-01	B	5	1/4/94	1/7/94	2/28/94	3	5/13/94	x							6/7/94
50-18244-01	B	5	5/25/94	6/14/94	8/5/94	2	8/30/94	x							

QMP Database

License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
50-19913-01	R	5	3/25/94			3	5/13/94	x							6/7/94
50-23214-01	R	5	6/29/94			3	7/25/94	x							
50-29059-01	R	5	6/15/94			3	7/25/94				x				
52-01946-07	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
52-04359-01	B	2	7/13/94	7/15/94	8/25/94	3	8/30/94	x				S			
52-06121-02	R	2	7/29/94			3	8/5/94	x							
52-08827-02	R	2	4/8/94			2	6/3/94	x							
52-10270-01	B	2	4/22/94	5/3/94	6/17/94	3	7/6/94	x							
52-11534-01	R	2	7/12/94			2	7/25/94	x							
52-11810-02	R	2	7/19/94			3	8/5/94	x							
52-11832-01	B	2	7/11/94	7/15/94	8/5/94	3	8/19/94	x							
52-13362-02	R	2	8/1/94			S	8/5/94	x				S	3/7/94	Y	
52-13471-01	B	2	5/20/94	6/14/94	8/5/94	3	8/19/94	x							
52-13471-02	B	2	6/13/94	6/14/94	8/5/94	3	8/19/94	x							
52-13598-01	B	2	7/14/94	7/22/94	8/15/94	3	8/19/94	x							7/6/94
52-13598-03	R	2	8/22/94			3	8/30/94	x				S			
52-13732-02	R	2	7/12/94			S	8/5/94	x				s			
52-14931-01	R	2	6/20/94			2	7/6/94	x							
52-15086-01	R	2	7/29/94			3	8/5/94	x							
52-15139-01	R	2	7/29/94			3	8/5/94	x							
52-16033-01	B	2	5/11/94	6/14/94	8/15/94	3	8/19/94	x							
52-16061-01	R	2	1/14/94			2	4/4/94	x							
52-16660-03	R	2	7/1/94			S	8/5/94	x				S			
52-17273-01	R	2	7/15/94			3	7/25/94	x							
52-17311-01	R	2	7/7/94			S	8/5/94	x				S			
52-17704-01	R	2	7/15/94			3	8/5/94	x				S			
52-19112-01	R	2	5/11/94			3	6/3/94	x							
52-19206-01	R	2	7/11/94			S	8/5/94	x				S			
52-19550-01	R	2	7/19/94			3	8/5/94	x							
52-19738-02	R	2	6/9/94			S	8/5/94	x				S			
52-19873-01	R	2	8/15/94			3	8/19/94	x							
52-19984-01	R	2	7/15/94			3	7/25/94	x							
52-21026-01	R	2	7/7/94			2	8/5/94	x				S			
52-21325-01	R	2	4/28/94			U	6/3/94	x							
52-23044-01	R	2	8/15/94			3	8/19/94	x							
52-23058-01	R	2	N/A				nQMPr	x							
52-24916-01	R	2	7/15/94			3	7/25/94	x							
52-24937-01	R	2	4/25/94			2	5/13/94	x							
52-24969-01	R	2	7/15/94			3	7/25/94	x							
52-25004-01	R	2	7/11/94			S	8/5/94	x				S			
52-25016-01	R	2	5/25/94			2	6/3/94	x							
52-25054-01	R	2	7/29/94			S	8/5/94	x				S			
52-25058-01	R	2	5/25/94			3	6/3/94	x							
52-25075-01	R	2	4/21/94			U	5/13/94	x							
52-25121-01	R	2	4/20/94			3	5/13/94	x							
52-25127-01	R	2	5/20/94			U	7/25/94	x							
52-25160-01	R	2	4/25/94			2	5/13/94	x							

QMP Database

License #	Facility Type	Region	Date Rtnd from Rvr	Date Sent to UCSF	Date rtnd from UCSF	Letter Type	Date to NRC- (See key for abbreviations)	File Status				S-90--HDR	Date add info rcvd	Rev Rvwd	Date Sent by Region to facility
								Complete	No File	QMP Only	Lic Only				
52-25223-01	R	2	7/15/94			3	7/25/94	x							
52-25232-01	R	2	4/1/94			3	5/13/94	x							
52-25255-01	R	2	4/1/94			3	7/25/94	x							
53-00458-04	B	5	6/21/94	7/15/94	8/15/94	3	8/19/94	x					11/1/93	Y	
53-03506-01	R	5	7/12/94			3	8/5/94	x				S	5/31/94		
53-04935-01	R	5	7/11/94			S	8/5/94	x				S			
53-05379-01	R	5	8/1/94			1	8/5/94	x				S			
53-11966-01	B	5	3/22/94	3/30/94	5/17/94	3	6/3/94	x							6/16/94
53-13061-01	R	5	4/25/94			2	5/13/94	x							6/7/94
53-13519-01	R	5	2/22/94			3	8/5/94	x				S	4/5/94	Y	
53-15737-01	R	5	7/22/94			3	8/5/94	x				S			
53-15984-01	R	5	3/22/94			2	5/13/94	x							6/7/94
53-16421-01	R	5	1/14/94			2	5/13/94	x							6/7/94
53-16533-02	B	5	4/22/94	5/3/94	6/17/94	3	7/6/94	x					5/31/94		6/7/94
53-16929-01	R	5	7/14/94			3	7/25/94	x					1/21/94	Y	
53-17797-01	B	5	1/4/94	1/7/94	2/16/94	3	5/13/94	x							6/7/94
53-17839-01	R	5	3/17/94			2	4/4/94	x							
53-18126-01	R	5	2/7/94			2	4/4/94	x				S	5/31/94		
53-18343-01	R	5	7/11/94			S	8/5/94	x				S	5/31/94		
53-23297-01	R	5	5/11/94			2	6/3/94	x							6/16/94
53-29004-01	R	5	6/15/94			3	7/6/94	x							
56-18134-01	R	5	1/14/94			3	6/3/94	x							6/16/94
IDA-66-2		4	N/A				T			x					

ATTACHMENT 1:

Regulatory Guide 8.33
Quality Management Program

U.S. NUCLEAR REGULATORY COMMISSION

October 1991

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.33
(Task DG-8001)

QUALITY MANAGEMENT PROGRAM

A. INTRODUCTION

According to § 35.32, "Quality Management Program," of 10 CFR Part 35, "Medical Use of Byproduct Material," applicants or licensees, as applicable, are required to establish a quality management (QM) program. This regulatory guide provides guidance to licensees and applicants for developing policies and procedures for the QM program. This guide does not restrict or limit the licensee from using other guidance that may be equally useful in developing a QM program, e.g., information available from the Joint Commission on Accreditation of Healthcare Organizations or the American College of Radiology.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 35, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 35 have been cleared under OMB Clearance No. 3150-0010.

B. DISCUSSION

The administration of byproduct material can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department when the authorized user prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as a radiation therapy physicist, dosimetrist, and radiation therapy technologist. Conducting the plan of treatment may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures.

The administration of byproduct material or radiation from byproduct material can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, or gamma stereotactic radiosurgery. For each modality, this regulatory guide recommends specific policies or procedures to ensure that the objectives of 10 CFR 35.32 are met. In general, this guide recommends that licensees have:

- Policies to have an authorized user date and sign a written directive prior to the administration,
- Procedures to identify the patient by more than one method,
- Procedures to be sure the plans of treatment are in accordance with the written directive,
- Procedures to confirm that, prior to administration, the person responsible for the treatment modality will check the specific details of the written directive (e.g., in radiopharmaceutical therapy, verify the radiopharmaceutical, dosage, and route of administration; or in oncology, verify the treatment site, total dose, dose per fraction, and overall treatment period),
- Procedures to record the radiopharmaceutical dosage or radiation dose actually administered.

C. REGULATORY POSITION

This regulatory guide provides guidance to licensees and applicants for developing a quality management program acceptable to the NRC staff for complying with 10 CFR 35.32. However, a licensee or applicant may use other sources of guidance and experience in addition to or in lieu of this regulatory guide. The NRC staff would review such a program on a case-by-case basis.

The licensee's QM program should contain the essential elements of the policies and procedures listed in the following sections.

1. SUGGESTED POLICIES AND PROCEDURES FOR CERTAIN RADIOPHARMACEUTICAL USES

1.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

1.2. Before administering a radiopharmaceutical dosage, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

1.3. The licensee should establish a procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the writ-

fractional dose. The responsibilities and conditions of supervision are contained in 10 CFR 35.32.

Manual dose calculations should be checked for:

(1) Arithmetic errors,

(2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,

(3) Appropriate use of nomograms (when applicable), and

(4) Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., patient contour, patient thickness at the central ray, depth of target, depth dose factors, treatment distance, portal arrangement, field sizes, or beam-modifying factors). Alternatively, the dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations.

If the manual dose calculations are performed using computer-generated outputs or vice versa, particular emphasis should be placed on verifying the correct output from one type of dose calculation (e.g., computer) to be used as an input in another type of dose calculation (e.g., manual). Parameters such as the transmission factors for wedges and the source strength of the sealed source used in the dose calculations should be checked.

2.9. The licensee should establish a procedure for independently checking certain full calibration measurements as follows:

After full calibration measurements that resulted from replacement of the source, or whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions should be performed. The independent check should be performed within 30 days following such full calibration measurements.

The independent check should be performed by either:

(1) An individual who did not perform the full calibration (the individual should meet the requirements specified in 10 CFR 35.961) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system should meet the requirements specified in 10 CFR 35.630(a)), or

(2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within 5 percent.

2.10. The licensee should establish a procedure to have full calibration measurements (required by 10 CFR 35.632) include the determination of transmission factors for trays and wedges. Transmission factors for other beam-modifying devices (e.g., nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) should be determined before the first medical use of the beam-modifying device and after replacement of the source.

2.11. The licensee should establish a procedure to have a physical measurement of the teletherapy output made under applicable conditions prior to administration of the first teletherapy fractional dose if the patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

2.12. If the authorized user determines that delaying treatment to perform the checks of (1) dose calculations for a prescribed dose that is administered in three fractions or less (see Regulatory Position 2.8) or (2) teletherapy output (see Regulatory Position 2.11) would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The authorized user should make a notation of this determination in the records of the calculated administered dose. The checks of the calculations should be performed within two working days of completion of the treatment.

2.13. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for teletherapy dose calculations. Acceptance testing should also be performed after full calibration measurements when the calibration was performed (1) before the first medical use of the teletherapy unit, (2) after replacement of the source, or (3) when spot-check measurements indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected

ing computer program for brachytherapy dose calculations when using high-dose-rate remote afterloading devices. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

3.1.10. The licensee should establish procedures to perform periodic reviews of the brachytherapy QM program for using the high-dose-rate remote afterloading device. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

3.2. All Other Brachytherapy Applications

3.2.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

3.2.2. Before administering a brachytherapy dose, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

3.2.3. The licensee should establish a procedure to verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, and source strengths should be confirmed to verify agreement with the written directive and plan of treatment.

3.2.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

3.2.5. The licensee should establish a procedure to have an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources.* The licensee may use any appropriate verification method, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, i.e., one location for each source strength. The responsibilities and conditions of supervision are contained in 10 CFR 35.25.

3.2.6. For temporary brachytherapy implants, the licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources or nonradioactive "dummy" sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). Whenever possible, nonradioactive "dummy" sources should be used before inserting the radioactive sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

3.2.7. For permanent brachytherapy implants, the licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources (e.g., iodine-125 sealed sources used for interstitial applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., templates) to establish the location of the sources and calculate the total dose, if applicable. In these cases, radiographs or other comparable images may not be necessary.

3.2.8. After insertion of the temporary implant brachytherapy sources (see Regulatory Position 3.2.6), the licensee should establish a procedure to have an authorized user promptly record the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or other appropriate record.

3.2.9. After insertion of the permanent implant brachytherapy sources (see Regulatory Position

*The term sealed sources includes wires and encapsulated sources.

4.5. The licensee should establish a procedure to verify, before administering each treatment, that the specific details of the administration are in accordance with the written directive and plan of treatment. The verification should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physicist, or radiation therapy technologist) other than the individuals who dated and signed the written directive and plan of treatment. Particular emphasis should be directed toward verifying that the stereotactic frame coordinates on the patient's skull match those of the plan of treatment.

4.6. The licensee should establish a procedure to check computer-generated dose calculations by examining the computer printout to verify that correct data for the patient were used in the calculations.

4.7. The licensee should establish a procedure to check that the computer-generated dose calculations were correctly input to the gamma stereotactic radiosurgery unit.

4.8. The licensee should establish a procedure to have the neurosurgeon or the oncology physician, after administering the treatment, date and sign or initial a written record of the calculated administered dose in the patient's chart or in another appropriate record. A record of the administered dose is required by 10 CFR 35.32(d)(2).

4.9. If the authorized user determines that delaying treatment in order to perform the checks of the dose calculations (see Regulatory Positions 4.6 and 4.7) would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of the treatment.

4.10. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for gamma stereotactic radiosurgery dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for gamma stereotactic radiosurgery dose calculations. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

4.11. The licensee should establish procedures to perform periodic reviews of the gamma stereotactic radiosurgery QM program. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

5. ORAL DIRECTIVES AND REVISIONS TO WRITTEN DIRECTIVES

A footnote to 10 CFR 35.32(a)(1) reads as follows:

> "If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.
>
> "Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.
>
> "If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive."

6. PERIODIC REVIEWS

The licensee should establish written procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceuticals, teletherapy, brachytherapy, and gamma stereotactic radiosurgery. The review should include, from the previous 12 months (or since the last review), a representative sample of patient administrations, all recordable events, and all misadministrations. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery. For example, using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate (or lot tolerance percent defective) of 2 percent, the number of patient cases to be reviewed (e.g., 115) based on 1000 patients treated would be larger than the number of patient cases to be reviewed (e.g., 85) based on 200 patients treated. In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly. For each patient's case, a comparison should be made between what was administered versus what was prescribed in the written directive. If the difference between what

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ATTACHMENT 2:

Code of Federal Regulations 10 CFR 35

of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 34 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 34 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§34.1, 34.2, 34.3, 34.8, 34.11, 34.51, 34.61, and 34.63.

[57 FR 55074, Nov. 24, 1992]

APPENDIX A TO PART 34

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E. Methods of controlling radiation dose:
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[44 FR 50808, Aug. 30, 1979, as amended at 55 FR 853, Jan. 10, 1990]

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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ation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized user means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dental use means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

Management means the chief executive officer or that person's delegate or delegates.

Medical Institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Ministerial change means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131:

(i) Involving the wrong patient or wrong radiopharmaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong patient or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more

(5) A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Teletherapy physicist means the individual identified as the teletherapy physicist on a Commission license.

Visiting authorized user means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

Written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(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).

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 34120, July 25, 1991]

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19247, May 27, 1988]

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements in this part under control number 3150–0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, Form NRC–313 is approved under control number 3150–0120.

(d) OMB has assigned control number 3150–0171 for the information collection

tions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements

§ 35.20 ALARA program.

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

§ 35.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

product material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

[51 FR 36951, Oct. 16, 1991, as amended at 56 FR 34121, July 25, 1991]

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for three years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

[56 FR 34121, July 25, 1991]

§ 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center[2] no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

[2] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 52 FR 31611, Aug. 21, 1987; 53 FR 19247, May 27, 1988]

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or

for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

(c)(1) From August 23, 1990, to December 31, 1994, a licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA), by following the directions of an authorized user physician.

(2) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations.

[51 FR 36951, Oct. 16, 1986, as amended at 57 CFR 45568, Oct. 2, 1992; 58 FR 39132, July 22, 1993]

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by § 20.1301 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee shall administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in § 20.1301 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated

millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by §20.1206(a) of this chapter a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

[51 FR 36951, Oct. 16, 1986, as amended at 54 FR 41821, Oct. 12, 1989]

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for three years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(b) Iodine-125 as a sealed source in a portable imaging device.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with § 35.51 of this part.

Subpart I—Teletherapy

§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:

(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§ 35.606 License amendments.

In addition to the changes specified in § 35.13 of this part, a licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

§ 35.610 Safety instruction.

(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if:

(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately

previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23471, May 21, 1991]

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606 (a) through (d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for three years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a) through (d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 millirem per hour and 2 millirem per hour, respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 20.1201 of this chapter; and

(ii) Radiation dose quantities per unit time in unrestricted areas do not

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:

(a) Is certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine; or

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Has had classroom and laboratory training and experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Be an authorized user identified on the licensee's license.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(1) 40 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection,

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent the misadministration of byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Review of the full calibration measurements and periodic spot checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent misadministrations;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(iv) Post-administration followup and review of case histories.

§ 35.961 Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who:

(a) Is certified by the American Board of Radiology in:

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in §§ 35.59, 35.632, 35.634, and 35.641 of this part.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of subpart J.

§ 35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart K—Enforcement

§ 35.990 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

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