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Pilot Program to Assess Proposed Basic Quality Assurance Requirements in the Medical Use of Byproduct Materials

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ABSTRACT

In January 1990, the Nuclear Regulatory Commission (NRC) proposed amendments to 10 CFR Part 35 that would require medical licensees using byproduct material to establish and implement a basic quality assurance program. A 60-day real-world trial of the proposed rules was initiated to obtain information beyond that generally found through standard public comment procedures. Volunteers from randomly selected institutions had opportunities to review the details of the proposed regulations and to implement these rules on a daily basis during the trial. The participating institutions were then asked to evaluate the proposed regulations based on their personal experiences.

The pilot project sought to determine whether medical institutions could develop written quality assurance programs that would meet the eight performance-based objectives of proposed Section 35.35. In addition, the NRC wanted to learn from these volunteers if they had any recommendations on how the rule could be revised to minimize its cost and to clarify its objectives without decreasing its effectiveness.

It was found that licensees could develop acceptable QA programs under a performance-based approach, that most licensee programs did meet the proposed objectives, and that most written QA plans would require consultations with NRC or Agreement State personnel before they would fully meet all objectives of proposed Section 35.35.

This report describes the overall pilot program. The methodology used to select and assemble the group of participating licensees is presented. The various workshops and evaluation questionnaires are discussed, and detailed findings are presented.

EXECUTIVE SUMMARY

The Nuclear Regulatory Commission (NRC) proposed amendments to 10 CFR Part 35 that would require medical licensees using byproduct material to establish and implement a basic quality assurance program. To obtain information beyond that generally found through standard public comment procedures the NRC implemented a real-world trial of the proposed rules that provided comments directly from the regulated medical community. A 60-day trial program was developed where volunteers from randomly selected institutions had opportunities to review the details of the proposed regulations and to implement these rules on a daily basis. The participating institutions were then asked to evaluate the proposed regulations based on their personal experiences.

The pilot project sought answers to three questions:

1. Could medical institutions develop written quality assurance programs to meet the eight performance-based objectives of proposed Section 35.35?

2. After reviewing these written programs would the NRC find that they met the proposed rule?

3. Would the NRC find these programs in compliance with the proposed rule based upon site visits and evaluations?

In addition, after the volunteers had tested the proposed rule, the NRC wanted to learn from them if they had any problems implementing the proposed rule or draft regulatory guide, and their estimates of incremental costs related to the proposed rule. The NRC also wanted to learn from these volunteers if they had any recommendations on how the rule could be revised to minimize its cost and to clarify its objectives without decreasing its effectiveness.

A pool of licensees was assembled to voluntarily participate in a program designed to address these questions. Volunteers were chosen using proportional stratified random sampling, where strata where established to represent characteristics of the population of licensees at large (e.g., location, size, ownership, and type of medical use). In addition, volunteers were selected to proportionally represent licensees from each NRC Region and the 29 Agreement States.

Volunteers were assembled at workshops held in each of the 5 NRC Regions, where the proposed rules (i.e., proposed Sections 35.33-35.35) and draft regulatory guide were discussed. They were asked to develop written QA programs to meet proposed Section 35.35 and to forward these programs to BNL. They then participated in a 60-day trial program during which they implemented these QA programs, keeping notes of how well each proposed Section 35.35 objective was met (including record keeping requirements, and costs associated with meeting the proposed regulations). During the 60-day trial period each written program was evaluated by staff at Brookhaven National Laboratory using a checklist developed by the NRC to determine how well the licensee met the proposed QA rule. Also during the 60-day period a team of NRC personnel made site visits to eighteen randomly selected volunteer institutions to determine how well these written plans were implemented in practice.

At the beginning of the trial each institution was sent two questionnaires to complete on an on-going basis. One questionnaire was developed to evaluate the proposed rule, and the

other to evaluate the draft regulatory guide. After the 60-day trial, participants from the volunteering institutions were then reconvened at regional workshops and asked to share their field experiences and to suggest changes to the proposed rules.

Of the 23 NRC licensees which participated in the 60-day pilot project, 19 had programs in diagnostic nuclear medicine, 17 had programs in therapeutic nuclear medicine, 11 had programs in teletherapy, and 10 had programs in brachytherapy. Of the 41 Agreement State licensees there were 30 programs in diagnostic nuclear medicine, 29 programs in therapeutic nuclear medicine, 22 programs in teletherapy, and 23 programs in brachytherapy. Many institutions had multiple byproduct material departments or programs. There were 91 individuals who provided information by attending one or more workshops and/or who submitted signed evaluation forms. Seven (7) of these were physicians, 41 physicists (including 13 PhDs), and 43 certified technologists. There were also 12 radiation safety officers among these individuals.

It was found that (1) licensees could develop acceptable QA programs under a performance-based approach, (2) most licensee programs did meet most of the proposed Section 35.35 objectives, and (3) most written QA plans would require consultations with NRC or Agreement State personnel before they would fully meet all objectives of proposed Section 35.35. However, site visits by NRC staff found that most institutional QA programs would almost completely meet the objectives in actual practices.

There were many instances in which the information obtained could only have resulted from a pilot program. Detailed suggestions can be found in publicly available workshop transcripts. Some more important findings include:

- Concern was expressed about the ability of small institutions to conduct an audit using personnel "who are not involved" in the activity being audited.

- Redundant patient identification procedures were lacking in most written (and as practiced) QA programs, particularly for outpatients. It was mentioned that this proposed objective did not specify redundancy.

- It was suggested by participants with teletherapy programs that depth-dose calculations be verified by the measurement of the ^{60}Co output. However, if the intent of Draft Regulatory Guide Section 5.10 was to check the accuracy of the treatment planning program, then much more detailed information would be necessary. It was suggested that this Section be dropped unless more specific details could be developed.

- It was mentioned that diagnostic procedures often involved oral directives in lieu of written referrals. It was also mentioned that outpatient written referrals were problematic because they could not always be dated and signed before administration. It was mentioned that verbal orders were sometimes approved by the authorized user. Other facilities entered the verbal referral information in a telephone log book at the referring and receiving ends.

- Guidelines to ensure that instructions were understood could probably be better met by requirements for personnel training and licensing.

- The terms prescriptions, referrals, requisitions, written orders, or chart orders or notes were often used interchangeably. It was suggested that these should be better defined.

- It was recommended that less stringent error reporting limits be allowed for certain types of measurements such as calibrations and calculations of daily therapy dose fractions. Participants expressed difficulty with the 2 rem organ and 0.5 rem whole body notification limits.

  They offered several alternatives: (1) replace "2 rem organ dose/0.5 rem WB" with "producing an organ dose or whole body dose twice that which would have been administered had no misadministration occurred..." (2) delete the 3rd criterion completely (3) one participant thought that a 5x error reporting requirement would be satisfactory if the dose was clinically significant. (4) several participants thought that the term organ dose could be eliminated if the 5x requirement was lowered to 3x dosage error. (5) another participant thought that the organ dose should be retained especially in the case where the wrong radiopharmaceutical was administered.

- It was suggested that some QA-related requirements be placed on manufacturers of computer software used in teletherapy and brachytherapy.

Many participants found the proposed QA rule required few incremental costs or added burdens. For example:

- Generally the proposed rule entailed few incremental costs (i.e., dollars and time) because many existing QA programs already were in compliance with most proposed requirements. For diagnostic nuclear medicine programs, the incremental costs were approximately equal to the existing QA program costs. The comparatively high incremental costs incurred by diagnostic nuclear medicine programs were thought to be principally due to the proposed requirement for written diagnostic referrals or prescriptions.

- The proposed rule was not overly burdensome as rated by participants responding to the evaluation form of proposed Section 35.35 objectives. This was generally true for all medical use groups.

However, a few participants expressed concern that the proposed regulations would adversely affect the cost of health care by requiring additional staff and tests. This small number of participants also felt that the smaller facilities would be affected more than their larger urban counterparts.

Some participants reported that they received additional benefits as a result of their participation in the pilot project. For example:

- Many existing QA programs were revised and improved.

- Physicians at several institutions became more interested in, and directly involved with, QA requirements.

- Two institutions developed new prescription and referral forms for diagnostic nuclear medicine and radiopharmaceutical therapy. They were accepted by all medical staff and were thought to result in better QA.

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1. INTRODUCTION

The Nuclear Regulatory Commission (NRC) has proposed amendments to 10 CFR Part 35 [55FR1439] that would require medical licensees using byproduct material to establish and implement a basic quality assurance program.[1] The medical use of byproduct materials includes applications in nuclear medicine and radiation therapy (e.g., teletherapy, brachytherapy). The objective of the performance-based proposed rule was to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. The amendment also modifies notification, reporting, and recordkeeping requirements related to the quality management program and misadministrations.

The NRC attempts to distinguish unavoidable risks attendant in purposefully prescribed and properly performed clinical procedures, from unacceptable risks of improper or careless use. The NRC reviewed therapy misadministrations, unusual occurrences, and diagnostic misadministrations in the therapy range over the period November 1980 through December 1990 for NRC licensees. This review found that the causes of these misadministrations or unusual occurrences could be classified into five categories: insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail, inadequate training, and lack of redundancy.

As part of its normal rulemaking procedures the NRC solicits public comment on proposed rules from the general public. In the case of 10 CFR Part 35 the NRC implemented a real-world trial of the proposed rules that provided comments directly from the regulated medical community as an additional source of information. Such an approach is not normally used by regulatory agencies, and provided a unique opportunity to obtain important first-hand information from the regulated community on how the proposed rule could be improved to accomplish their objectives.

A 60-day trial program was developed where volunteers from randomly selected institutions had opportunities to both review the details of the proposed regulations, and to implement these rules on a daily basis. The participating institutions were then asked to evaluate the proposed regulations based on their personal experiences.

Brookhaven National Laboratory was contracted to assist in the development of the pilot program. This included design and implementation of a random selection process to choose and assemble a team of potential participants, to organize several workshops at which these participants would be gathered to learn about their experiences during the 60-day trial program, to evaluate quality assurance (QA) plans, to summarize evaluations of the 60-day trial from these participating institutions, and to provide additional logistical assistance as necessary.

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[1] The final rule [Federal Register, Vol. 56, Number 143, pp. 34104-34122, July 25, 1991] uses the phrase "quality management program" instead of "basic quality assurance program," as found in the original proposed rule [55FR1439]. In addition, it is noted that proposed Section 35.35 has now become Section 35.32 in the final rule.

This report summarizes the overall pilot program, provides details of all parts of the program, and evaluates information provided by volunteers participating in the program. The interested reader is referred to appropriate appendices for details.

2. OBJECTIVES

A pilot project was initiated to develop information about the proposed rule (i.e., proposed Section 35.35) as a result of active participation by randomly selected institutions in the affected medical community. The generic objective of this project was to determine what impacts (if any) would result from the implementation of proposed quality assurance performance criteria in the medical use of by-product materials. Specifically, the project sought answers to three questions:

1. Could medical institutions develop written quality assurance programs to meet the eight performance-based objectives of proposed Section 35.35?

2. After reviewing these written programs would the NRC find that they met the proposed rule?

3. Would the NRC find these programs in compliance with the proposed rule based upon site visits and evaluations?

In addition, after the volunteers had tested the proposed rule, the NRC wanted to learn from them if they had any problems implementing the proposed rule or draft regulatory guide, and their estimates of incremental costs related to the proposed rule. The NRC also wanted to learn from these volunteers if they had any recommendations on how the rule could be revised to minimize its cost and to clarify its objectives without decreasing its effectiveness.

3. APPROACH

3.1 Overview

Answers to these questions could only be obtained from a real-world test of the proposed rule at licensee institutions. Other useful information from such a test would include to what extent do these institutions already follow QA requirements similar to proposed Section 35.35, and how well do these institutions implement these procedures in actual practice?

A pool of licensees was assembled to voluntarily participate in a program designed to address the above mentioned questions. Volunteers were chosen using proportional stratified random sampling, where strata where established to represent characteristics of the population of licensees at large (e.g., location, size, ownership, and type of medical use). In addition, volunteers were selected to proportionally represent licensees from each NRC Region and the 29 Agreement States.[2]

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[2] An Agreement State has entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by Section 274 of the Atomic Energy Act). These states issue licenses and currently regulate about 4000 institutions. There were 29 such States during the pilot program. As of April 1, 1991 there are 28 Agreement States.

Volunteers were assembled at workshops held in each of the 5 NRC Regions, where the proposed rules (i.e. proposed 10 CFR Parts 33-35) and regulatory guide were discussed. They were asked to develop written QA programs to meet proposed Section 35.35 and to forward these programs to BNL.

They then participated in a 60-day trial program during which they implemented these QA programs, keeping notes of how well each proposed Section 35.35 objective was met (including record keeping requirements, and costs associated with meeting the proposed regulations). During the 60-day trial period each written program was evaluated by staff at Brookhaven National Laboratory using a checklist developed by the NRC to determine how well the licensee met the proposed QA rule. Also during the 60-day period a team of NRC personnel made site visits to eighteen randomly selected volunteer institutions to determine how well these written plans were implemented in practice.

At the beginning of the trial each institution was sent two questionnaires to complete on an on-going basis (See Appendices G and H). One questionnaire was developed to evaluate the proposed rule, and the other to evaluate the draft regulatory guide. After the 60-day trial, participants from the volunteering institutions were then reconvened at regional workshops and asked to share their field experiences and to suggest changes to the proposed rule.

3.2 Selecting and Convening the Team of Volunteers

A selection process was required such that a pool of volunteers could be assembled whose characteristics represented the population of licensees at large. This process was intended to ensure that inferences based on the pool of volunteers could be extrapolated to the overall community of potentially affected medical licensees. Proportional stratified random sampling was used to select the desired population because estimates of some characteristic within a stratum will approximate the estimate of that characteristic in the population at-large. (See Appendix A.) In statistical parlance this means that these estimates are estimators of the same characteristic in the total (i.e., unstratified) population. (See Cochran, [1977].) The number of licensees selected from any NRC Region or Agreement State was therefore determined on the basis of the proportion of such licensees when compared to the overall number of NRC or Agreement State licensees, respectively (see Appendix B).

Strata were created in a manner which would reflect the way certain attributes of licensees might affect (or in some way relate to) the implementation of the proposed rule could impact on licensees. As a result of conversations with a consulting radiologist and with NRC and BNL personnel, these attributes were defined as medical services offered (e.g., diagnostic or therapeutic), institutional size (e.g., would the proposed rule overwhelm a small group?), location (e.g., are medical physicists available to keep a rural institution in compliance?), and ownership (e.g., would a profitmaking institution find it too costly to meet the proposed rule?).

The population of each stratum was determined by partitioning the at-large population of licensees according to several characteristics definable by available data: generic type of license (i.e., diagnostic nuclear medicine, radiopharmaceutical therapy, teletherapy, and brachytherapy), ownership (i.e., private public), size (i.e., large if > 250 beds, small if otherwise), and location

(i.e., urban if within a US Bureau of Census Standard Metropolitan Statistical Area, or rural). (See Appendix B for details.)

Based on the nationwide pool of approximately 6000 licensees and using known sampling concepts it was decided to select a pool of 72 licensees: 24 volunteers licensed by the NRC, and 48 volunteers licensed by Agreement States. (See Appendix B.) A database of NRC licensees was assembled using computer readable information provided by the NRC headquarters. This information came from the NRC's Automated Information Documentation System, which contains more than 85 different data elements describing each NRC licensee. A small subset of these data elements was extracted for each NRC licensee and entered within a new database structure using commercially available PC-based software (Q&A, by Symantec, Inc.).

Information for each data element was not always available from the NRC for each licensee. Supplementary data were obtained from other sources such as the American Hospital Association (i.e., private or public ownership, number of beds, and whether brachytherapy was practiced at the institution) [AHA, 1988]. Table B1 of Appendix B illustrates some of the information obtained from this guide. A determination was also made of whether the licensee was located in an urban or rural setting using information from the U.S. Bureau of Census [U.S. Bureau of Census, 1988] together with a standard travel atlas [Rand McNally, 1980].

Each Agreement State was asked by the NRC to provide the same information about its own licensees as was provided by the NRC itself. All but three Agreement States provided such information in the form of printed tables, and hence the Agreement State database existed as a collection of written information. As with the NRC database, supplementary information was obtained from the AHA Guide and the U.S. Bureau of Census.

The distributions of medical uses and characteristic categories of licensees in each NRC Region and Agreement State were determined using each database separately. The rationale for choosing licensee attributes and characteristic category definitions are given in Appendix B. From these distributions the number of volunteers required in each NRC Region and Agreement State was determined using the assumption of proportional representation as discussed above and in Appendices A and B. A selection protocol was established since it was found that the number of volunteers required in most regions or states was too small to accommodate the large number of combinations and permutations of possible licensee attributes. This protocol is described in Appendix C.

Each NRC or Agreement State licensee was assigned a unique serial number based on the order in which it appeared in its respective database. A volunteer was chosen using a pseudo random number generator and compared with a medical license type and characteristic category required to comply with proportional sampling techniques within an NRC Region or Agreement State (i.e., the selection protocol). If the attributes matched, the institution was selected. Otherwise, another institution was chosen using the next random number that was generated. This process was repeated until either the number of institutions with appropriate attributes, or the original list of random numbers were depleted. This process continued until all NRC Regions and Agreement State participants were selected. Details of this selection procedure are given in Appendix C. The entire process was repeated to produce an additional list of potential volunteers to be held in reserve as needed.

Each of the 72 institutions which were chosen in the first round of selections was sent a letter of introduction which described the program and invited participation in the pilot project. Also enclosed was a copy of the proposed rules and draft regulatory guide. (Letters to NRC volunteers was slightly different from those sent to Agreement State volunteers. See Appendix D for the texts of these letters.) Because of the voluntary nature of the program each institution had the opportunity of selecting the professionals (e.g., physicians, physicists, technologists, etc.) to be sent to workshops and to complete evaluation questionnaires. A call was made to ascertain whether or not the institution would participate if after a period of four weeks the responsible party at each licensee had not as yet replied. By the end of two additional weeks a total of 31 institutions had volunteered during this initial selection (14 NRC licensees, 17 from Agreement States).

This selection process was repeated a second time and an additional 25 NRC licensees were selected at random, as were 48 licensees from Agreement States. The same letter of introduction was sent to these institutions. After a month of waiting and phoning an additional 37 volunteers were added to the project (13 NRC, 24 Agreement States). Seven Agreement State volunteers were therefore still required. A third round of selections resulted in letters and phone calls to 30 institutions, from which 8 agreed to participate. This resulted in a final set of seventy-six (76) institutions which had volunteered to participate (27 NRC licensees, 49 Agreement States licensees). During the period following these selections and extending to the last post-trial workshop, 4 NRC and 8 Agreement State licensees dropped out of the program, leaving a total of 64 institutions which participated in the program. See Appendix E (Table E1) for a complete list of institutions which were asked to participate in the pilot program.

Of the 23 NRC licensees which participated in the 60-day pilot project, 19 had programs in diagnostic nuclear medicine, 17 had programs in therapeutic nuclear medicine, 11 had programs in teletherapy, and 10 had programs in brachytherapy. Of the 41 Agreement State licensees[3], there were 30 programs in diagnostic nuclear medicine, 29 programs in therapeutic nuclear medicine, 22 programs in teletherapy, and 23 programs in brachytherapy. It should be noted that many institutions had multiple byproduct material departments or programs.

3.3 Pre-trial Workshops

A series of one-day pretrial workshops were held to explain the purpose and logistics of the projects, and to review the wording and intent of proposed Section 35.35 and accompanying Draft Regulatory Guide. These workshops were held in 1990 in New York on March 29th, Chicago April 4th, Atlanta April 6th, Dallas April 18th, and San Francisco on April 20th. Fifty six institutions (and sixty attendees) were represented at these pretrial workshops.

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[3] After July 3, 1991, it was determined that two Agreement State licensees had actually dropped out of the program. This resulted from the fact that while these two institutions had given verbal assurances that they were participating in the program, at the end of the last post-trial workshop they had not submitted their written QA plans or their evaluation questionnaires, nor had they attended any workshops. There were thus 28 programs in diagnostic nuclear medicine, 27 programs in therapeutic nuclear medicine, 21 programs in teletherapy, and 22 programs in brachytherapy. Table E3 is based on attendance information prior to July 3, 1991.

The first session of each one-day workshop reviewed objectives of proposed Section 35.35, the reporting and recordkeeping requirements of proposed Sections 35.33 and 35.34, and the objectives and contents of the draft regulatory guide. It was explained how attendees would be expected to use the next 30 days preparing written QA plans for their institutions which could be based on the draft regulatory guide and which would meet (from the individual perspective of each institution) the objectives of the proposed regulations. These QA plans were then to be forwarded to BNL.

Participants had opportunities to comment on the proposed rules during the second session.[4] Some of the information they provided was used to modify both the pilot project and the proposed rules. One important suggestion which was immediately adopted concerned excluding ^{131}I-hippuran from considerations pertaining to the use of NaI in diagnostic nuclear medicine. This suggestion was made because of hippuran's short biological half life ($T_{1/2}B$ = 25 minutes) and different chemical form when compared to NaI. [ICRP53, 1988] Another important area concerned requirements for written diagnostic referrals in diagnostic nuclear medicine, which in practice are often communicated via telephone.

During the pre-trial workshop it was explained that each written QA plan would be reviewed by personnel at the NRC and BNL to determine whether or not objectives of the proposed QA rule were met. Moreover, it was explained that eighteen (18) volunteering institutions would be randomly selected for site visits during the 60-day trial by a team of NRC personnel. If such a licensee was in an Agreement State then state personnel would be invited to participate in the site visit. It was explained that the purpose of these visits was to evaluate whether the program practiced during the 60-day trial agreed with the written plan and met the proposed objectives.

3.4 Sixty-day Trial Period

Implementation of the 60-day trial began mid-May 1990, during which time each institution's written QA plan was reviewed by BNL personnel. At the beginning of the trial 18 participating licensees were randomly selected for site visits. The selection process was the same as that discussed previously.

All QA plans were evaluated using a standardized checklist. This evaluation was meant as only a first attempt in determining compliance with the proposed regulations. No attempt was made to clarify questionable statements in the programs that were submitted for review. A total of 65 written QA programs were received and evaluated. Completed evaluations were returned to their authors during the post-trial workshop, where participants had opportunities to review and discuss results with NRC or BNL staff. Completed checklists from the 18 licensees selected for site visits were independently analyzed and compared by NRC and BNL staff to assure uniformity in evaluating written QA programs.

It was found that most written QA programs lacked redundant patient identification and independent audit procedures. Medical use QA programs that require prescriptions (i.e.,

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[4] Transcripts were prepared of each workshop and are publicly available at the NRC Public Document Room, 2120 L Street NW (lower level), Washington. D.C. For detailed comments see these transcripts.

therapeutic nuclear medicine, teletherapy, and brachytherapy) often did not provide sufficient information to assure that the contents of the prescriptions met the proposed regulations. Also, changes in the prescriptions were typically not documented in the written QA programs submitted for evaluation.

The 18 licensees selected for site visits (11 NRC, 7 Agreement State) included 15 diagnostic nuclear medicine programs, 12 therapeutic radiopharmaceutical programs, 8 teletherapy programs, and 5 brachytherapy programs. The site visit team found that the number of facilities which met objectives during the site evaluations was far greater than the number of facilities which met the objectives of the proposed rule during evaluations of their written programs. Generally, almost all institutional QA programs almost completely met the objectives in actual practice.

At the beginning of the 60-day trial period each participating institution was sent two evaluation forms: one for the proposed rule, the other for the draft regulatory guide (see Appendices G and H). These forms were completed by volunteers and forwarded to BNL at the end of the trial for compilation and evaluation. One important finding was that generally the proposed rule would not be costly to implement. For most institutions the proposed rule entailed few incremental costs (i.e., dollars and time) because existing QA programs already complied with most proposed requirements. For some institutions, however, particularly those practicing diagnostic nuclear medicine, incremental costs would be high primarily because of the proposed requirement for written prescriptions or diagnostic referrals. (See Figure F.1) Another important finding was that the proposed rule was not overly burdensome. This was generally true for all medical use groups.

3.5 Post-Trial Workshops

Five 2-day workshops were held during the Fall of 1990 in Philadelphia on 8/16-17, in Chicago on 8/23-24, in Atlanta on 9/6-7, in Dallas on 9/13-14, and in Rockville, MD, on 10/25-26 (the latter was held to accommodate various participants who could not attend any of the previous workshops). Participants from 53 institutions were in attendance.

Most available time at these 2-day meetings was devoted to the participants themselves, when they had opportunities to relate to NRC staff their experiences during the 60-day trial period, as well as inform staff as to potential difficulties with meeting any of the eight objectives in proposed Section 35.35 or any new record keeping requirements. In addition to their anecdotal comments, participants were asked to complete two questionnaire-style evaluation forms, one for the proposed regulations and the other for the Draft Regulatory Guide.

These workshops were held: (1) to learn about the experiences of volunteer's as they implemented their written QA programs, (2) to discuss problems they encountered, and (3) to allow volunteers to make recommendations on how to revise the proposed rules and draft regulatory guide. It is important to note that unlike the pre-trial workshops where most comments were made by NRC staff, almost every presentation at post-trial workshops was made by individuals from participating volunteer institutions. The evaluation of written institutional QA plans were returned to volunteers for their review. Private discussions of these evaluations were held between volunteers and NRC and BNL staff . Some important comments included (for details see Appendix F):

- A participant indicated that medication errors for non-radioactive drugs (4 per 1000 orders) was much greater than the rate for radioactive drugs and he was therefore unsure of the need for this rule. The participate requested that the word "require" be changed to "encourage," and indicated that most misadministrations in nuclear medicine could be prevented by requiring that nuclear medicine technologists be licensed.

- Several participants had difficulty with the phrase "high confidence that errors in medical use will be prevented" because errors would always be made and quantification of these errors was difficult. Suggested changes included, "detect errors to prevent misadministrations", "high confidence that clinically significant errors will be detected and minimized" and "high confidence that errors in medical use will be ALARA."

- It was suggested that NRC make word usage in the proposed rules compatible with QA programs of other relevant professional organizations.

- According to participants, proposed objective (a)(2) should be modified to assure clarity. For example, "Ensure, prior ... made for (a) radiopharmaceutical therapy procedures, (b) brachytherapy procedures, (c) teletherapy procedures and (d) diagnostic radiopharmaceutical procedures involving more than 30 μCi of ^{125}I or ^{131}I."

- Several participants requested that ^{131}I-hippuran be exempted from this Section because of its short biological half life ($T_{1/2}B$ = 25 minutes) and different chemical form when compared to NaI.

- The definition of prescription required modification, particularly with procedures where prescriptions were often not written prior to medical use. In brachytherapy medical use often began at the time of application and when many physicians often do not yet know all their targets and desired doses. Oftentimes a written prescription was completed only after the procedure was completed. In such cases it was suggested that the written prescription be allowed to be completed within 2-3 hours or within a certain percentage of the total treatment time after the start of the procedure.

- It was mentioned that diagnostic procedures often involved oral referrals in lieu of written referrals. It was mentioned that outpatient written referrals were problematic because they could not always be dated and signed before administration. It was mentioned that verbal orders were sometimes approved by the authorized user. Other facilities entered the verbal referral information in a telephone log book at the referring and receiving ends.

- Participants suggested that the use of computer terminals and fax machines also be allowed. This was particularly important considering the large amount of oral referrals currently allowed in some institutions. It was mentioned that in the proposed rules the definition of referral requests a written document, but referrals made on a computer would be typed and not written. Also, there was a question concerning the signature of the user for electronic referrals (authentication). If necessary, clarification of the instructions could be requested from the approved user before administration.

- The definition of "unintended deviations" required clarification. For example, were after-the-fact changes which are often necessary as a result of unanticipated conditions

considered unintended deviations? The procedures necessary to document that unintended deviations were identified and corrected were questioned. Did "deviation" refer specifically to dose deviation? Delivered doses in teletherapy can routinely vary from prescribed doses by as much as 10%. It was suggested that these should not be considered deviations.

- It was suggested that the term "treatment plan" be defined because practicing clinicians often think of it differently than a "prescription." According to some participants, this definition should state, in broad terms, the objectives of the authorized user including the approximate dose, palliative or curative nature of the treatment, etc. For brachytherapy and teletherapy procedures, changes in the treatment plan often occurred during the course of therapy.

  Participants indicated that a detailed treatment plan could not be written before administration and requested that the term "prescription" be replaced with the term "pre-plan." For clarification it was suggested that the phrase "treatment planning" be replaced with "medical use." Other suggestions included using the following terms: "dose treatment plan" and "dose calculations and delivery."

- Many participants suggested that "licensee management" not evaluate audits because they were often perceived to lack such expertise. It was suggested that the audit function would be better suited by the Radiation Safety Committee, Radiology Department Committee, Department Chairperson, QA Committee, etc. A suggestion was made that such evaluations be made "by individuals whose qualifications are determined by management."

4. RESULTS

Overall, 64[5] institutions participated in all aspects of the project (23 NRC licensees, 41 Agreement States licensees). There were 91 individuals who provided information by attending one or more workshops and/or who submitted signed evaluation forms. Seven (7) of these were physicians, 41 physicists (including 13 PhDs), and 43 certified technologists. There were also 11 radiation safety officers among these individuals.

The pilot project specifically sought answers to three important questions (see Section 2). It was found that (1) licensees could develop acceptable QA programs under a performance-based approach, (2) most licensee programs did meet most of the proposed Section 35.35 objectives, and (3) most written QA plans would require consultations with NRC or Agreement State personnel before they would fully meet all objectives of proposed Section 35.35. However, site visits by NRC staff found that most institutional QA programs would almost completely meet the objectives in actual practices.

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[5] See footnote 3 above.

There were many instances in which the information obtained could only have resulted from a pilot program. Detailed suggestions can be found in publicly available workshop transcripts. (See footnote 4.) Some more important findings include:

- Concern was expressed on the ability of small institutions to conduct an audit using personnel "who are not involved" in the activity being audited.

- Redundant patient identification procedures were lacking in most written (and as practiced) QA programs, particularly for outpatients. It was mentioned that this proposed objective did not specify redundancy.

- It was suggested by participants with teletherapy programs that depth-dose calculations be verified by the measurement of the ^{60}Co output. However, if the intent of Draft Regulatory Guide Section 5.10 was to check the accuracy of the treatment planning program, then much more detailed information would be necessary. It was suggested that this Section be dropped unless more specific details could be developed.

- It was mentioned that diagnostic procedures often involved oral directives in lieu of written referrals. It was also mentioned that outpatient written referrals were problematic because they could not always be dated and signed before administration. It was mentioned that verbal orders were sometimes approved by the authorized user. Other facilities entered the verbal referral information in a telephone log book at the referring and receiving ends.

- Guidelines to ensure that instructions were understood could probably be better met by requirements for personnel training and licensing.

- The terms prescriptions, referrals, requisitions, written orders, or chart orders or notes were often used interchangeably. It was suggested that these should be better defined.

- It was recommended that less stringent error reporting limits be allowed for certain types of measurements such as calibrations and calculations of daily therapy dose fractions. Participants expressed difficulty with the 2 rem organ and 0.5 rem whole body notification limits.

  They offered several alternatives: (1) replace "2 rem organ dose/0.5 rem WB" with "producing an organ dose or whole body dose twice that which would have been administered had no misadministration occurred..." (2) delete the 3rd criterion completely (3) one participant thought that a 5x error reporting requirement would be satisfactory if the dose was clinically significant. (4) several participants thought that the term organ dose could be eliminated if the 5x requirement was lowered to 3x dosage error. (5) another participant thought that the organ dose should be retained especially in the case where the wrong radiopharmaceutical was administered.

- It was suggested that some QA-related requirements be placed on manufacturers of computer software used in teletherapy and brachytherapy.

Many participants found the proposed QA rule required few incremental costs or added burdens. For example:

- Generally the proposed rule entailed few incremental costs (i.e., dollars and time) because many existing QA programs already were in compliance with most proposed requirements. For diagnostic nuclear medicine programs, the incremental costs were approximately equal to the existing QA program costs. The comparatively high incremental costs incurred by diagnostic nuclear medicine programs were thought to be principally due to the proposed requirement for written diagnostic referrals or prescriptions.

- The proposed rule was not overly burdensome as rated by participants responding to the evaluation form of proposed Section 35.35 objectives. This was generally true for all medical use groups.

However, few participants expressed concern that the proposed regulations would adversely affect the cost of health care by requiring additional staff and tests. This small number of participants also felt that the smaller facilities would be affected more than their larger urban counterparts.

Some participants reported that they received additional benefits as a result of their participation in the pilot project. For example:

- Many existing QA programs were revised and improved.

- Physicians at several institutions became more interested in, and directly involved with, QA requirements.

- Two institutions developed new prescription and referral forms for diagnostic nuclear medicine and radiopharmaceutical therapy. They were accepted by all medical staff and were thought to result in better QA.

5. REFERENCES

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APPENDIX A

STATISTICS OF PROPORTIONAL STRATIFIED RANDOM SAMPLING

Nationally there are about 2000 NRC licensees and about 4000 Agreement State licensees. Based on the total population size of about 6000 and using published tables described in 10CFR32.110, NRC decided to seek 72 volunteers to participate in the pilot project. Because of administrative considerations it was desired to preserve the same ratio of agreement state and non-agreement state (i.e., NRC) licensees in the study as was found nationally, which resulted in a selection of 24 NRC licensees and 48 licensees from Agreement States. Seventy two (72) NRC licensees were initially selected by simple random sampling. Institutions with appropriate attributes were selected based on proportional random sampling from the population of both NRC and Agreement State licensees.

Licensees potentially affected by proposed Section 35.35 represent a heterogeneous population. They each offer several different kinds of byproduct material medical services, and possess attributes which relate physically to the licensee itself. For example, some licensees are private medical practices while others are institutions. They differ in size and location. These characteristics relate to how the proposed rules may affect the administration of byproduct material as already discussed above in Section 4 and in Appendix C below.

To better understand how the proposed rules may affect licensees it was useful to divide the overall population into subpopulations each of which was homogeneous in some respects. Random selections would then be made in each stratum. In the present example stratification would generally produce lower uncertainties when the population was composed of institutions with widely different attributes which can be easily characterized (e.g., medical groups 1 or 2; or the number of beds for institutions).

Assume y is the variable that is being measured. The overall population of N units is divided into subpopulations N_1, N_2, . .., N_M (i.e., $N = N_1 + N_2 + ... + N_M$). There are a total of n units sampled, with n_1 units sampled from N_1, n_2 from N_2, and so on (i.e., $n = n_1 + n_2 + ... + n_M$). Then let $\underline{y}_i$ be the sample mean of the i-th stratum, $\underline{y}_{stratum}$ be the mean of the sampled stratified population n, $\underline{Y}_i$ the true mean of N_i, and $\underline{Y}$ be the true mean of the entire population N. (See Cochran, 1977.) Then define $\underline{y}_{stratum}$ as:

$$\underline{y}_{stratum} = \frac{\sum_{i=1}^{M} N_i \underline{y}_i}{N} \qquad (1)$$

The estimate $\underline{y}_{stratum}$ would generally not be the same as the sample mean $\underline{y}$, defined as:

$$\underline{y} = \frac{\sum_{i=1}^{M} n_i \underline{y}_i}{n} \tag{2}$$

However, $\underline{y}$ does equal $\underline{y}_{stratum}$ when, for every stratum,

$$\frac{n_i}{n} = \frac{N_i}{N} \tag{3}$$

This type of stratification is called proportional. The procedure is called stratified proportional random sampling if sampling is done randomly from each of the i strata. Of great importance is the theorem which states that if in every stratum the sample estimate $\underline{y}_i$ is unbiased, then $\underline{y}_{stratum}$ is an unbiased estimate of the population mean $\underline{Y}$. In this procedure there are several other important theorems and corollaries which define sample estimates, their variances and confidence limits. Moreover, if these variances and confidence limits are known, optimal values for n_i can be obtained (these values are not always the sample sizes estimated using proportional sampling).

For the pilot program it is important to note that no *a priori* quantitative metric (i.e., measuring scale) existed to measure potential impacts of proposed Section 35.35. Nevertheless, it was decided to use stratified proportional random sampling to select potential volunteers based on a number of factors, including (1) the attributes of the medical community using byproduct materials, (2) the known benefits to be gained by stratified sampling, and (3) a knowledge that proportional allocation does not result in very large increases in variance over optimal stratification.

This project used such a strategy to meet two goals. The first was to relatively preserve among the group of selected licensees the distributions of medical services and characteristic categories found within the larger population. The second was to obtain information on how licensees with different attributes may or may not be negatively affected by various aspects of the new proposed regulations.

APPENDIX B

DISTRIBUTION OF LICENSEES IN NRC REGIONS AND AGREEMENT STATES

B.1 Distribution of Licensees in NRC Regions and Agreement States

Information contained in the NRC database that was used in selecting potential volunteers included the name and address of the licensee (or institution), the NRC Region, licensed radionuclides and associated quantities, and the responsible individual.

Information that was not readily available from the NRC database was obtained from the AHA Guide [AHA, 1988]. This information was particularly useful for Agreement State licensees and included medical use categories and public or private classifications. See Table B1 below.

Table B1 Supplementary Information from AHA Guide

AHA Facility Code	Medical Use Categories Description
7	X-ray radiation therapy
8	Megavoltage radiation therapy (i.e., teletherapy)
9	Radioactive implants (i.e., brachytherapy)
10	Diagnostic radioisotope facility
11	Therapeutic radioisotope facility

AHA Classification Code	Ownership Public or Private	Description
Government, nonfederal		
12	Public	State
13	Public	County
14	Public	City
15	Public	City-county
16	Public	Hospital district or authority
Nongovernment, not-for-profit		
21	Public	Church operated
23	Public	Other
Investor-owned (for profit)		
31	Private	Individual
32	Private	Partnership
33	Private	Corporation
Government, federal		
41	Public	Air Force
42	Public	Army
43	Public	Navy
44	Public	Public Health Service (other than 47)
45	Public	Veterans Administration
46	Public	Federal (other than 41-45, 47-48)
47	Public	Public Health Service Indian Service
48	Public	Department of Justice
Osteopathic		
61	Public	Church operated
63	Public	Other not-for-profit
71	Private	Individual for-profit
72	Private	Partnership for-profit
73	Private	Corporation for-profit

Each licensee was categorized as belonging to one of two medical groups, using codes defined as follows (see Section B.2 below):

Table B2 Categories of Medical Use Groups for Selection Protocol

BNL Group	NRC Program Codes	Title
1	02110	Medical Institution Board
	02120	Medical Institution Other - Group
	02121	Medical Institution Other - Nongroup
2	02200	Medical Private Practice - Group
	02201	Medical Private Practice - Nongroup
	02220	Mobile Nuclear Medicine Service

There were no *a priori* reasons for assuming that national or regional distributions of medical uses or characteristic categories of NRC licensees would differ from those of Agreement States. It was therefore reasonable to investigate such distributions using the more easily manipulated computer-readable NRC data. Tables B3 and B4 illustrate how medical groups 1 and 2 and characteristic categories were distributed nationally and regionally. It is seen that these distributions are comparable across regions.

Table B3 Number of Active NRC Licensees

BNL Group	Total in Group	Region 1	Region 2	Region 3	Region 4	Region 5
1	1541	525	177	646	150	43
2	488	198	59	206	20	5
Total	2029	723	236	852	170	48

Table B4 Number of Active Licensees in Agreement States

BNL Group	Total in Group	Region 1	Region 2	Region 3	Region 4	Region 5
1	3421	362	966	307	833	953
2	1013	264	343	64	257	85
Total	4434	626	1309	371	1090	1038

[Note to Table B4: Numbers may be inaccurate because: (1) data supplied to BNL by Agreement States were predominantly hard copy, thus making data interpretation difficult in some cases, and (2) medical use classification systems of many Agreement States were different from those used by NRC (this was especially true for teletherapy and brachytherapy).]

B.2 Rationale for Choice of Licensee Attributes

Of specific interest to NRC were potentially large impacts to specific sectors of the regulated community. These sectors could be defined in terms of specific attributes which were determined in consultation with a consulting physician and health physicists from BNL and NRC personnel involved in site inspections. The final set of attributes included: kinds of services offered (hereafter called medical services or departments), whether licensees were located in agreement or non-agreement states, whether they were located in urban or rural regions, the size of the institution, and whether it was in the public (i.e., not-for-profit) or private (i.e. profitmaking) sectors.

Another concern was whether proposed Section 35.35 would affect private practices more than they would broad scope licensees. Consequently each licensee was categorized as belonging to one of two medical groups as shown in Table B2 above.

It was also recognized that some institutions practicing only teletherapy (NRC code 02300) would be missed during the selection process unless they too were classified as belonging to either Group 1 or 2. Hence each institution with only a teletherapy license was grouped accordingly, using other available information to help in classifying to which medical group the institution belonged (e.g. AHA Guide, codes used by Agreement States, or NRC data indicating the use of Co-60).

It was more difficult classifying an institution as performing brachytherapy. The NRC had no program codes in its database for this medical use. For NRC licensees it was necessary to use a supplementary database which used nomenclature related to brachytherapy use (i.e., Group 6 licensees). For other institutions (i.e., those in Agreement States) it was necessary to use AHA codes, or information provided by individual states themselves.

Proposed Section 35.35 may be affected by the size and location of the institutions/licensees. For example, a larger institution may have existing staff capable of fulfilling recordkeeping requirements, whereas smaller institutions would be forced to hire additional staff (at the expense of other needed professionals). An urban institution would likely find it easier to locate (and pay for) physicists than would a rural institution where physicists may be available only as visiting consultants. A for-profit hospital or private practice might find potential additional costs more onerous than would licensees in the public sector.

The concept of standard metropolitan statistical areas (SMSAs)[6] was used to classify a licensee as urban or rural. [U.S. Department of Census] Based on information provided to BNL by a physician consultant it was decided that an institution would be classified as large if it had more than 250 beds. Licensees owned by governments or religious groups were classified as "public" (i.e., non-profit or not-for-profit).

[6] An SMSA is defined by the US Office of Management and Budget as an area that has a central city of at least 50,000 individuals or an urbanized area (comprising one or more towns) with a population of at least 50,000 located in a county (or counties) with a total population of at least 100,000. An SMSAs borders coincide with the boundaries of the surrounding county (or counties). Some SMSA's cross state boundaries.

APPENDIX C

SELECTION PROTOCOL

C.1 Overview

NRC Licensees

Table B3 described previously formed the basis of first level selections. For example, 35% of licensees are in Region 1, 12% in Region 2, and so on. Hence 8 (or 33%) of the required 24 NRC volunteers would be located in Region 1, 3 (12%) in Region 2, etc. Table C1 illustrates the distribution of medical groups among the 24 NRC volunteers.

Table C1 Number of Selected NRC Licensees Grouped by NRC Region

BNL Group	Total in Group	Region 1	Region 2	Region 3	Region 4	Region 5
1	19	6	2	8	2	1
2	5	2	1	2	0	0
Total	24	8	3	10	2	1

Agreement State Licensees

The selection process was identical for Agreement State licensees as it was for NRC licensees. Results are shown below:

Table C2 Number of Selected Agreement State Licensees Grouped by NRC Region

BNL Group	Total in Group	Region 1	Region 2	Region 3	Region 4	Region 5
1	39	4	11	4	9	11
2	9	3	2	1	2	1
Total	48	7	13	5	11	12

Table C3 Number of Agreement States Volunteers and Licensees Grouped by State

Agreement State	Group 1		Group 2	
	Volunteers	Licensees	Volunteers	Licensees
AL	1	97	0	25
AR	1	60	0	9
AZ	1	82	1	43
CA	8	729	0	7
CO	1	62	0	3
FL	2	228	2	207
GA	2	152	0	8
IA	1	45	0	10
ID	0	16	0	5
IL	3	262	1	54
KS	1	86	0	20
KY	1	89	0	14
LA	1	99	0	2
MD	1	65	1	63
MS	1	67	0	17
NC	1	130	0	37
ND	0	31	0	3
NE	0	37	0	4
NH	0	23	0	0
NM	0	26	0	21
NV	0	15	0	10
NYC	1	93	1	90
NYS	2	190	1	105
OR	1	69	0	8
RI	0	14	0	6
SC	1	55	0	6
TN	2	140	0	29
TX	5	454	2	165
UT	0	22	0	12
WA	1	58	0	17

BNL evaluated the distribution of Agreement State licensees across BNL groups. The process of selecting 48 potential participating institutions from the total pool of licensees ensured that at least 6 were either small or large, at least six were either public or private, and at least 6 were either urban or rural. An attempt was made to select licensees with attributes such that at least one selected licensee was small or large, at least one was public or private, and at least one was rural or urban.

A stratified-random sampling strategy was then devised which produced a subset of volunteers having regional distributions matched as closely as possible to the population at large. This strategy was based on proportional random sampling.

The next hierarchy in the selection process was based on characteristic categories. It was recognized that within any NRC Region or Agreement State there were eight possible combinations in the selection process. Unfortunately there were too few selections to adequately account for these requirements. Based on Tables C1 and C3 it is seen that only in Regions 1 and 3 (for NRC licensees) and the States of California and Texas (for Agreement States) would selections on the basis of statistical distribution of characteristic categories be possible. As a rule-of-thumb, proportional random sampling was used to the extent possible.

C.2 Procedure Used to Select Individual Volunteers

Volunteers were selected using the following procedure:

1. Choose an NRC region or Agreement State;

2. Use the established selection procedures to determine the attributes of medical license types and characteristic categories required for the volunteers in the specific region or state.

3. Determine the number of volunteers required (n), and the highest numerical value assigned to any institution in that region or state (m);

4. Use a pseudo-random number generator[7] to produce n random numbers uniformly distributed between 1 and m;

5. Starting with the first random number, compare the attributes of the associated institution with those required by the established selection procedure. If the attributes match then select the institution, otherwise go to the next random number;

6. Repeat this process until either the number of institutions with appropriate characteristics was reached, or the original list of n random numbers was depleted;

7. If the required number of institutions was found then go to step 1. and repeat the process until all regions and states are processed; or

---

[7]A pseudo-random number generator is a numerical algorithm written such that various properties of number theory and computer hardware are combined to produce a sequence of numbers which are essentially random, based on a number of statistical tests.

8. If the first set of n random numbers was depleted, then go to step 4 and repeat the process until all regions and states are processed.

9. Repeat the entire process to produce an additional list of potential volunteers to be held in reserve as needed.

C.3 Selection Procedure for NRC Licensees

Twenty four (24) volunteers were randomly selection based on information provided in Table C1. On the advice of the NRC, BNL first randomly selected one volunteer from the group of VA hospitals, and one volunteer from the group of Navy and Air Force hospitals. Of this group of potential volunteers (i.e., VA, Navy, and Air Force) it was predetermined to first randomly select a hospital that had both teletherapy and brachytherapy uses. If such a hospital was non-existent, a hospital that had only teletherapy was to be randomly selected. The selected VA and Navy or Air Force hospitals were allowed to be in any Region, as long as they were not in the same Region. Inclusion of a VA and a Navy or Air Force hospital was necessary to assess potential medical use QA differences in government-run hospitals. Navy and Air Force hospitals were grouped together because they are all under the same NRC license governing all activities, including medical use.

The remaining 22 volunteers were selected after the above-mentioned hospitals were chosen. All volunteers were allocated to BNL medical groups and to NRC Regions in proportion to the total number of NRC licensees within any BNL medical group or NRC Region, respectively.

The NRC required that at least one volunteer from each NRC Region be selected. In the case of Region 5 this volunteer was to be randomly selected from the only non-agreement states in the region (i.e., Hawaii and Alaska), unless one of the two volunteers from the VA and Navy or Air Force was from Region 5.

The NRC decided that a minimum number of teletherapy and brachytherapy licensees should be selected from the 19 remaining Group 1, NRC regional participating licensees. The rationale for this decision was based on potentially large doses and radiological impacts involved with teletherapy or brachytherapy misadministrations. The number of Group 1 teletherapy and brachytherapy volunteers for each NRC Region is given in Table C4. No distinction on the specific medical use program was required for the remaining volunteers in each Region.

Table C4 Number of Teletherapy and Brachytherapy Volunteers for the NRC Group 1 Licensees

	Region 1	Region 2	Region 3	Region 4	Region 5
Teletherapy and Brachytherapy	2	1	3	1	1
Any medical use	4	1	5	1	0

NRC decided that a minimum number of brachytherapy and teletherapy licensees should be selected from the five remaining Group 2 NRC Regional participating licensees, because Group 2 licensees were composed of private practice licensees, many of whom performed only teletherapy procedures without brachytherapy or nuclear medicine. It was decided to group teletherapy licensees with teletherapy facilities that also conducted nuclear medicine procedures. Of the 5 Group 2 NRC licensees to be selected, two were from the teletherapy or teletherapy/nuclear medicine use groups, representing Regions with the largest number of Group 2 NRC licensees. The remaining selections were allowed to represent any medical use but again represented Regions with the largest number of Group 2 licensees. Results are shown in Table C5.

Table C5 Number of Volunteers for NRC Group 2 Licensees

	Region 1	Region 2	Region 3	Region 4	Region 5
Teletherapy or Teletherapy/ Nuclear Medicine	1	0	1	0	0
Any medical use	1	1	1	0	0

Where possible, representation was sought of each of the eight characteristic categories (i.e., combinations of large vs. small, public vs. private, and urban vs. rural). Ideally this would require at least one volunteer for each of the eight characteristic categories within an NRC Region or Medical Use Groups. However, as can be seen in Table C1, this was only possible for Group 1 licensees in Region 3. In this case it was decided that if the number of volunteers was greater than the number of characteristic categories (i.e., because some categories did not exist), then some categories would have up to two volunteers. If the number of volunteers was smaller than the number of characteristic categories, each category would have up to one volunteer. If the number of selections needed for any Medical Use Group or NRC Region was less than eight, volunteers were selected without regard to characteristic categories.

Before the selection process began it was determined that no more than one mobile nuclear medicine volunteer would be sought.

C.4 Selection Procedure for Agreement State Licensees

Additional volunteers from each Region and Group were randomly selected and held in reserve in the event an original selectee did not agree to participate in the pilot program. The reserve volunteer was selected following the same selection rules as the original volunteer.

Agreement State volunteers were randomly selected in proportion to the number of Group 1 or 2 licensees within the 29 Agreement States. Tables C2 and C3 list the number of Agreement State licensees selected, grouped by NRC Region and Agreement State, respectively.

The NRC decided that a minimum number of volunteers conducting teletherapy, brachytherapy, and therapeutic nuclear medicine, should be chosen because of (a) health risk implications of a misadministration for this medical use, and (b) the number of misadministrations reported to NRC for these medical use categories.

For Group 1 licensees in Agreement States the number of volunteers selected that performed either teletherapy, brachytherapy, or therapeutic nuclear medicine procedures was based on the number of Group 1 volunteers listed in Table C3. Table C6 lists the allocation of Group 1 volunteers.

Table C6 Allocation of Agreement State Licensees by Medical Use Category

If the Number of Volunteers in any Agreement State is (from Table C3)	Then Allocate Volunteers as Follows	
	Teletherapy, Brachytherapy, or Therapeutic Nuclear Medicine	Any Medical Use
1	1	---
2	1	1
3	2	1
5	3	2
8	4	4

APPENDIX D - LETTERS OF INVITATION SENT TO SELECTED LICENSEES

(A) LETTER OF INVITATION SENT TO NRC LICENSEES

Radiological Sciences Division
FAX (516) 282-5810

January 3, 1990

Dear :

I am writing this letter to you on behalf of the Nuclear Regulatory Commission (NRC). The NRC will soon publish a proposed rule for public comment that would amend 10 CFR Part 35 and significantly change the regulatory approach to quality assurance for medical use licensees. Under current regulations, a licensee is required to report certain misadministrations to the NRC, but is not specifically required to have a quality assurance program to prevent errors in medical use. The proposed rule would require that each medical use licensee establish a quality assurance program. Each licensee would be allowed to develop a quality assurance program tailored to its institution because the proposed rule is performance-based, rather than prescriptive. A draft regulatory guide will be available for licensees who desire specific guidance.

NRC plans to conduct a pilot program in parallel with the public comment period on the proposed rule. The purpose of the pilot program is to obtain information on the actual experience of licensees using a quality assurance program based on the proposed rule. The NRC will incorporate this information in formulating the final rule. The Brookhaven National Laboratory is under contract to NRC to assist in conducting the pilot program.

Your institution has been chosen as a possible participant by a random selection process designed to ensure that each NRC region or Agreement State, class of licensee, and type of institution is proportionally represented. NRC plans to have a total of 72 participants (24 NRC and 48 Agreement State licensees) in this pilot program. Although your participation is entirely voluntary, we believe that your involvement is vitally important and would make a significant contribution in the formulation of the final rule.

As a participant in the pilot program, your institution would be asked to (a) develop a new (or modify an existing) quality assurance program based on the proposed rule and provide a copy to the NRC, (b) use the quality assurance program for a 60-day test period, (c) maintain certain records, (d) attend two regional workshops, and (e) provide your written evaluation and suggestions to NRC after the test period.

Two sets of regional workshops will be held. A pre-test workshop will be conducted to discuss the pilot program's protocol, and a post-test workshop will be conducted to discuss results from the 60-day test period. One representative from each institution participating in the program will be requested to attend these workshops. For this effort, you will be reimbursed to

the extent of travel expenses (transportation and government per diem rate) if other sources of funding are unavailable.

As part of the post-test evaluation, participants will be asked to rate each part of proposed 10 CFR 35.35(a), including the specific objectives, with respect to effectiveness and cost. Evaluation forms will be provided.

As a participant, your institution may be selected as one of the sites for a 1-day visit by an NRC quality assurance team during the 60-day test period. However, the NRC will not be able to visit all participants. The purpose of the site visit will be to determine how well the quality assurance program is being implemented.

Enclosed for your information are: (a) the purpose and specific objectives of the quality assurance program from proposed 10 CFR 35.35(a), (b) the relevant definitions from proposed 10 CFR 35.2; (c) Draft Regulatory Guide DG-8001, "Basic Quality Assurance Program for Medical Use"; and (d) a tentative schedule for the pilot program. If you have any questions concerning the enclosed package or the pilot program, please call me or Dr. Edward Kaplan at (516) 282-4209, or Mr. John Telford, NRC, at (301) 492-3796.

I plan to contact you in about a week to answer any questions you may have and to find out if you would agree to participate in the pilot program. We do look forward to your participation.

Sincerely,

Charles B. Meinhold, Head
Radiological Sciences Division

CBM/ek
Enclosures:

1. Purpose and specific objectives of the quality assurance program
2. Relevant definitions
3. Draft Regulatory Guide DG-8001
4. Tentative Schedule for Pilot Program

(B) LETTER OF INVITATION SENT TO AGREEMENT STATE LICENSEES

Radiological Sciences Division
FAX (516) 282-5810

January 3, 1990

Dear :

I am writing this letter to you on behalf of the Nuclear Regulatory Commission (NRC). The NRC will soon publish a proposed rule for public comment that would amend 10 CFR Part 35 and significantly change the regulatory approach to quality assurance for medical use licensees. Under current regulations, a licensee is required to report certain misadministrations to the NRC, but is not specifically required to have a quality assurance program to prevent errors in medical use. The proposed rule would require that each medical use licensee establish a quality assurance program. Each licensee would be allowed to develop a quality assurance program tailored to its institution because the proposed rule is performance-based, rather than prescriptive. A draft regulatory guide will be available for licensees who desire specific guidance. Because the proposed amendment has safety significance for Agreement State licensees as well as the NRC licensees, it will be a matter of compatibility for the Agreement States.

NRC plans to conduct a pilot program in parallel with the public comment period on the proposed rule. The purpose of the pilot program is to obtain information on the actual experience of licensees using a quality assurance program based on the proposed rule. The NRC will incorporate this information in formulating the final rule. The Brookhaven National Laboratory is under contract to NRC to assist in conducting the pilot program.

Your institution has been chosen as a possible participant by a random selection process designed to ensure that each NRC region or Agreement State, class of licensee, and type of institution is proportionally represented. NRC plans to have a total of 72 participants (24 NRC and 48 Agreement State licensees) in this pilot program. Although your participation is entirely voluntary, we believe that your involvement is vitally important and would make a significant contribution in the formulation of the final rule.

As a participant in the pilot program, your institution would be asked to (a) develop a new (or modify an existing) quality assurance program based on the proposed rule and provide a copy to the NRC, (b) use the quality assurance program for a 60-day test period, (c) maintain certain records, (d) attend two regional workshops, and (e) provide your written evaluation and suggestions to NRC after the test period.

Two sets of regional workshops will be held. A pre-test workshop will be conducted to discuss the pilot program's protocol, and a post-test workshop will be conducted to discuss results from the 60-day test period. One representative from each institution participating in the program will be requested to attend these workshops. For this effort, you will be reimbursed to

the extent of travel expenses (transportation and government per diem rate) if other sources of funding are unavailable.

As part of the post-test evaluation, participants will be asked to rate each part of proposed 10 CFR 35.35(a), including the specific objectives, with respect to effectiveness and cost. Evaluation forms will be provided.

As a participant, your institution may be selected as one of the sites for a 1-day visit by an NRC quality assurance team during the 60-day test period. The team will consist of a staff member of a regulatory agency from your Agreement State and an NRC quality assurance team. However, not all participants will be visited. The purpose of the site visit will be to determine how well the quality assurance program is being implemented.

Enclosed for your information are: (a) the purpose and specific objectives of the quality assurance program from proposed 10 CFR 35.35(a), (b) the relevant definitions from proposed 10 CFR 35.2; (c) Draft Regulatory Guide DG-8001, "Basic Quality Assurance Program for Medical Use"; and (d) a tentative schedule for the pilot program. If you have any questions concerning the enclosed package or the pilot program, please call me or Dr. Edward Kaplan at (516) 282-4209, or Mr. John Telford, NRC, at (301) 492-3796.

I plan to contact you in about a week to answer any questions you may have and to find out if you would agree to participate in the pilot program. We do look forward to your participation.

Sincerely,

Charles Meinhold, Head
Radiological Sciences Division

CM/ek
Enclosures:

1. Purpose and specific objectives of the quality assurance program
2. Relevant definitions
3. Draft Regulatory Guide DG-8001
4. Tentative Schedule for Pilot Program

cc: Agreement State Administrator

APPENDIX E

DESCRIPTION OF INSTITUTIONS PARTICIPATING IN PILOT PROGRAM

E.1 List of Institutions Agreeing to Participate

During the project 14 institutions decided to withdraw, leaving 62 actually completing the entire program. Volunteers selected and participating provided medical services and had characteristic categories which were representative of the regions and/or states from which they were selected.

Table E1 provides a list of all institutions which were selected and asked to participate in the pilot program. For each institution this table also indicates associated NRC region and state, medical group (1 = institutional, 2 = private practice), medical uses licensed (NM = nuclear medicine, T = teletherapy, and B = brachytherapy), as well as characteristic categories [U = urban, R = rural, L = large (> 250 beds), S = small, Pu = publicly owned, Pr = privately owned.]

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project

A. NRC Licensees

First Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
U.S. Navy, Bethesda[a]	1	MD	1	NM/T/B	ULPu
New England Deaconess Hospital	1	MA	1	NM/B	ULPu
Pittsburg University Hospital[a]	1	PA	1	NM/T/B	ULPu
Aroostook Medical Center	1	ME	1	NM/T	RSPu
Hunt Memorial Hospital	1	MA	1	NM	USPu
St. Joseph Hospital	1	ME	1	NM	RLPu
Chandra Polam, MD[a]	1	PA	2	NM	USPr
Sharlin Radiological Associates[a]	1	NJ	2	T	USPr
U.S. Army, Fort Jackson[b]	2	SC	1	NM	USPu
University of Puerto Rico[a]	2	PR	1	NM/T/B	ULPu
McGuire Clinic	2	VA	2	T	USPr
North Detroit General Hospital	3	MI	1	NM	ULPu
Gentry County Memorial Hospital	3	MO	1	NM	RSPu
Mercy Hospital[a]	3	MI	1	NM	ULPu
Harrison County Hospital[a]	3	IN	1	NM	RSPu
St. Mary's Hospital	3	WI	1	NM	USPu
Marquette General Hospital[a]	3	MI	1	NM/T/B	RLPu
Miller-Dwan Medical Center[a]	3	MN	1	NM/T/B	USPu
Sinai Hospital[b]	3	MI	1	NM/T/B	ULPu
Central Ohio Medical Clinic[b]	3	OH	2	NM	USPr
Michael Lala, MD	3	MI	2	NM	USPr
Krause, Lubert, & Associates, Inc.[a]	3	OH	2	T	USPr

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project (continued)

Second Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
VA Hospital, Dallas[a]	4	TX	1	NM/T	ULPu
U.S. Army, Tripler	5	HI	1	NM/T/B	ULPu
Baystate Medical Center[a]	1	MA	1	T/B	ULPu
Armstrong County Medical Center[a]	1	PA	1	T/B	RSPu
Raritan Bay Medical Center	1	NJ	1	NM	ULPu
Carbondale General Hospital[a]	1	PA	1	NM	USPu
Fox Chase Cancer Center	1	PA	1	NM	USPu
Taylor Hospital	1	PA	1	NM	RSPu
U.S. Navy, Portsmouth[a]	1	VA	2	NM/T/B	ULPr
Nafisa Poonawala	1	NJ	2	NM	USPr
University of Virginia[a]	2	VA	1	T/B	RLPu
Arlington Hospital[a]	2	VA	1	NM	ULPu
Donald Pritt, MD	2	WV	2	NM	USPr
St. Rita's Medical Center[b]	3	OH	1	T/B	ULPu
St. John's Medical Center	3	OH	1	T/B	RLPu
Clermont Mercy Hospital	3	OH	1	T/B	RSPu
St. Joseph's Community Hospital	3	WI	1	NM	USPu
Elkhart General Hospital[a]	3	IN	1	NM	RLPu
Alliance City Hospital	3	OH	1	NM	USPu
Mt. Sinai Medical Center[a]	3	WI	1	NM	ULPu
Radiology Inc.	3	OH	1	NM	USPr
Hoffman, Birmingham & Assoc.	3	OH	2	T	RSPr
NOVI Diagnostic Center[a]	3	MI	2	NM	USPu
Kalamazoo Cardiology[a]	3	MI	2	NM	USPu
VA Houston[a]	4	TX	1	NM/T/B	ULPu
Moore Hospital Properties, Inc.	4	OK	1	NM	USPr
U.S. Army Madigan Medical Center[a]	5	WA	1	T/B	ULPu

B. Agreement State Licensees

First Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
Greater Baltimore Medical Center[a]	1	MD	1	B	ULPu
James Ross, MD	1	MD	2	NM	USPr
Joint Diseases North General Hospital	1	NYC	1	T	USPu
Andrew Silverman, MD	1	NYC	2	NM	USPr
Northern Westchester Hospital	1	NYS	1	NM/T/B	ULPu
Massapequa General Hospital	1	NYS	1	NM	USPr

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project (continued)

B. Agreement State Licensees

First Round Selections

Licensee	Region NRC	State	Group Medical	Medical Uses By-Product	Categories Characteristic
Marvin Lipman, MD	1	NYS	2	NM	USPr
Jackson Hospital & Clinic	2	AL	1	T/B	ULPu
South Seminole Community Hospital	2	FL	1	NM	USPr
Jess Parish Memorial Hospital	2	FL	1	NM/B	USPu
Orlando Regional Medical Center	2	FL	1	B	ULPu
Radiology & Imaging Specialists of Lakeland	2	FL	2	NM	USPr
Kenneth Mishkin, MD	2	FL	2	NM	USPr
Memorial Radiotherapy Center[a]	2	FL	2	T	USPr
Griffin-Spalding Hospital[a]	2	GA	1	NM	RSPr
Hamilton Memorial Hospital[a]	2	GA	1	B/T	USPu
Edgardo Mucha, MD	2	GA	2	NM	USPr
University of Kentucky Medical Center[b]	2	KY	1	T	ULPu
Mercy Regional Medical Center	2	MS	1	T	RSPu
New Hanover Memorial Hospital	2	NC	1	B	RLPu
Medical University of South Carolina[b]	2	SC	1	T	ULPu
St. Mary's Medical Center	2	TN	1	T	ULPu
Covenant Medical Center	3	IA	1	NM/B	ULPu
St. Joseph's Medical Center[a]	3	IL	1	T/B	ULPu
St. Joseph's Hospital & Medical Center[a]	3	IL	1	T/B	USPu
Richard Polisner, MD	3	IL	2	NM	USPr
Doctor's Hospital	4	AR	1	NM	ULPr
McKee Medical Center	4	CO	1	NM/B	USPu
St. John's Hospital	4	KS	1	T	RSPu
St. Patrick Hospital[b]	4	LA	1	NM/B	USPu
Outpatient Diagnostic Ctr. of New Orleans	4	LA	2	NM	USPr
Presbyterian Hospital of Kauffman	4	TX	1	NM/B	USPu
Northwest Texas Hospital[a]	4	TX	1	NM	ULPu
Wichita General Hospital	4	TX	1	T	USPu
Baylor College of Medicine[a]	4	TX	1	T	ULPu
Diagnostic X-Ray of Clear Lake	4	TX	2	NM	USPr
Bryan Radiology Associates	4	TX	2	T	USPr
Yuma Regional Medical Center	5	AZ	1	NM/B	RLPu
Arthur Radow/Arizona Radiology Associates	5	AZ	2	NM[c]	USPr
Desert Hospital[a]	5	CA	1	B	ULPu
Sutter Coast Hospital[b]	5	CA	1	B	RSPu
Visalia Community Hospital	5	CA	1	NM	RSPr
Brookside Hospital[a]	5	CA	1	NM/B	USPu
Ontario Community Hospital	5	CA	1	NM	USPr
Coastal Radiological Onocology Center[a]	5	CA	2	B	USPr
Imperial Valley Ref. Lab & Medical Group	5	CA	2	NM	RSPr

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project (continued)

B. Agreement State Licensees

First Round Selections

Licensee	Region NRC	State	Group Medical	Medical Uses By-Product	Categories Characteristic
Mercy Medical Center[a]	5	OR	1	B	RSPu
Providence Hospital[a]	5	WA	1	NM/B	USPu

Second Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
Washington Adventist Hospital[a]	1	MD	1	NM/T/B	ULPu
Drs. Schultze, Snider, & Associates[a]	1	MD	2	NM	USPr
Montefiore Hospital[a]	1	NYC	1	NM/T/B	ULPu
LaGuardia Medical Group	1	NYC	2	NM	USPr
Samaritan Hospital[a]	1	NYS	1	NM/T/B	ULPr
WCA Hospital[a]	1	NYS	1	NM/T	RSPu
Gerald A. Cohen, MD	1	NYS	2	NM[c]	USPu[d]
Southeast Alabama Medical Center[a]	2	AL	1	NM/T/B	RLPu
Jay Hospital	2	FL	1	NM	USPu
Riverside Hospital[a]	2	FL	1	NM/B	USPu
Memorial Hospital[a]	2	FL	1	NM/B/T	ULPu
Kenneth Kassin, MD	2	FL	2	NM[c]	USPu
Sarasota (Venice) Oncology Center[a]	2	FL	2	NM	USPu
Drs. Subbio, Batey, & Calabria[a]	2	FL	2	NM	USPu
West Georgia Medical Center[a]	2	GA	1	NM/T/B	RLPu
Glynn-Brunswick Memorial Hospital	2	GA	1	NM/T	RLPu
Gwinnet Radiation Therapy Center	2	GA	2	NM	USPr
Caldwell County Hospital	2	KY	1	NM	RSPu
Forrest General Hospital[a]	2	MS	1	T	RLPu
Valdese General Hospital[a]	2	NC	1	NM/T/B	USPu
Baptist Medical Center[a]	2	SC	1	NM/T/B	ULPu
Holston Valley Community Hospital	2	TN	1	NM/T/B	ULPu
St. Francis Hospital & Medical Center	3	IL	1	NM	ULPu
Freeport Memorial Hospital[a]	3	IL	1	NM/T/B	RSPu
Luis Owano, MD	3	IL	2	NM	USPu
Marian Health Center[a]	3	IA	1	NM/T/B	ULPu
Union Medical Center[a]	4	AR	1	NM/B	RLPu
Penrose Hospital[a]	4	CO	1	NM/T/B	ULPu
St. John's Hospital[a]	4	KS	1	T	RSPu
Glenwood Regional Medical Center	4	LA	1	NM/T/B	USPu

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project (continued)

B. Agreement State Licensees

Second Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
Sonotopes, Inc.	4	LA	2	NM	USPr
Denton Community Hospital	4	TX	1	B	USPr
University of Texas Health Science Center	4	TX	1	NM/T/B	ULPu
Memorial Medical Center[a]	4	TX	1	NM/T/B	ULPu
Rosewood General Hospital	4	TX	1	NM/T/B	USPr
MASI Healthcare Services[a]	4	TX	2	NM	USPr
Cancer Therapy & Research Center[a]	4	TX	2	T	USPr
White Mountain Community Hospital[b]	5	AZ	1	NM	RSPu
Harry Watters, DO	5	AZ	2	NM	USPu
Mt. Zion Hospital-Medical Center	5	CA	1	NM/T/B	ULPu
Harbor View Medical Center	5	CA	1	NM/B	USPr
San Joaquin General Hospital[a]	5	CA	1	NM	USPu
St. Elizabeth Community Hospital	5	CA	1	NM	RSPu
Alhambra Community Hospital	5	CA	1	NM	USPr
Sherman Oaks Radiology Medical Group	5	CA	2	NM/B	USPu
Yorba Linda Medical Clinic	5	CA	2	NM	USPu
St. Charles Medical Center	5	OR	1	NM/T/B	RSPu
Tacoma Radiation Center	5	WA	1	NM/T	ULPu

Third Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
Lena Doshi, MD[b]	1	NYC	2	NM	USPr
Irwin Schlossberg, MD	1	NYC	2	NM[c]	USPr[d]
Walter Futterweit, MD	1	NYC	2	NM[c]	USPr[d]
Howard Heimowitz, MD	1	NYS	2	NM[c]	USPr[d]
North Shore Hematology	1	NYS	2	NM[c]	USPr[d]
New York Diabetes/Endocrine	1	NYS	2	NM[c]	USPr[d]
Halifax Hospital[a]	2	FL	1	NM/T/B	ULPu
St. Mary's Hospital	2	FL	1	NM/T/B	ULPu
Rockdale-Newton[a]	2	GA	2	NM/T	USPr
Meridian Regional Hospital	2	MS	1	NM/B	RSPr
Singing River Hospital	2	MS	1	NM	ULPu

Table E1 Institutions Selected Randomly and Invited to Participate in Pilot Project (continued)

B. Agreement State Licensees

Third Round Selections

Licensee	NRC Region	State	Medical Group	By-Product Medical Uses	Characteristic Categories
Le Bonheur Childrens Medical Center	2	TN	1	NM/B	USPr
Lincoln Regional Hospital	2	TN	1	NM/B	USPu
Maury County Hospital[a]	2	TN	1	NM/T/B	RLPu
St. Francis Hospital	2	TN	1	NM/T/B	ULPu
Carey Dachman, MD	3	IL	2	NM	USPu
Hawthorne Place Surgical Center	3	IL	2	NM[c]	USPu
Noninvasive Diagnostics, Inc.	3	IL	2	NM	RSPr
Mary Bird Perkins Cancer Center[a]	4	LA	2	B	USPr
Digital Diagnostics Center, Inc.	4	LA	2	NM	USPr
Feliciana Medical Center	4	LA	2	NM	RSPr[d]
Hermann Hospital[a]	4	TX	1	NM	ULPu
Associates in Radiation Oncology, PC	5	AZ	2	T	USPu
Lawrence Spitalny, MD	5	AZ	2	NM	USPr
Northern Arizona Tumor Institute	5	AZ	2	NM[c]	USPr[d]
American Mobile Imaging Services	5	CA	2	NM	USPr
Fullerton Cardiovascular Medical Group	5	CA	2	NM	USPu
Harbor View Medical Center	5	CA	2	NM	USPr
Radiology Medical Group[b]	5	CA	2	NM	USPr
UCLA Medical Center/Nucl. Med. Clinic[b]	5	CA	1	NM/B/T	ULPu

Notes to Table E1:

[a] Accepted invitation and participated in program.
[b] Accepted invitation but later dropped out.
[c] Information provided by state unclear; assume nuclear medicine.
[d] Information provided by state unclear; could be public or private.

E.2 Enumeration of distributions and comparisons

Tables E2-E4 compare the distributions of medical groups and characteristic categories of volunteers who participated in all aspects of the program. Table E5 illustrates the types of professionals participating in this study. It is seen that medical physicists and technologists were represented about equally, with one third of the former holding PhDs. In addition to the 7 MDs there were also two registered nurses. Twelve of the physicists and technologists were Radiation Safety Officers (RSOs).

Table E2 Regional Distribution of Participating Licensees According to Medical Groups

	Group 1	Group 2
Region 1	12	3
Region 2	13	4
Region 3	10	3
Region 4	9	3
Region 5	6	1

Table E3 Comparison of Participating Departments for NRC and Agreement State Licensees

	NRC Licensees (23)	Agreement State Licensees (41)
Nuclear Medicine/Diagnostic	19	30
Nuclear Medicine/Therapy	17	29
Teletherapy	11	22
Brachytherapy	10	23

Table E4 Comparison of Characteristic Categories for NRC and Agreement State Licensees Completing All Phases of Program

	NRC Licensees (23)	Agreement State Licensees (41)
ULPu*	10	14
ULPr	0	1
USPu	3	8
USPr	5	8
RLPu	3	5
RLPr	0	0
RSPu	2	4
RSPr	0	1

*Note: U = urban L = large (> 250 beds) Pu = public
Pr = private S = small R = rural

Table E5 Professions of Participants Who Provided Information by Attending One or More Workshops and/or Signed Evaluation Forms

	Number	Percent of Total
Physicians	7	8
Physicists	41	45
Technologists	43	47

APPENDIX F

SUGGESTIONS OF PARTICIPANTS USING POST-TRIAL EVALUATION QUESTIONNAIRES

Near the end of the 60-day trial period volunteers were sent copies of two evaluation forms: one for the proposed regulations, the other for the draft regulatory guides. These are shown in Appendices G and H.

The cost effectiveness of the proposed regulations was evaluated by reviewing the questionnaire and establishing a rating scale applicable to each objective (1 to 5, 1=least burdensome/costly or most effective, 5=most burdensome/costly or least effective). The degree to which respondents thought objectives were important, unimportant, onerous, burdensome, etc. was evaluated by computing averages of these values for each combination of applicable medical use, and characteristic, categories. For each objective a similar rating scale was developed to indicate the ease with which each objective could be implemented. Results are shown in Figure F1 at the end of this Appendix.

The incremental costs associated with implementing the proposed QA rule are shown in Figure F1 for each medical use. Estimates of incremental costs were determined by evaluating the questionnaires returned to BNL and by comments received from the licensees at the pre- and post-trial workshops. Incremental costs were represented in person-hours so that regional differences in cost of living could be removed. Most participants (and particularly those in nuclear medicine) estimated that requirements of proposed Section 35.35 would not result in significant incremental costs over what was now incurred. As shown in the figure, only for nuclear medicine did incremental costs approach existing costs. For this medical use incremental costs were reanalyzed in terms of characteristic categories. It was found that potential differences between urban and rural nuclear medicine licensees were insignificant. Small, urban institutions (whether public or private) indicated increased incremental costs for the proposed rule as compared to their costs at present. Based on comments received at the workshops, it is anticipated that the majority of these increased costs are related to the requirements for written diagnostic referrals.

Table F1 Suggestions Concerning Proposed Section 35.35

35.35(a)(1) It was suggested that objectives (a)(1) and (a)(5) be combined because (a)(5) should cover objective 35.35(a)(1) if the medical use was in accordance with the referral or prescription.

It was suggested that the auditing process was extremely time consuming.

A participant indicated that (a)(1) needed to be more specific to allow the licensee to know how to implement the plan.

According to one participant, the definition of "medical condition" was not specific enough. [Note: the proposed rule did not contain a definition of "medical condition."]

35.35(a)(2) It was mentioned that the definition of teletherapy prescription should not include the number of fractions because the dose rate per fraction could be changed during the course of the treatment without biological significance.

Exclude diagnostic doses of ^{131}I or ^{125}I.

35.35(a)(3) It was suggested that verbal orders should be acceptable providing that a clinical indication or relevant patient history was provided at the time of the request.

It was requested that a verbal order from the referring physician be allowed if a written order was not available.

It was suggested that forms of iodine other than NaI should be excluded from this objective.

It was mentioned that it should be sufficient to have the office of the referring physician read the patient's chart for any requested clarification [i.e., not only the referring physician].

It was suggested that "not involving more" be replaced with "less than 30 μCi of ^{125}I or ^{131}I or any other isotope."

It was suggested that the terms "diagnostic referral" and "prescription" be eliminated and "written record" or equivalent be used instead.

35.35(a)(4) It was mentioned that this objective is presupposed by (a)(5).

A participant indicated that NRC may monitor, i.e., "double check," for errors after treatment begins or precheck for clarity but can't "ensure" prior understanding.

A participant was unsure how to ensure that a "prescription in understood." According to the participant, it seemed as though this objective was covered by other objectives. It was also mentioned that the emphasis should be placed on technician training rather than procedures. A signed statement that all procedures have been reviewed and understood should be sufficient.

It was suggested that a requirement for certified responsible individuals should satisfy this objective.

A participant did not know how to evaluate whether someone understood the prescription.

It was suggested that phone orders be accepted.

It was suggested that this objective would be impossible to verify, inspect, or monitor for compliance. Problems with this objective involved human error and clarification of (a)(2) and (a)(3) would correct this.

35.35(a)(5) It was suggested that this objective was too ambiguous.

A newer or seldom used procedure may not be in the manual.

A participant indicated that NRC may monitor, i.e., "double check," for errors after treatment begins or precheck for clarity but cannot "ensure" prior understanding.

It was suggested that (a)(4) be modified to include the intentions of (a)(5).

A participant indicated that this objective was redundant and already accomplished in (a)(1).

35.35(a)(6) It was asked whether documentation of verification was necessary.

It was requested that more information was needed in order to satisfy this objective.

It was mentioned that not all outpatients would have a written referral or prescription and that a phone referral should be sufficient.

35.35(a)(7) It was requested that the amount of deviation be defined per institution similar to JCAHO.

A participant indicated that (a)(7) seemed to duplicate (a)(5).

A participant suggested that the phrase "but does not have to be documented unless a misadministration has occurred" be added after "evaluated."

A further explanation of "evaluation" was requested. Included in this evaluation would be an acceptable error range.

35.35(a)(8) It was asked whether the prescription referred to dose information only or to guidelines for treatment planning.

A participant indicated that (a)(8) was already covered by (a)(5).

Add "and clinical history" to the end of the sentence.

A participant suggested that (a)(8) was redundant with (a)(7).

It was suggested that (a)(8) be placed after (a)(5).

Table F2	Suggestions Concerning the Draft Regulatory Guide
General Comments:	It was mentioned that "Guidelines" would tend to be interpreted by inspectors as "shall" statements and would not allow for anomalies.
Reg. Guide 1.1:	It was suggested that "regularly review" be changed to "review annually as a minimum. Further, the review and audit should be conducted by the authorized user , chief technologist and another physician. It was suggested that "regularly review" be changed to "annually reevaluate."
Reg Guide 1.2:	It was suggested that the external audit time interval should be extended beyond 12 months while internal audits could be accomplished perhaps more frequently. Clinical follow-up could help determine if the procedure was appropriate. Change "no greater than 12 months" to "no greater than 6 months." It was suggested that Section 1.2 was too onerous and already covered by Section 1.1. It was suggested that the 12 month audit be changed to 24 months or schedule audits at the request of the NRC, not to exceed more than one per year. It was suggested that the phrase "Annual audits to evaluate basic QA program" be used. In addition, the definition of auditors needed to be changed. A participant indicated that Section 1.2 would be difficult to satisfy for free standing clinics. It was suggested that "... management and reaudited ... and follow-up" be changed to "... will be audited by management and reaudited as determined by management. Audit reports will be available for review and follow-up." The phrase "Audits will be conducted...determined by management" should be changed to "Audits will be reviewed by department personnel, authorized users and management. At the discretion of the management, qualified personnel who are not involved with the activity being audited may also be included." Also, the last sentence should be deleted. It was suggested that the phrase "not involved with the activity being audited." be defined by the NRC.

The efficacy and adequacy of the QA program should be reported to the appropriate hospital committee on a quarterly basis.

It was suggested that monthly or quarterly audits would be more adequate in improving patient care.

It was suggested that 24 months be used as a time period between evaluations.

Reg. Guide 2.1: It was suggested that verbal orders should be allowed.

Reg. Guide 2.3: It was requested that "except in emergent situations" be deleted.

It was suggested that "workers" be replaced with "reasonable individual."

Reg. Guide 2.3 & 2.4: These regulatory guide points seemed to be the same as 2.2.

Reg. Guide 2.4: It was suggested that "medical use is in...manual" be changed to "medical use of therapy in accordance to the prescription and medical use of diagnostic tests according to the procedures manual."

Reg. Guide 3: It was suggested that 100 μCi of ^{131}I was more appropriate.

Another participant requested that activities of ^{131}I less than 200 μCi should be allowed without a written order.

Reg. Guide 3.1 "Before writing a prescription..." should be changed to "Before writing a therapeutic prescription..."

Reg. Guide 3.2: It was suggested that the phrase "therapy radiopharmaceutical" be added.

Reg. Guide 3.3: It was unknown what was meant by "appropriate record."

Reg Guide 3.5: It was suggested that the phrase "...and this person will record.." be deleted.

It was mentioned that the indication of final dose delivered and a note from the approved user if the deviation was greater than 10% would be sufficient to satisfy this point.

It was suggested that the phrase "...and this person...administration and the prescription" be deleted.

Clarification was requested on what would satisfy agreement or lack thereof.

A participant suggested that the phrase "...a qualified person..." be changed to "...the person administering the dose..."

Reg. Guide 4.2: A participant suggested that for brachytherapy, a generalized prescription was made and specific information such as exact source loading was not available until treatment began.

It was mentioned that an emergent nature clause be added which allowed 72 hours for the prescription to be written.

Reg. Guide 4.2, 4.4-4.6: It was suggested that the wording be changed to "The authorized user will "log-out" of the isotope storage the labeled isotopes, and specify the number, type and activity for utilization in a specific patient. Any change in the number of labeled isotopes implanted, as opposed to the number "logged-out", will be noted in the isotope storage log book."

Reg. Guide 4.5: It was suggested that high dose rate applicators be excluded from this Section.

It was requested that the following statement be used, "After the placement of the brachytherapy source, or after the placement of marker sources in the location of the radioactive sources, radiographs will be obtained. These radiographs may be used as the basis for calculating at the delivered dose. This may not apply to surface applications of radioactive sources."

Use the following statement, "Whenever the geometrical arrangement of each source relative to the prescription point(s) and to any critical points is not otherwise known, x-ray imaging will be used for determining it. In the case of afterloadable implants, the x-ray imaging should be obtained before implantation of the sources by using dummies radiographically and geometrically equivalent to the sources."

The following wording was suggested, "Radiographs will be obtained for source localization purposes and, where appropriate, used as the basis for calculation of the delivered dose (this may not apply for sources used for surface applications)."

Reg.Guide 4.6: It was mentioned that Section 4.6 was already covered in Section 4.7.

"...qualified person under the supervision of an authorized user" should be changed to "authorized user."

Reg. Guide 4.7: Does a sign-off for the final chart review satisfy the requirements of this objective?

It was suggested that the phrase "and this person...and the prescription" be deleted.

It was suggested that Section 4.7 was redundant with Section 4.6.

Reg. Guide 4.8: It was suggested that "Before 50%..." be changed to "Within one day..."

Reg. Guide 4.8 & 4.9: One participant suggested the following wording, "As soon as possible and preferably prior to delivery of 50% of the prescribed dose, a second check of the original dosimetry calculation shall be performed by a credentialed physicist or medical dosimetrist who did not make the original calculation." For some brachytherapy, especially with high dose rate afterloading brachytherapy, it was not practical to perform checks on the calculation before 50% of the prescribed dose. There are instances that even the initial calculation could not be completed before 50% of the prescribed dose was delivered. This was especially true when brachytherapy was performed at one institution but computer dosimetry was done at another institution. Sometimes dosimetry is performed days or weeks after the brachytherapy is performed.

Reg. Guide 4.9: It was suggested that the sentence "The prescribing physician...the administered dose" be deleted. It should not be necessary for the physician to make a notation in the records that he/she decided to perform a procedure without delay.

It was suggested that "within two working days of the treatment" be changed to "as soon as is reasonable."

It was suggested that dose calculations be performed "within 24 hours."

Insert "as soon as possible" before "within two working days."

Reg. Guide 5.2: It was mentioned that it was unclear whether treatment volume referred to field size or to a treatment point. Prescriptions are usually made to a treatment point.

Add an emergent nature clause.

It was suggested that "treatment plan" be changed to "treatment scheme."

Reg. Guide 5.4: It was suggested that the phrase "..between the..and the prescription" be eliminated.

It was suggested that high dose rate applicators be excluded from this Section.

Initialing a record should be allowed.

It was suggested that "sign" be changed to "initial."

Reg. Guide 5.5: It was suggested that the phrase "detect errors in the daily cumulative dose summations" be changed to "detect errors in treatment parameters (e.g. mu's or time)."

It was suggested that "weekly" be changed to "periodic."

Reg. Guide 5.6:	A participant indicated that the phrase "or before one week has passed since start of treatments, whichever is greater" be added after "Before 25%...had been administered." Also it was suggested that the requirement for a second individual be deleted. "Before 25%" should be changed to "before second treatment" It was suggested that "Before 25%..." be changed to "Before five treatment fractions..." It was suggested that 50% be used instead of 25%. One participant suggested the following wording, "Before the third working day after treatment is administered, or 25% of the prescribed dose, whichever occurs first, a check of the initial treatment calculation or isodose distribution shall be performed by another physicist or medical dosimetrist."
Reg Guide 5.6.3:	It was asked whether this Section was necessary because this item was already covered in 5.6.1 and 5.6.2. It was suggested that "radioactivity" be changed to "output."
Reg Guide 5.7.1:	According to one participant, changing the source would always result in an output difference of more than 5% when compared to the previous calibration. This participant recommended the following change, "After a full calibration or spot check measurement that resulted in a difference of more that 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay...."
Reg. Guide 5.7.1 and 5.7.2:	It was suggested that when purchasing a source, the manufacturer should required to provide the source strength in units of RHM. The individual calibration should be checked against this number and if there was a discrepancy of more than 3% then TLD or other methods of calibration should be performed.
Reg Guide 5.8:	Transmission measurements may not be necessary for all devices. It was suggested that the phrase "recastable block material" be deleted because measurement of this material was not practical.
Reg. Guide 5.9:	It was suggested that the phrase "full calibration" in the last line be deleted and replaced with "most recent measurement."
Reg. Guide 5.10:	It was mentioned that an "open field in air at eight angles to isocenter" did not serve any purpose. It was recommended that the following statement be used instead, "(1) a square field (10 x 10) at several depths (5,8, and 10 cm.) at the isocenter and 3 cm to either side of the central

axis. (2) a rectangular field (20 x 6) at several depths (5,8, and 10 cm) at the isocenter and 3 cm. to either side of the central axis."

It was suggested that tissue equivalent phantoms should be used to calculate dose.

The following substitution was suggested for Section 5.10: "Before the first use of new or modified computer code for human dose calculations, depth dose calculations will be made for typical treatment techniques and compared with phantom measurements using the same exposure conditions. If the computer code uses the teletherapy source strength or output rate in absolute terms, a typical reference set-up would be calculated with the computer code and compared with phantom measurements using the same exposure conditions after any source change or full calibration pursuant to 10CFR35.632 (a)(1) and (a)(2). If the computer code does not use the source strength or output rate in absolute terms, a source change would not necessitate the above check unless the source physical dimensions or radioisotope change, in which case the typical treatment techniques comparison referenced in this subsection (5.10) will apply."

It was suggested that the phrase "...(1) an open field..field into water" be replaced with "(1) a field with and without the wedge of greatest angle into water; and (2) an irregular mantle field into water."

The following wording was suggested, "Before the first use of a computer program for dose calculation after performing full calibration measurements pursuant to 10CFR35.632 (a)(1) and (a)(2), isodose curves generated by the computer shall be checked with phantom measurement with (1) 3 different field sizes, (2) with and without wedges (3) and with an irregular field calculation."

Reg. Guide 5.11:

It was suggested that "within two working days of the treatment" be changed to "as soon as is reasonable."

Enter "as soon as possible" before "within two working days."

New Objectives Proposed by Participants:

Documentation of patient education as to the nature of the exam. Prior to performing the exam, a patient should have explained what the test involves, This would lessen the number of misadministrations.

Extend objectives to accelerators used in therapy because ^{60}Co accounts for only 20% of all external radiation therapy treatments.

Make QC program an integral part of NRC licensing or registration requirement because all existing QC programs are "voluntary" and lack "teeth." Management and physicians pay attention only if it is mandatory to keep their license "alive."

Specific staff designation with authority and responsibility for development of QC program should be identified.

Limit the number of injection attempts to two then consult with physician.

Verify syringe content again prior to injection. Documentation of the verification such as a tag could be placed on the patient's chart.

All nuclear medicine therapies and all NaI solution doses should be verified by the technician and the authorized user. Errors often involve preparing the wrong stock solution or misreading a decimal point on the dose calibrator.

Evaluate the technical quality of the nuclear medicine study to assure high quality procedure and minimize the patient radiation exposure due to repeat studies.

Ensure prior to medical use of a radiopharmaceutical that a female patient in reproductive age is not pregnant.

Evaluate all canceled or unsatisfactory studies to ensure that prompt high quality service is being provided and the possible trends could be identified.

Have a requirement for appropriately qualified and trained individuals who have met continuing education requirements.

Establish a uniform pregnancy surveillance policy.

Radiopharmaceuticals shall be administered and studies performed only by an authorized user or a certified nuclear medicine technologist.

Authorized users or their certified nuclear medicine technologist designees shall assay each dose in a dose calibrator prior to administration.

For teletherapy, monitor unit/time settings would be more adequate in improving patient care.

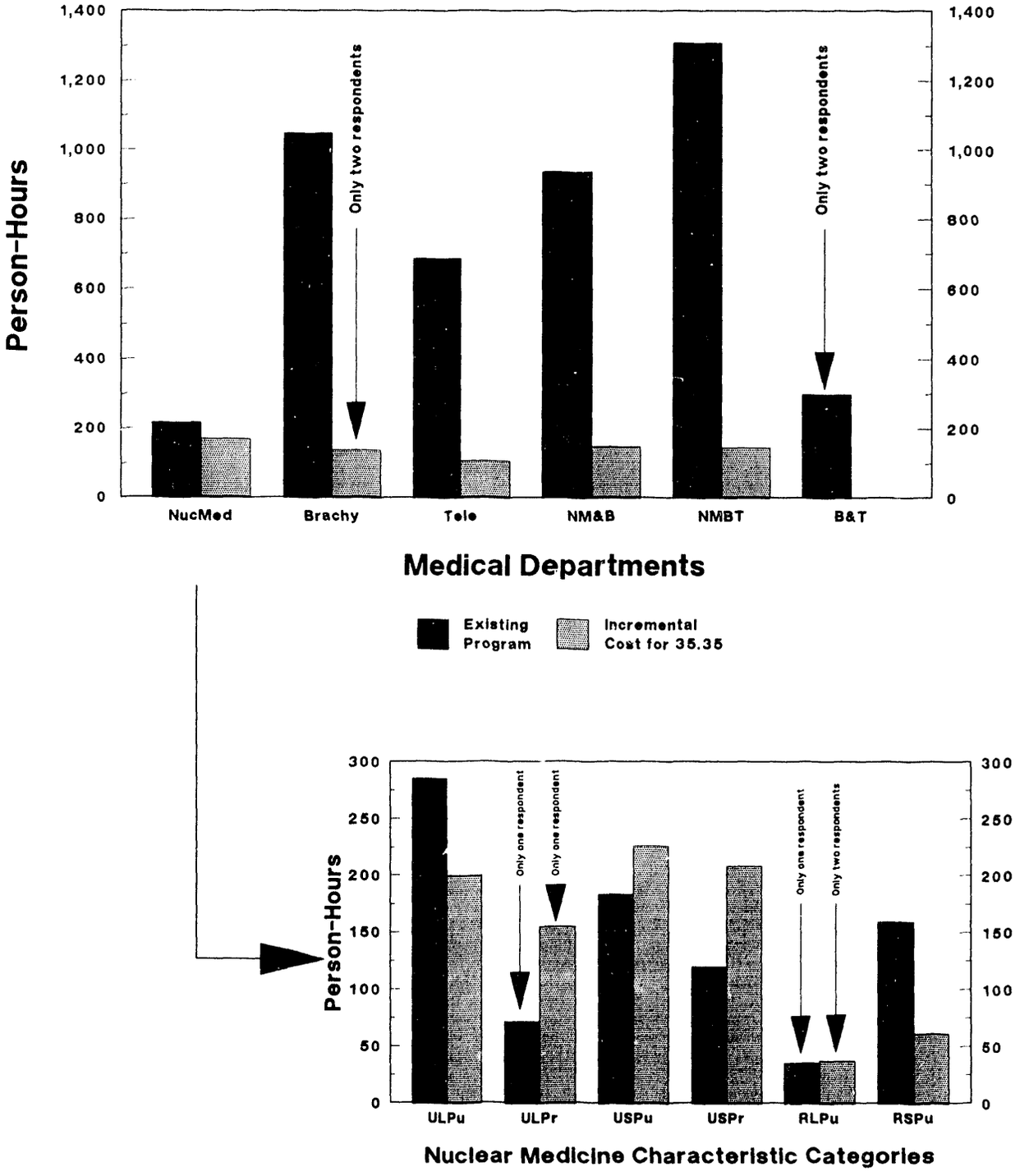
QA audit results should be part of the annual ALARA report to the Radiation Safety Committee (RSC). This assures oversight by the RSC.

Suggestions for new version:

Add requirements for patient radiation survey, nursing instructions and disscharge instructions for ^{131}I patients.

Add requirements for patient room, nursing instructions and source inventory records for brachytherapy sources.

Figure F1 Comparison of Existing and Incremental Costs By Medical Use Categories



APPENDIX G

FORM USED TO EVALUATE PROPOSED 35.35 OBJECTIVES

Hospital or Clinic: _____

Person Completing This Form - Name: _____

Title: _____

This Evaluation Form covers the following services (Check appropriate boxes):

Nuclear Medicine	( )
Brachytherapy	( )
Teletherapy (Co-60 machine)	( )

NOTE: You may use one Evaluation Form to cover all services listed above, or you may use one form for each service. Please copy this form if you need more than one.

I. Please grade each objective on the scale of A, B, C, D, or F.

For effectiveness, grade A means very likely to prevent mistakes and F means not likely to prevent mistakes. For cost, grade A means not costly and F means extremely costly.

A list of the Section 35.35 objectives are attached (see page 6) for your use.

Sec. 35.35 Objectives	Effectiveness in Preventing Mistakes	Cost of Meeting Objective
1	( )	( )
2	( )	( )
3	( )	( )
4	( )	( )
5	( )	( )
6	( )	( )
7	( )	( )
8	( )	( )

II. In order to develop the optimal set of objectives, please answer one of the following questions on each objective:

A. Would you retain this objective without modification? If so, why?

B. Would you modify this objective? If so, how?

C. Would you delete this objective? If so, why?

Sec. 35.35 Objectives	Check One	Remarks
1	A ( )	
	B ( )	
	C ( )	
2	A ( )	
	B ( )	
	C ( )	
3	A ( )	
	B ( )	
	C ( )	
4	A ( )	
	B ( )	
	C ( )	
5	A ( )	
	B ( )	
	C ( )	
6	A ( )	
	B ( )	
	C ( )	

II. Retain, modify, or delete objectives - Continued

Sec. 35.35 Objectives	Check One	Remarks
	A ( )	
7	B ( )	
	C ( )	
	A ( )	
8	B ( )	
	C ( )	

III. In order to develop the optimal set of objectives, would you add any objectives? If, so, why?

New Objective: _____

_____

Why: _____

_____

_____

New Objective: _____

_____

Why: _____

_____

_____

III. Add new objectives - continued

New Objective:_____

_____

Why:_____

_____

_____

IV. Were any of these objectives covered, in whole or part, by your previous QA program (before the pilot program)?

Sec. 35.35 Objectives	Check one for each objective: Covered	Partially Covered	Not Covered	Remarks
1	( )	( )	( )	
2	( )	( )	( )	
3	( )	( )	( )	
4	( )	( )	( )	
5	( )	( )	( )	
6	( )	( )	( )	
7	( )	( )	( )	
8	( )	( )	( )	

V. Cost Estimates (in dollars or person-hours).

A. Please estimate the annual operating cost of your previous QA program (before the pilot program).

$_____ or Person-hours_____

B. Please estimate the incremental annual operating cost of the additional work, that was not part of your previous QA program, but was added to meet the Section 35.35 Objectives.

$_____ or Person-hours_____

VI. Additional Information

1. How many diagnoses or treatments were given during the 60-day trial period? (Please complete the following table for the services you checked on page 1.)

Services	No. of Patients
Nuclear medicine-diagnostic	
Nuclear medicine-therapy	
Brachytherapy	

Service	No. of Fractional Treatments
Teletherapy (Co-60 machine)	

2. Can you provide some examples from the 60-day trial period that your QA program works; that is, errors that were detected?

1. _____

2. _____

3. _____

4. _____

5. _____

3. Can you provide any examples from the 60-day trial period that your QA program did not work; that is, an error in medical use that was not detected, but was subsequently detected by other methods?

1. _____

2. _____

3. _____

4. _____

PROPOSED § 35.35 OBJECTIVES

(Please note that some of these objectives have been reworded for clarity; the meaning remains the same as those objectives published in the Federal Register notice.)

(1) Ensure that the medical use is indicated for the patient's medical condition;

(2) Ensure, prior to medical use, that a prescription is made for (a) any teletherapy procedure, (b) any brachytherapy procedure, (c) any radiopharmaceutical therapy procedure, or (d) any radiopharmaceutical procedure involving more than 30 microcuries of I-125 or I-131;

(3) Ensure, prior to medical use, that a diagnostic referral (or prescription) is made for any diagnostic radiopharmaceutical procedure. Note that those procedures involving more than 30 microcuries of I-125 or I-131 require a prescription.

(4) Ensure, prior to medical use, that either (a) the diagnostic referral and the diagnostic clinical procedures manual or (b) the prescription is understood by the responsible individuals;

(5) Ensure that the medical use is in accordance with either (a) the diagnostic referral and the diagnostic clinical procedures manual or (b) the prescription;

(6) Ensure, prior to medical use, that the patient's identity is verified as the individual named on (a) the diagnostic referral or (b) the prescription;

(7) Ensure that any unintended deviation from either (a) the diagnostic referral and the diagnostic clinical procedures manual or (b) the prescription is identified and evaluated; and

(8) Ensure that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

APPENDIX H

FORM USED TO EVALUATE DRAFT REGULATORY GUIDE OR ALTERNATIVE ELEMENTS USED

Hospital or Clinic:_____

Person Completing This Form - Name:_____

Title:_____

This evaluation form covers the following services (check appropriate boxes):

Nuclear Medicine ( )

Brachytherapy ( )

Teletherapy (Co-60 machine) ( )

In order to develop the optimal set if elements, please complete the following three parts, when applicable, on the pages to follow.

Part 1. If you used the draft regulatory guide, please answer one of the following questions on each element:

A. Would you retain this element without modification? If so, why?

B. Would you modify this element? If so, how?

C. Would you delete this element? If so, why?

Part 2. Please provide elements that you would substitute in place of those elements in the draft regulatory guide.

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide.

1. Responsibility, Authority, and Audit

Part 1. Please answer on of the three questions (A,B,or C from page 1):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question you are answering (A,B,or C)	Remarks
1.1	( )	( )	
1.2	( )	( )	

Part 2. Please provide elements that you would substitute in place of those elements of the draft regulatory guide:

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide:

2. General Elements for All Medical Use

Part 1. Please answer one of the three questions (A,B, or C form page 1):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question answering (A,B,or C)	Remarks
2.1	( )	( )	
2.2	( )	( )	
2.3	( )	( )	
2.4	( )	( )	

Part 2. Please provide elements that you would substitute in place of those elements in the draft regulatory guide:

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide:

3. Specific Elements for Radiopharmaceutical Therapy and Certain Iodine

Part 1. Please answer one of the three questions (A,B, or C from page 1)):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question you are answering (A,B, or C)	Remarks
3.1	( )	( )	
3.2	( )	( )	
3.3	( )	( )	
3.4	( )	( )	
3.5	( )	( )	

Part 2. Please provide elements that you would substitute in place of those elements in the draft regulatory guide:

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide:

Specific Elements for Brachytherapy

Part 1. Please answer one of the three questions (A,B, or C from page 1):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question you are answering (A,B,or C)	Remarks
4.1	( )	( )	
4.2	( )	( )	
4.3	( )	( )	
4.4	( )	( )	
4.5	( )	( )	
4.6	( )	( )	
4.7	( )	( )	
4.8	( )	( )	
4.8.1	( )	( )	
4.8.2	( )	( )	
4.8.3	( )	( )	
4.9	( )	( )	

Part 2. Please provide elements that you would substitute in place of those elements in the draft regulatory guide:

4. Specific Elements for Brachytherapy - continued

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide:

_____

_____

_____

_____

_____

5. Specific Elements for Teletherapy

Part 1. Please answer one of the three questions (A,B, or C from page 1):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question you are answering (A,B,or C)	Remarks
5.1	( )	( )	
5.2	( )	( )	
5.3	( )	( )	
5.4	( )	( )	
5.5	( )	( )	
5.6	( )	( )	
5.6.1	( )	( )	
5.6.2	( )	( )	
5.6.3	( )	( )	

5. Specific Elements for Teletherapy - continued

Part 1. Please answer one of the three questions (A,B, or C from page 1):

Elements in Draft Reg. Guide	Did you use this element in pilot program (Y or N)	Write in one letter for the question you are answering (A,B,or C)	Remarks
5.7	( )	( )	
5.7.1	( )	( )	
5.7.2	( )	( )	
5.8	( )	( )	
5.9	( )	( )	
5.10	( )	( )	
5.11	( )	( )	

Part 2. Please provide elements that you would substitute in place of those elements in the draft regulatory guide:

Part 3. Please provide elements that you would add in addition to those elements of the draft regulatory guide:

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U.S. NUCLEAR REGULATORY COMMISSION

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

In January 1990, the Nuclear Regulatory Commission (NRC) proposed amendments to 10 CFR Part 35 that would require medical licensees using byproduct material to establish and implement a basic quality assurance program. A 60-day real-world trial of the proposed rules was initiated to obtain information beyond that generally found through standard public comment procedures. Volunteers from randomly selected institutions had opportunities to review the details of the proposed regulations and to implement these rules on a daily basis during the trial. The participating institutions were then asked to evaluate the proposed regulations based on their personal experiences. The pilot project sought to determine whether medical institutions could develop written quality assurance programs that would meet the eight performance-based objectives of proposed Section 35.35. It was found that licensees could develop acceptable QA programs under a performance-based approach, that most licensee programs did meet the proposed objectives, and that most written QA plans would require consultations with NRC or Agreement State personnel before they would fully meet all objectives of proposed Section 35.35. This report describes the overall pilot program. The methodology used to select and assemble the group of participating licensees is presented.

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