UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

PDR

December 6, 1996

The Honorable Lauch Faircloth, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510-6175

Dear Mr. Chairman:

I am responding to your letter dated October 8, 1996, concerning the National Academy of Sciences, Institute of Medicine (IOM) report entitled, "Radiation in Medicine: A Need for Regulatory Reform." The Commission's responses to your specific questions are enclosed (Enclosure 1).

The NRC intends to respond to the IOM recommendations through a deliberate process. The NRC is currently completing an agency-wide Strategic Assessment and Rebaselining initiative. As part of the Strategic Assessment initiative, the Commission continues to review carefully the IOM report. A general discussion, categorization, and summary of the broad range of comments received on the report are enclosed (Enclosures 2 and 3).

The Steering Committee for the NRC's Strategic Assessment initiative identified five options on NRC's future role in the medical program. These options ranged from expanding the program, to retaining and revising the existing program, to entirely eliminating the medical regulatory program. The specific options considered were (1) increase NRC's regulatory responsibility with the addition of X-ray, accelerators, and naturally occurring and accelerator-produced radioactive materials; (2) continue with the current program with improvements; (3) decrease oversight of low-risk activities with continued emphasis on high-risk activities; (4) discontinue regulation of all medical activities except for NRC oversight of devices and manufacturers; and (5) discontinue the NRC's medical program.

On September 16, 1996, the Commission published for comment its preliminary views on 16 strategic program areas, including medical use. The Commission's preliminary view and current consensus is that the NRC would retain its regulatory authority for the medical use of byproduct material, but should make modifications to the current program utilizing a risk-informed, performance-based approach while protecting public health and safety, e.g., focusing on high-risk procedures (Option 2). Where regulations can be relaxed or eliminated without undue increases in risk, it would be our intent to amend our regulations (Option 3). Such modifications would require rulemaking that likely would be initiated in 1997. The opportunity for input will be afforded

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to the regulated community, professional organizations, the Agreement States, the public, and others. The public comment period closed December 2, 1996. The Commission expects to make a final decision on the specific direction of the medical use program after consideration of public comments in early 1997.

Regarding the IOM report, the Commission has been concerned that the report's conclusions were not substantiated. The report recommends removing NRC's authority and relying more on the States and the Conference of Radiation Control Program Directors (CRCPD) to increase uniformity. It should be noted that the CRCPD commented that the absence of Federal authority in medical use may have immediate and undesirable consequences. Further, the CRCPD stated that it does not support automatic selection of the Department of Health and Human Services (DHHS) as the lead Federal agency, as recommended in the IOM report. The Organization of Agreement States (OAS) and others highlighted the need for Federal oversight. Some States identified the NRC as the Federal agency of choice. Some non-Agreement States expressed significant concern regarding the lack of State resources to assume more regulatory responsibility. The DHHS commented that the IOM report does not make a compelling health and safety argument for the DHHS to take on such a substantial new role, and that it is unlikely that the DHHS would have adequate resources made available to assume such responsibility. A copy of the DHHS letter is enclosed (Enclosure 4).

Particularly noteworthy in the IOM report is the dissenting opinion of Mr. Robert S. Adler, a University of North Carolina law professor. Mr. Adler strongly disagrees that a case was made to repeal Federal authority over medical uses of ionizing radiation and states that the IOM Committee's recommendations lack supporting evidence and constitute unwise public policy. Also worthy of mention is that during the public Strategic Assessment meeting conducted in Washington, D.C., the American College of Nuclear Physicians and Society of Nuclear Medicine indicated that they have modified their previous support for the IOM position and now support the Commission's preliminary views on its medical use regulatory program.

Such comments, combined with acknowledgement in the report that the extent of State regulatory programs varies, that the CRCPD guidelines are adopted to varying degrees by individual States, and that the lack of data for comparing the risks associated with different types of ionizing radiation limited the scientific basis of the IOM Committee's findings, have caused the NRC to question the report's conclusions and recommendations.

Like the IOM, the NRC recognizes the benefits derived from the use of ionizing radiation in medicine, its potential for harm, and the need to achieve the appropriate balance between the costs and benefits of regulation in this area. Most importantly, the NRC takes very seriously its responsibility to protect patients, workers, and the public as described in the agency's 1979 Medical Use Policy Statement (Enclosure 5). In adhering to the policy statement and recognizing the unique hazards and benefits associated with the deliberate administration of byproduct material for medical use, the NRC regulates this area very differently from others. Since 1992, the NRC has made three revisions to its medical use regulations using a performance-based approach to provide greater flexibility to its licensees in the areas of reportable

misadministrations, the practice of radiopharmacy, and criteria for the release of patients from confinement post-treatment. As a result, members of the general public could receive a dose of up to five times that allowed from other types of licensed operations.

Regarding the safety risks associated with accelerator-produced versus byproduct material, there is nothing unique about radioactive materials originating from a nuclear reactor (byproduct material). Generally, the same safe handling and use techniques apply to both. However, under its Atomic Energy Act (AEA) authority and responsibility, the NRC develops regulations and associated guidance for the safe medical use of byproduct material only. While the IOM has stated that the NRC only regulates approximately 10 percent of medical use, that percentage includes virtually all of the high risk procedures, with the exception of linear accelerator therapy. In addition, the NRC's regulatory program impacts significant portions of the remaining non-NRC regulated medical use. For example, the CRCPD and some States have used NRC's regulatory products for their own programs.

Regarding the effectiveness of State radiation control programs, the NRC conducts periodic reviews of Agreement State materials programs in the 29 Agreement States, including byproduct medical use programs. The NRC does not review the effectiveness of State radiation control programs as they relate to the non-Atomic Energy Act areas in any State. Therefore, the NRC is not aware of specific problems or deficiencies in how the States have handled the regulation of ionizing radiation, other than byproduct material, in medicine.

The NRC reviews reported events and maintains an event database to identify root cause and generic implications and determine whether modifications to its regulatory program are needed to further reduce errors. Neither the IOM nor the NRC is aware of a similar event database, maintained by the States, for events involving non-AEA material.

I will continue to keep you informed about significant Commission decisions concerning this issue. If I can be of further assistance to you on this issue, please contact me.

Sincerely,

Shirley Ann Jackson

Enclosures:
1. Responses to Questions
2. General discussion of comments on IOM report
3. Specific Comments on IOM report
4. DHHS letter
5. 1979 Medical Use Policy Statement

cc: Senator Bob Graham

RESPONSES TO QUESTIONS

QUESTION 1. Regarding the use of radiopharmaceuticals for diagnostic treatments for the period that such records are available: How many associated Unusual Incidents have been noted? How many of these were only administrative in nature and how many involved actual misapplications? Of the latter, how many resulted in patients, occupational workers, or members of the general public receiving harmful levels of diagnostic or therapeutic radiopharmaceuticals? And of those receiving harmful levels, how many actually have displayed symptoms of radiation sickness?

After providing specific numerical responses for the above categories, please provide any other quantifiable information that is available and may help to put the data into proper perspective.

ANSWER.

The NRC has required reporting of misadministrations involving radiopharmaceuticals since 1980. For the period between 1980 and 1991, diagnostic misadministrations of radiopharmaceuticals averaged approximately 400 per year, while therapeutic misadministrations (involving radiopharmaceuticals and sealed sources) averaged approximately 30-40 per year. In January 1992, the NRC revised its misadministration definitions and has not required reporting of unusual incidents involving the administration of diagnostic radiopharmaceuticals, with the exception of the use of greater

than 30 microcuries of sodium iodide. The 30 microcurie reporting threshold for sodium iodide was selected because it results in a dose to the thyroid gland (approximately 50 Rem) consistent with other NRC regulatory limits for an individual organ dose. The 1992 revision was based on the relatively low risk to public health and safety associated with the administration of most radiopharmaceuticals used for diagnostic purposes. As a result of the revised misadministration definitions, from 1992 through 1995, misadministrations involving radiopharmaceuticals have averaged approximately 7[1] per year. The IOM report estimates that over 8 million diagnostic radiopharmaceutical procedures are performed annually, and references an NRC estimate of 60,000 therapeutic radiopharmaceutical procedures annually. It is important to note that the cited 8 million diagnostic procedures annually consists primarily of administrations of technetium-99m, which is rarely subject to misadministration because of the higher dose threshold associated with reporting of diagnostic misadministrations.

Regarding the administrative nature of some misadministrations, the NRC revised its misadministration definitions and associated record keeping, reporting, and notification requirements based on potential harm to a patient rather than root cause. As a result, the NRC receives reports of events that meet the misadministration definitions and associated requirements, but could be considered by some to be administrative in nature (e.g., correct dosage delivered in the absence of a complete written prescription). Such events tend to be in the minority.

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[1] Reference: NUREG-1272 - AEOD annual report for calendar years 1992, 1993, and fiscal years 1994 and 1995. Data for 1996 is not yet published.

Very few of the reported misadministrations involving radiopharmaceuticals resulted in harm to an individual. However, there are isolated examples, such as a 1991 event involving the administration of a diagnostic dosage of sodium iodide for whole body scanning to a nursing female patient occurred at Tripler Army Hospital in Hawaii. As a result, the nursing infant received an unintended radiation dose that destroyed the function of her thyroid gland.

Events such as the Tripler incident, or other cases resulting in harm to individuals from the medical use of byproduct material, are reported as Abnormal Occurrences (AO) to Congress on an annual basis. From May 1990 to May 1995, there have been 20 AOs involving radiopharmaceuticals reported to Congress. Although some AOs resulted in unintended or increased radiation doses to an individual or organs such as the thyroid or bladder, in most cases, a medical consultant determined that no harmful effects to the patient were anticipated as a result. Selected portions of the AO reports involving radiopharmaceuticals, from 1990 to present, are included in Attachment 1.

The NRC is aware of misadministrations involving sealed sources administered for therapeutic purposes that have resulted in harm or potential harm to a patient. For example, in November 1992, a patient undergoing a sealed source implant for the treatment of cancer subsequently died after receiving a significant radiation overdose due to the failure of a sealed source device. Currently, the NRC is reviewing the circumstances and potential patient harm associated with approximately 100 misadministrations involving a sealed source used to treat an eye disease referred to as pterygium. Each misadministration

event is reviewed by the NRC to determine whether modifications to its existing regulatory program are needed to further reduce the likelihood of similar events.

QUESTION 2. What studies or any other work has the NRC performed or had performed to compare either the cost of compliance of its regulatory program with the benefits of the medical use of byproduct material, or to compare other statistical evidence associated with the use of radiopharmaceuticals with similar types of statistical evidence associated with the success or failure of medical procedures not involving radioactive material?

ANSWER.

The NRC has not conducted studies specifically to compare the cost of regulatory compliance with the societal benefit of a given technology. The benefits of the technology are assumed to be the same with or without regulatory oversight. However, the costs associated with every rulemaking are analyzed. The cost data are summarized and submitted to the Office of Management and Budget (OMB) as part of the clearance process associated with information collection rulemaking. The most recent NRC submittals to the OMB for 10 CFR Part 35 are provided in Attachment 2. Although it is difficult to make precise quantitative comparisons regarding costs versus benefit given the general lack of availability of statistical evidence in this and other medical areas, the NRC believes that the costs associated with compliance are commensurate with the benefits to public health and safety by ensuring the safe use of byproduct material and reducing the likelihood of misadministrations.

QUESTION 3. What is the range of costs that medical facilities must incur for compliance, inspection, and licensing? Has NRC done a cost versus risk assessment to form an opinion as to whether the costs are reasonable? If so, what is that opinion?

ANSWER.

The NRC developed a fee structure, which is set forth in 10 CFR Parts 170 and 171, to facilitate 100 percent recovery of its budget as required by the Omnibus Budget Reconciliation Act of 1990. These parts set forth the schedule of annual fees charged for licensing and other forms of registration or certification, and inspections. Fees are set annually by rulemaking. Attachment 3 provides a copy of 10 CFR Parts 170 and 171.

The NRC charges a fee for a license application, amendment and renewal. These costs range from $400 to $6,000, depending on the scope of the program. The annual fee for facilities subject to Part 35 ranges in cost from $5,000 to $25,000 depending on the scope of the program. According to the estimate submitted to the OMB for the information collections requirements in Part 35, the annual cost of compliance averages $25,000 per licensee.

The NRC performs a regulatory impact analysis, including a cost benefit analysis, with each rulemaking, including medical use. The NRC estimates costs associated with implementation of its regulations and submits these estimates for OMB review. The costs to individual medical facilities vary due to the significant variations in the scope of licensee programs and their

efficiency at achieving cost reduction. Also, it is difficult to separate the costs that would be incurred regardless of NRC involvement. However, the NRC believes that the costs associated with compliance are commensurate with the benefits to public health and safety by ensuring the safe use of byproduct material and reducing the likelihood of misadministrations.

QUESTION 4. What views has the Commission formed on any of the recommendations on page 22 of the report? If the Commission has not yet reached a consensus on any particular recommendation, what positions have any of the individual Commissioners formed? What information is the Commission awaiting that is imperative for determining a complete response to this report's recommendations?

ANSWER.

The Commission has considered the IOM recommendations within the framework of the agency's Strategic Assessment and Rebaselining initiative, which began in August 1995. As a result, on September 16, 1996, the Commission made its preliminary views on the medical use regulatory program publicly available for comment. The current consensus of the Commission is that the NRC would maintain its current regulatory program for the medical use of byproduct material, but should make modifications to the current program, utilizing a risk-informed, performance-based approach with opportunity for input from the regulated industry, professional organizations, the Agreement States, the public and others. The Strategic Assessment public comment period closes December 2, 1996. Shortly thereafter, the staff will review, collate, and summarize the public comments. The staff expects to provide a summary of the public comments to the Commission and the public in early 1997, after which a final Commission decision on the specific direction of the medical use program will be made. For your information, Strategic Assessment Direction-Setting

Issues paper number 7, "Materials/Medical Oversight," and number 12, "Risk-Informed, Performance-Based Regulation," are attached (Attachment 4 and 5, respectively).

QUESTION 5. With regard to the individual public opinions on NRC oversight in the nuclear medicine field that may be received from the Strategic Assessment Rebaselining process, do you expect those additional public opinions to reflect new, important views outside the range of comments that have already been received?

ANSWER.

As mentioned previously, the Strategic Assessment public comment period closes December 2, 1996. It would be premature for the Commission to prejudge what opinions public commenters might express. After careful review of the public comments received, the Commission expects to make a final decision on the specific direction on the medical use regulatory program and provide direction to the staff.

Attachments:
A. Selected portions of AO reports
B. Supporting Statement for 10 CFR Part 35
C. 10 CFR Parts 170 and 171
D. DSI No. 7, "Materials/Medical Oversight"
E. DSI No. 12, "Risk-Informed, Performance-Based Regulation"

ITEMNO	LICENSEE	CITY	STATE	EVTDATE
900313	OVERLOOK HOSPITAL	SUMMIT	NJ	5/14/90
900347	MERCY-MEMORIAL MEDICAL CENTER, INC.	SAINT JOSEPH	MI	6/5/90
900388	TRIPLER ARMY MEDICAL CENTER	TRIPLER AMC	HI	6/19/90
900478	COPLEY HOSPITAL	MORRISVILLE	VT	8/7/90
900558	WEST SHORE HOSPITAL	MANISTEE	MI	9/22/90
900597	WILLIAM BEAUMONT HOSPITAL	ROYAL OAK	MI	10/15/90
900787	V.A. MEDICAL CENTER	SAN DIEGO	CA	11/26/90
910181	HUTZEL HOSPITAL	DETROIT	MI	1/16/91
910413	CLARA MAASS MEDICAL CENTER	BELLEVILLE	NJ	3/28/91
910705	I. GONZALEZ MARTINEZ ONCOLOGIC HOSPIT	HATO REY	PR	6/17/91
910985	WILLIAM BEAUMONT ARMY MEDICAL CENT	EL PASO	TX	8/30/91
920487	INGHAM MEDICAL CENTER CORP.	LANSING	MI	5/11/92
920488	BAYSTATE MEDICAL CENTER, INC.	SPRINGFIELD	MA	5/18/92
940005	PAPASTAVROS' ASSOCIATES MEDICAL IMA	WILMINGTON	DE	1/14/93
940090	OSTEOPATHIC HOSPITAL FOUNDERS ASSOC	TULSA	OK	7/27/93
941413	WELBORN CANCER CENTER	EVANSVILLE	IN	3/9/94
941355	STAMFORD HOSPITAL	STAMFORD	CT	5/16/94
941670	SAINT JOSEPH MERCY HOSPITAL	PONTIAC	MI	7/26/94
941719	V.A. MEDICAL CENTER	LONG BEACH	CA	8/9/94
950645	MASSACHUSETTS GENERAL HOSPITAL	BOSTON	MA	5/9/95

Attachment A

implemented pending the licensee's Radiation Safety Officer's full investigation and review.

NRC - An NRC Region IV inspector conducted a special safety inspection on October 3 and 5, 1990, of the circumstances associated with the misadministration, and identified violations of NRC requirements as well as deviations from the licensee's documented procedures (Ref. 1). A Confirmatory Action Letter (CAL) was issued on October 10, 1990, to confirm commitments made by the licensee during this inspection (Ref. 2). These commitments include conducting a retrospective review of patient treatments to determine if similar errors had been made. A decision regarding enforcement action is currently under consideration.

Future reports will be made as appropriate.

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90-17 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - May 14, 1990; Overlook Hospital; Summit, New Jersey.

Nature and Probable Consequences - On June 1, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at the hospital.

An outpatient was scheduled for a nuclear medicine study by the referring physician's office by telephone. The nuclear medicine department understood the doctor's office to request an appointment for an iodine-131 scan. The patient brought the written prescription to the outpatient department and then proceeded to the nuclear medicine department for the scheduled study. The written prescription was not received by the nuclear medicine department until after the study was completed. When the nuclear medicine department received the written prescription, it was noted that the referring physician's written prescription requested a thyroid scan, not an iodine-131 scan. (A thyroid scan typically means a study using approximately 100-500 microcuries of iodine-123 as the imaging radionuclide. An iodine-131 scan usually refers to a whole body scan, utilizing a dose of approximately 1 to 5 millicuries.)

The patient involved in the misadministration had a benign tumor removed from a lobe of the thyroid in June 1989. Subsequent thyroid scans of the individual (an uptake study was performed in November 1989, after the thyroid lobectomy) indicated that the patient had a normally functioning thyroid.

The intended dose to the patient's thyroid was approximately 4 rads from 300 microcuries of iodine-123. The administered dose to the patient's thyroid, as a result of the misunderstanding of the physician's request, was approximately

1820 rads from 1.4 millicuries of iodine-131. The licensee does not expect any significant consequences to the patient.

Cause or Causes - The cause of the event is attributed to inadequate procedures. The verbal request for the nuclear medicine study had not been verified by a written prescription prior to the study being performed.

Actions Taken to Prevent Recurrence

Licensee - After a telephone call on September 21, 1990, from NRC Region I staff to the licensee in regard to the incident, the licensee convened a Radiation Safety Committee meeting on October 2, 1990, to review the cause of the misadministration and to determine the corrective actions required to prevent a recurrence. The licensee established a procedure requiring receipt of a written prescription by the nuclear medicine department prior to administering any iodine for studies. This information was communicated to NRC Region I by telephone on October 3, 1990.

NRC - NRC Region I inspectors will review the incident during the next routine inspection at this facility. The timeliness of the licensee's response (reviewing the cause and determining corrective actions following the May 14, 1990 incident) will also be reviewed.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

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90-18 Significant Breakdown in Management and Procedural Controls at a Medical Facility

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on the public health or safety can be considered an abnormal occurrence. In addition, the third general criterion in Appendix A notes that major deficiencies in management controls for licensed facilities or material can be considered an abnormal occurrence.

Date and Place - July 19-27, 1990; North Detroit General Hospital; Detroit, Michigan.

Nature and Probable Consequences - This event involved the apparent use of fraudulent films from 30 diagnostic nuclear medicine studies that rendered all but one of them invalid. Such an event could have potentially resulted in significant adverse health effects to patients (e.g., a serious disease may not be diagnosed, or a correct diagnosis could be significantly delayed). The details of the event are as follows:

On August 14, 1990, the licensee reported to NRC Region III that films from diagnostic nuclear medicine studies were apparently fraudulent. The films involved 30 studies performed on 27 patients during the time period July 19-

90-13 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - June 5, 1990; Mercy Memorial Medical Center; St. Joseph, Michigan.

Nature and Probable Consequences - A 79-year-old female patient was scheduled to undergo a diagnostic evaluation to determine whether she was suffering from an enlarged thyroid gland (substernal thyroid). No prescribed dose was indicated.

The scan was scheduled for the following day. The technologist, in attempting to order the proper amount of radioactive material, noted that her standard dose chart (created by authorized users) did not list dosage for a substernal thyroid gland study.

She then referred to the department's procedures manual, which indicated that the proper dose for a substernal thyroid gland study was 3-5 millicuries of iodine-131, or 100-200 microcuries of iodine-123. The technologist then asked an authorized user which isotope to use. He instructed her to order a sufficient quantity of iodine-131 to visualize the thyroid gland. On June 5, 1990, the patient was given 4.3 millicuries of iodine-131, which conformed to the procedures manual. The dosage listed in the procedure, however, was wrong. The standard dose for a substernal thyroid scan should have been 50 to 100 microcuries of iodine-131, or approximately one-fiftieth of the amount noted in the manual. The mistake was identified by the Chief of the Nuclear Medicine Department on June 6 and reported as a misadministration to the NRC on June 8, 1990.

The licensee estimated that the misadministration resulted in a mean dose to the thyroid gland of 5,752 rads. The NRC's medical consultant investigated the case. Based on certain assumptions, the consultant estimated the dose to be 3,400 rads to the thyroid gland which, according to the consultant, would yield a 10 percent chance of hypothyroidism over five years. The licensee is monitoring the patient's condition.

Cause or Causes - The Nuclear Medicine Department's procedures manual listed the wrong iodine-131 dosage for a substernal thyroid scan. The dosage was not reviewed by an authorized user prior to its administration.

Actions Taken to Prevent Recurrence

Licensee - The license has been amended to incorporate the following changes in iodine-131 procedures: (1) Two nuclear medicine technologists will independently verify the prescribed dosage and check the dose calibrator assay; (2) A written prescription by an authorized user will be required before the procedure is carried out; and (3) Two signatures or initials will be required on all documents involving iodine-131. The licensee also

corrected the department's procedures manual to reflect the proper dosage for a substernal thyroid scan. Dosage for a substernal thyroid scan also was added to the department's Standard Dose Chart.

NRC - An NRC inspection was conducted on June 19, 1990 (Ref. 6). Seven violations of NRC requirements (unrelated to this event) were identified. The licensee's corrective actions to prevent recurrence were found to be satisfactory. The NRC notified its medical consultant who reviewed the circumstances. He made certain procedural recommendations for consideration by the licensee.

This item is considered closed for the purposes of this report.

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90-14 Administration of Iodine-131 to a Lactating Female With Uptake by Her Infant

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - June 19, 1990; Tripler Army Medical Center; Honolulu, Hawaii.

Nature and Probable Consequences - A nursing mother was given a 4.89 millicurie dose of iodine-131 at an NRC licensed medical facility that resulted in an unintentional radiation dose to her infant's thyroid gland estimated at 30,000 rads and a dose to the infant's whole body of 17 rads. The error was detected on June 21, 1990, when the patient returned to the medical center for a whole body scan. The scan indicated an unusually high breast uptake of iodine-131. In the opinion of the patient's physician and an NRC medical consultant, the infant's thyroid function will be completely lost. The infant will require artificial thyroid hormone medication for life to ensure normal growth and development.

Cause or Causes - The physician and nuclear medicine technologist failed to confirm that the patient was not breast feeding. The patient arrived at the medical center from a remote South Pacific island. Communication between the island physician and the Army physicians was poor and the Tripler physicians were not aware that the mother had given birth on June 1, 1990.

Actions Taken to Prevent Recurrence

Licensee - Immediately following discovery of the error the licensee began using a new questionnaire that more clearly requires the collection and documentation of information concerning patient pregnancy and breast feeding. The Commanding Officer has ordered a special investigation to define the cause and appropriate corrective actions. The licensee has contacted the patient and the patient's physician and is finalizing arrangements for long term follow-up medical care.

These violations were indicative of a breakdown of management control of the licensee's nuclear medicine program.

Actions Taken to Prevent Recurrence

Licensee - As a result of this occurrence, the licensee has strengthened its screening procedures for prospective employees, both temporary and permanent. Training procedures have also been broadened and intensified. There will be more ongoing supervision and review of work by new employees.

NRC - The NRC conducted a special inspection August 15 through September 7, 1990, to review the circumstances surrounding the fraudulent films. A number of violations were identified. On October 29, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of $2,500 (Ref. 3), which was paid by the licensee on November 26, 1990.

This item is considered closed for the purposes of this report.

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90-19 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - August 7, 1990; Copley Hospital; Morrisville, Vermont.

Nature and Probable Consequences - On August 14, 1990, NRC Region I was notified by the licensee in writing that a diagnostic misadministration involving iodine-131 (I-131) had occurred at the hospital on August 7, 1990. Further information was obtained in a follow-up phone call to the licensee on September 24, 1990. A 63-year-old woman patient, undergoing I-131 treatment for primary hypothyroidism, was administered 112 microcuries instead of a routinely prescribed 10 microcuries. The dose to the thyroid, based upon the results of an uptake scan, was calculated at 3.9% uptake, resulting in an estimated actual dose to the thyroid of 29 rads. The licensee does not expect any adverse consequences to the patient.

The hospital reported that a supply of I-131 capsules had been ordered with incorrect amounts of I-131. Instead of ordering 5 capsules with a total activity of 100 microcuries, the 5 capsules were ordered as 100 microcuries each. On the day of the event, the technologist measured the capsule in the dose calibrator prior to administration and incorrectly interpreted the dose calibrator reading of 112 microcuries as 11.2 microcuries. The error was identified by another technologist measuring the uptake by the patient's thyroid the following day.

Cause or Causes - The causes of the event were attributed to human errors. The wrong I-131 capsules had been ordered, and the technologist incorrectly interpreted the dose calibrator reading.

Actions Taken to Prevent Recurrence

Licensee - The licensee reviewed the policies and procedures for assaying doses with all nuclear medicine technologists. In addition, the licensee's procedure was revised to require that only the technologist who orders the iodine capsules is allowed to administer them to patients.

NRC - NRC Region I inspectors will review the incident during the next routine inspection at this facility.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

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90-20 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes than an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - September 22, 1990; West Shore Hospital; Manistee, Michigan

Nature and Probable Consequences - On September 24, 1990, the licensee's consultant informed Region III that an 84-year-old female cancer patient received a 175 millicurie dose of a technetium-99m (Tc-99m) labeled radiopharmaceutical for an imaging scan of her gall bladder instead of the 8 millicurie dose prescribed in the Nuclear Medicine Department's procedures manual.

The misadministration occurred on Saturday, September 22, 1990, when the patient's physician ordered a hepatobiliary (liver and gall bladder) scan. The radiopharmaceutical was prepared and administered by a part-time technician who was on weekend call. The technician had received only two weeks of training in Nuclear Medicine Department procedures the previous February and had performed only two nuclear medicine procedures since then (during one procedure, she was directly supervised by the Radiology Manager; during the other, the Radiology Manager "coached" her through the procedure by telephone). After receiving the order on September 22, the technician telephoned the Radiology Manager at home for guidance. She was told to prepare the dose according to the Department's procedures manual, which stated that an 8 millicurie (mCi) dose of Tc-99m mebrofenin was needed for hepatobiliary scans. Tc-99m mebrofenin is prepared by adding free Tc-99m to a reagent kit containing the mebrofenin.

According to the technician, she eluted 392 mCi from the molybdenum-technetium generator, and then took 4 milliliters of the eluate and injected it into the reagent kit. After mixing, she withdrew 1 milliliter of the solution, put it on a dose calibrator, which she claimed read 8 mCi, and then injected the radiopharmaceutical into the patient. When she saw a "bright spot" forming on

the scanning screen where the sharp image of the gall bladder should have been, she telephoned the Radiology Manager and informed him that something was wrong.

A reconstruction of the event by NRC and licensee consultants indicated that the dose to the patient was 175 mCi instead of the intended 8 mCi. The amount of Tc-99m mixed with the mebrofenin was probably around 440 mCi, instead of the manufacturer's maximum recommendation of 100 mCi. The NRC consultant concluded that the technician misread or misunderstood the activity reading on the dose calibrator prior to injecting the patient. The medical consultant also evaluated the medical consequences of the incident and concluded that no biological effects should be expected from the misadministration. It is estimated that the doses to the patient's bladder and upper large intestine were about 36 rads and 26 rads, respectively.

Cause or Causes - The cause of the event was the licensee's failure to properly train and supervise an inexperienced technician. The individual either misread or misunderstood instructions, and in some cases used guesswork in carrying out the procedure.

Actions Taken To Prevent Recurrence

Licensee - The licensee's corrective action includes more orientation and training of new employees; additions to the computerized quality assurance system to remind staff to hold required meetings and perform required tests; and additional oversight of the licensee's program by management and the Radiation Safety Officer. Also, the technician is no longer employed at the hospital.

NRC - NRC Region III conducted a special inspection on September 27, 1990, and identified 10 violations of NRC requirements. Seven of the 10 violations pertained to this incident, including failure to instruct the technician in NRC regulations and license requirements, and failure to prepare the reagent kit in accordance with manufacturer's instructions. The Region contacted a medical consultant who reviewed the case. On November 16, 1990, the NRC issued a Notice of Violation and proposed a civil penalty of $4,375 (Ref. 4). The licensee has paid the civil penalty. The corrective actions will be further reviewed during a future routine NRC inspection.

This item is considered closed for the purposes of this report.

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AGREEMENT STATE LICENSEES

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. For this period, the Agreement States determined that one of these events was an abnormal occurrence.

sent the radiographer to a physician for examination and blood tests. No clinical manifestations of the overexposure were evident.

Cause or Causes—The radiographer failed to conduct a radiation survey of the exposure device after the exposure. Without a radiation survey, the radiographer was not aware that the source was disconnected and had not returned to the shielded position. His willful removal of dosimetry devices complicated subsequent dose calculations.

Actions Taken to Prevent Recurrence

Licensee—The licensee's proposed corrective actions include temporarily removing the radiographer from radiography duties, doubling the number of management audits and safety meetings, revising company policy on the number of hours worked, and increasing safety training from 16 hours per year to 32 hours per year.

NRC—NRC Region IV transmitted its inspection report on December 9, 1990 (Ref. 2), and conducted an Enforcement Conference with the licensee on December 7, 1990, to discuss the event. Escalated enforcement action is pending. NRC issued an immediately effective order on January 28, 1991 (Ref. 3), prohibiting the radiographer from engaging in NRC-licensed activities on behalf of the licensee for a period of 1 year.

Future reports will be made as appropriate.

90–23 Medical Therapy Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—October 15, 1990; William Beaumont Hospital; Royal Oak, Michigan.

Nature and Probable Consequences—On October 10, 1990, a 60–year–old female patient was referred to the nuclear medicine department for iodine–131 thyroid ablation therapy after undergoing a thyroidectomy for cancer. After reviewing the clinical data on the patient, the authorized physician-user prescribed 175 millicuries of iodine–131 to be administered orally on October 15.

On October 15, the licensee received the patient's oral iodine–131 solution from a distributor. In addition, the licensee also received a second vial containing 140 millicuries of iodine–131. This vial is a weekly standing-order for the hospital and is used as needed during the week.

The two vials were assayed by a technologist. The one vial contained 180 millicuries, and this amount was later approved by the authorized physician for the patient's treatment. The standing-order vial contained 140 millicuries. After the assay, the technologist placed both vials side by side in the fume hood located in the nuclear pharmacy. Both were still in their original leaded shields and labeled as to their contents.

At 10:30 a.m., the authorized physician-user was ready to administer the iodine–131 to the patient, and called for the material. Since the technologist who had prepared the dosage was not readily available, another technologist went to the pharmacy to obtain the radiopharmaceutical. The technologist who had prepared the dosage did not indicate to the administering technologist how many vials were to be administered. The administering technologist picked up both vials, assuming they were to be administered to the patient. The technologist did not review the labels on the containers, assuming they were the proper doses. The technologist also did not consider the administration of more than one vial to be unusual since this was a common occurrence at this facility.

After reviewing the dosage record, the authorized physician instructed the technologist to administer the dose to the patient. The technologist then proceeded with the administration of both vials containing 320 millicuries. The physician did not review the labeling on the containers, believing that since the patient's unit dose record was complete and indicated a dosage of 180 millicuries, the two vials were the proper ones for administration.

On October 16, the nuclear pharmacist received a request for 25 millicuries of iodine–131, but could not find the standing-order vial. The resulting investigation determined that the vial had been erroneously administered the previous day. The patient and her doctor were subsequently informed of the misadministration. The licensee's radiation safety officer also was notified.

NRC Region III contracted with a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The consultant's evaluation indicated that the misadministration should not have any significant medical effects on the patient; the estimated bone marrow dose received by the patient was between 40 and 50 rads, which should be well tolerated by the patient.

Cause or Causes—The three primary causes were: (1) the stock solution of iodine-131 was stored in the same location as the patient's dose, (2) the administering-technologist was never informed by the technologist who actually prepared the dose that only one vial was to be used, and (3) the administering technologist and physician did not review the labels on the container.

Actions Taken to Prevent Recurrence

Licensee—On October 18, 1990, the hospital requested that its NRC license be amended to include the following modifications to its iodine-131 administration procedures: (1) on all iodine-131 therapy doses, the person administering the dose must either be present in the radiopharmacy when the dose is assayed, or the person must personally assay the dose before it is taken out of the radiopharmacy; (2) the dose sheeting must indicate the number of vials that comprise the dose; (3) just prior to the administration, the physician will verify the assay dose activity with the prescribed dose and initial the dose sheet; and (4) the standing order of therapeutic iodine-131 will be stored in the hot locker and will be placed in the fume hood only when needed for dispensing. On October 29, 1990, these new procedures were incorporated into the hospital's NRC license via an amendment.

NRC—NRC Region III conducted an inspection at the facility on October 17, 1990 (Ref. 4). Although no violations of NRC requirements were identified, concerns were expressed over the storage of stock iodine-131 with the patient's intended dose and the lack of communication between the technologist who prepared the dose and the technologist who administered the dose. The NRC medical consultant indicated that the licensee's corrective action program was appropriate. Corrective actions will be examined by the NRC Region III during future inspections.

This item is considered closed for the purposes of this report.

90-24 Radiation Overexposure of a Radiographer

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Example 1 of "For All Licensees") of this report notes that an exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

Date and Place—November 12, 1990; Tumbleweed X-Ray Company; Greenwood, Arkansas; the radiation overexposure occurred at a temporary jobsite in Burns Flat, Oklahoma.

Nature and Probable Consequences—On November 26, 1990, the licensee notified the NRC that on November 12, 1990, a radiographer's assistant may have sustained a possible radiation overexposure to his right hand. The licensee stated that it was not informed of the incident by the radiographer until the morning of November 25, 1990, because the radiographer did not think an overexposure had occurred until the assistant radiographer's right hand became red and his fingers began to swell. On the day of the incident, the radiographer and his assistant were performing radiographic operations at a temporary jobsite with a radiography device that contained a 49-curie iridium-192 sealed source. NRC Region IV sent an inspector to investigate the incident; based on interviews with the radiographer, the assistant, and the owner of the company, the circumstances associated with the radiation overexposure are described below.

The radiographer and his assistant were performing radiographic exposures of welds on a 48-inch diameter tank at a fabrication shop. After the sixth exposure, the radiographer left the immediate area to load film in a belt. While the radiographer was away, the assistant set up the seventh exposure and cranked out the source. The assistant had turned the crank about two or three turns when he saw that the magnetically mounted stand, that held the guide tube near the exterior of the tank, had fallen.

The assistant radiographer's alarming personnel dosimeter (chirper) had alarmed loudly when the guide tube had fallen. The assistant stated that he froze for about 5 seconds, then he cranked the source back to the shielded position. The assistant's chirper had quit alarming, so he thought the source was in the shielded position in the radiography device. The assistant radiographer then stated that he failed to pick up and use his survey instrument to perform a survey of the radiography device and the source guide tube, because his chirper was not alarming. (The licensee later reported that the chirper had been dropped a couple of times that night and upon subsequent testing was found to be malfunctioning due to a shorted ground wire.) Instead, he walked over to the tank and repositioned the magnetic stand and source guide tube. After the assistant radiographer correctly positioned the guide tube with his right hand, he returned to the crank handle to proceed with the exposure.

When he performed this exposure, he noted that his chirper did not alarm when the source was cranked out. Because of this, after the exposure was completed, he looked at his pocket dosimeter and noticed that it was off scale (greater than 200 millirem). At about the same time, the radiographer returned and the assistant told him what had happened and that his

pocket dosimeter had gone off scale. The assistant told the radiographer that he did not think that he had received an overexposure, but that he thought his pocket dosimeter was off scale because he had bumped it earlier. The radiographer and his assistant continued to work and did not inform the Radiation Safety Officer of the incident until after the assistant's hand showed clinical signs of a radiation injury.

The assistant radiographer stated that he grasped the guide tube with his right hand just below where the guide tube was taped to the magnetic stand. The radiation injuries that the assistant radiographer sustained to his hand indicated that he grasped the guide tube with the thumb, index, and middle fingers, and that the source had to be directly beneath the point grasped. This information may indicate that the assistant radiographer mistakenly cranked the source out, instead of in, when the incident first occurred. From reenactments, clinical observations, and calculations, the dose to the assistant radiographer's hand was estimated by the NRC to be between 1500 to 3000 rem. The whole body dose to the assistant, as measured by his thermoluminescent dosimeter, was 365 millirem. Blood samples were taken from the assistant for cytogenetic tests; the results indicated an equivalent whole body exposure of less than 10 rem.

On November 29, 1990, the NRC inspector noted that the assistant's thumb, index, and middle fingers were severely blistered and swollen. On this date the assistant was admitted to a burn center in Oklahoma City, Oklahoma, for medical care. The assistant remained in the hospital for approximately two weeks, and during that period had a skin graft performed on his index finger. On January 22, 1991, the physician contacted NRC and stated that the assistant's middle finger and thumb appeared to be healing and that the index finger was grafted due to lesions that were not healing. The physician also stated that the assistant would remain under his care, and he would supply NRC with periodic reports.

Cause or Causes—The radiographer failed to supervise the assistant properly, and the assistant failed to conduct a radiation survey of the exposure device.

Actions Taken to Prevent Recurrence

Licensee—The assistant radiographer is no longer employed by the licensee. Additional actions to be taken by the licensee will be discussed at an upcoming enforcement conference with the NRC.

NRC—During the investigation of this event, an Order modifying the license was issued on December 4, 1990, prohibiting the radiographer and the assistant from participating in licensed activities (Ref. 5). NRC Region IV issued an inspection report to the licensee on February 5, 1991 (Ref. 6) and plans to conduct an enforcement conference with the licensee.

Future reports will be made as appropriate.

90–25 Medical Diagnostic Misadministration

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—November 26, 1990; Veterans Administration Medical Center; San Diego, California.

Nature and Probable Consequences—On November 26, 1990, a patient scheduled for the administration of 5 millicuries of indium–111 labeled anti-CEA monoclonal antibody for diagnostic imaging of colorectal cancer was mistakenly administered 168 millicuries of technetium–99m pertechnetate.

Prior to the administration, a nuclear medicine physician instructed his technical assistant to obtain the indium–111 from the Nuclear Medicine Preparation Lab. However, the assistant erroneously picked up a syringe containing the technetium–99m pertechnetate. The physician failed to positively identify the label on the syringe before injecting the contents of the syringe into the patient.

The error was discovered by the licensee within minutes after the misadministration and the patient was administered 10 drops of iodide and 1 gram of perchlorate to block and flush the thyroid gland respectively.

The patient was placed in an isolated room normally used for therapy for two days. The patient was scanned approximately thirty hours after the misadministration and the thyroid gland showed no elevated radioactivity. A small residual amount of technetium–99m was detected in the bladder. Following the scan, the patient was noted to be clinically unchanged and was discharged from the licensee's medical center.

Had the blocking and flushing agents not been administered, the organ receiving the highest exposure would have been the stomach wall, receiving an estimated 42 rem compared to about 5 rem for indium–111. Administration of the blocking and flushing agents reduced the radiation exposure to all organs except the bladder wall. It is estimated the bladder wall received about 17 rem from the technetium–99m compared to about 3 rem for indium–111.

Cause or Causes—The main cause of the misadministration was the failure of the nuclear medicine physician and his technical assistant to read the label on the technetium-99m syringe at the time of the injection. A contributing cause of the misadministration was inadequate training of the physician's technical assistant who was provided a description of the radiopharmaceutical based only on the color and shape of a container and not the label.

Actions Taken to Prevent Recurrence

Licensee—The physician's privilege to inject patients has been temporarily revoked. Additional training of the nuclear medicine staff is planned. Recommendations of a licensee internal quality assurance investigation board are currently being considered.

NRC—A special NRC team inspection was conducted at the licensee's facility following the misadministration. An inspection report was issued on January 3, 1991 (Ref. 7) and an Enforcement Conference was held with the licensee on January 10, 1991. On March 13, 1991, a Notice of Violation was issued to the licensee for violations identified during the inspection (Ref. 8). None of the violations pertained to the misadministration and no civil penalty was proposed.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

Agreement State Licensees

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. For this period, the Agreement States reported no events as abnormal occurrences.

Cause or Causes—The licensee identified the probable causes of the November 28 event to be (1) less than adequate piping layout that allowed uranium solutions to flow into the unfavorable geometry tank and (2) personnel-related inadequacies in that operators had no knowledge of the potential for crossover of highly concentrated uranium solutions into unfavorable tanks as a result of open valves or other anomalies in the piping systems.

Following a review of the incident, the NRC concluded that there appeared to be other root causes in addition to those given by the licensee. These root causes include:

1. The safety basis for the plant was less than adequate because a documented safety analysis was not available.

2. As a result of the lack of a detailed safety analysis, equipment important to safety, such as valves, were not properly identified, protected, emphasized in plant control documents and training sessions, tested and maintained appropriate to their safety function, and did not possess positive closure indication.

3. The design basis of the plant was less than adequate. The system drawings lacked adequate detail.

The licensee missed an opportunity to preclude the problems several years earlier when modifications were made to the piping system. The licensee's reviews of the modifications failed to identify the significant potential for uranium solutions to flow into unfavorable geometry vessels.

Actions Taken to Prevent Recurrence

Licensee—Corrective actions included modification of the piping system to prevent highly concentrated uranium solutions from flowing into the unfavorable geometry tanks. A review of the fuel recovery facility was initiated to identify the nuclear safety features and controls for each unfavorable geometry vessel. A Nuclear Criticality Safety Performance Improvement Program (PIP), that had been instituted prior to the incident, was accelerated and expanded to address the root causes. Training was also given to fuel recovery personnel to make them aware of the problem.

NRC—The special NRC team inspection (Ref. 2) identified two violations dealing with (1) failure to perform an adequate evaluation of equipment joined by piping for the possibility of siphoning and (2) failure to adhere to the administrative criticality safety limit of 350 grams of uranium-235 in unfavorable geometry tanks.

The NRC inspected the actions taken and, following the licensee's identification of the safety features and controls, issued a letter authorizing resumption of solution transfers on December 18, 1990 (Ref. 3). An Enforcement Conference with the licensee was held on January 18, 1991. On March 20, 1991, the NRC forwarded a Notice of Violation (for the violations identified during the special NRC team inspection) and proposed a civil penalty of $10,000 (Ref. 4). The two violations were classified as Severity Level II on a scale in which Severity Levels I and V are the most and least significant, respectively. The licensee has paid the civil penalty.

In early 1991, the NRC prepared an action plan for the licensee's facility. This plan is updated quarterly and tracks the completion of the licensee's PIP items, quarterly NRC and licensee management meetings on the PIP status, and NRC technical reviews of PIP. Other items addressed in the plan include license renewal milestones and management meetings on decommissioning activities. A full-time resident inspector started at the facility on April 22, 1991.

This item is considered closed for the purposes of this report.

Other NRC Licensees
(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are currently over 8000 NRC nuclear material licenses in effect in the United States, principally for use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category from licensees such as radiographers, medical institutions, and byproduct material users. The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that four events were abnormal occurrences.

91-2 Medical Diagnostic Misadministration at Hutzel Hospital in Detroit, Michigan

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or

more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—January 17, 1991; Hutzel Hospital; Detroit, Michigan.

Nature and Probable Consequences—On January 24, 1991, the licensee notified NRC Region III that a medical diagnostic misadministration had occurred at its facility on January 17, 1991, when a patient was administered a dosage of iodine-131 that was 100 times greater than prescribed. A written report was received by Region III on February 1, 1991.

On January 16, 1991, a 37-year-old female patient (who had given birth to a baby 2 days earlier) was scheduled to have a thyroid scan to determine if she had a substernal goiter (beneath the breastbone). The licensee's normal procedure for such a thyroid scan usually involves administration of a 50-microcurie dosage of iodine-131. This would typically result in a thyroid dose in the range of 50–70 rads. The prescription for the procedure was prepared by a physician's assistant at the direction of the referring physician. The nuclear medicine technologist subsequently discussed the procedure with the physician's assistant and questioned whether or not the thyroid scan was the appropriate procedure. The technologist indicated a whole body scan to identify thyroid tissue throughout the body would be the appropriate test. The physician's assistant agreed and submitted a new order for the whole body scan. The iodine-131 was administered to the patient on January 17, 1991, with the whole body scan performed on January 18, 1991. The procedure constitutes a misadministration because the referring physician had not intended to perform a whole body scan using iodine-131.

The whole body scan involved a dosage of 5 millicuries of iodine-131 instead of 50 microcuries, which would have been used for the diagnostic procedure actually prescribed by the referring physician. Although the whole body scan is a diagnostic test—intended for patients who have had their thyroid removed—the 5-millicurie dosage is in the range that may be used for treatment of thyroid disorders.

Prior to administering the iodine-131, the technologist determined that the patient was not breast-feeding her baby and did not intend to breast feed. (Breast-feeding a baby is a concern because the radioactive iodine can be passed to the baby through the milk.) Some direct radiation exposure was received by the baby due to the presence of the iodine-131 in the mother's body. This exposure, however, was minimal (estimated to be approximately 0.5 millirads) because the baby was with the mother for only a 30-minute period because of the mother's medical problems. After the misadministration was discovered, contact between the mother and baby was restricted for two days to avoid further radiation exposure to the infant.

The NRC retained a medical consultant to evaluate the circumstances of this case. The consultant estimated that the patient received a dose of approximately 6500 rads to her thyroid. This exposure would carry a slightly increased risk of developing hypothyroidism or thyroid cancer. Because the patient was lactating, thus concentrating the radioactive iodine in the breasts, there would also be an increase in the patient's risk of breast cancer. The consultant recommended periodic monitoring of the patient for hypothyroidism and for breast and thyroid cancer.

Cause or Causes—This misadministration was caused by the modification of the intended diagnostic procedure as a result of the discussion between the physician's assistant and the nuclear medicine technologist. This modification, which involved substantially increasing the dosage of radioactive iodine-131, was not reviewed by or approved by the patient's physician. The physician, in fact, desired the thyroid scan procedure using the lower dosage.

An NRC inspection to review the circumstances of the misadministration (Ref. 5) also determined that the hospital had not provided training in the proper ordering and administration of radiopharmaceuticals to individuals working under the supervision of a physician designated on the NRC license.

Actions Taken to Prevent Recurrence

Licensee—The hospital adopted new procedures requiring specific approval by an authorized physician prior to the oral administration of more than 50 microcuries of iodine-131. This authorization is to be obtained immediately prior to the planned administration. The hospital also reaffirmed that the technologist and physician's assistants are not permitted to change an order given by an attending physician.

The hospital recommended that the patient be placed on a thyroid hormone to inhibit the growth of thyroid nodules and that she be monitored for possible development of hypothyroidism or other complications.

NRC—A special inspection was conducted February 19, 1991, to review the circumstances surrounding the misadministration (Ref. 5). The inspection identified two apparent violations associated with the incident: (1) failure to instruct supervised individuals on the principles of radiation safety, and (2) use of NRC-licensed material by unauthorized individuals. These

beginning of the treatment, resulting in a total treatment dose of about 59,000 rads to the base of the tumor and 19,500 rads to the apex of the tumor. The licensee stated that the dose received by the tumor was within acceptable medical treatment protocols for that type of tumor, and that no acute effects were observed in the patient.

NRC Region I contacted an NRC medical consultant to review the event. The consultant stated that there was an increased risk of long term adverse effects, (e.g., cataract, tissue damage).

Cause or Causes—The causes are attributed to human error on the part of the licensee's staff physicist, lack of written procedures, and lack of dual verification of dose calculations prior to administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee's planned corrective actions include establishing written protocol for this procedure, including a second verification of the treatment calculations prior to administration of dosages to patients.

NRC—An NRC Region I inspector conducted a special inspection of the circumstances surrounding this misadministration on February 25, 1991. The inspection report was forwarded to the licensee on March 11, 1991 (Ref. 6). The report notes that the inspector suggested that the licensee establish a written protocol for the procedure and the licensee agreed. The report also identified one violation of NRC requirements, i.e., failure to notify the NRC of the therapy misadministration within 24 hours of discovery. A management meeting between NRC Region I and licensee management was conducted on March 21, 1991, to review the licensee's actions to prevent recurrence.

This item is considered closed for the purposes of this report.

91-5 Medical Therapy Misadministration at Clara Maass Medical Center in Belleville, New Jersey

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—March 28, 1991; Clara Maass Medical Center; Belleville, New Jersey.

Nature and Probable Consequences—On March 28, 1991, the licensee informed NRC Region I that a therapeutic misadministration, involving administration of iodine-131 to the wrong patient, had occurred earlier that day.

A radiotherapy physician prescribed a therapeutic dosage of 10 millicuries of iodine-131 to a patient for the treatment of hyperthyroidism. The physician that was familiar with the patient was not able to administer the therapeutic dosage and asked another physician to administer it. In the meantime, a transporter, while reviewing the patient transport requests, noted that the patient was listed in a bed that she believed was occupied by another patient. The transporter notified the nuclear medicine secretary to check into the discrepancy. The secretary referred to a patient list for the patient's name, noted the area of the hospital where the patient's room was, and changed the request form. The secretary did not know that there were two patients in the hospital with the exact same names. (The second patient was in the hospital for a lung condition.) Also, the secretary did not know the computer program that generated the patient list did not print duplicate entries. The patient's name who was to undergo treatment for hyperthyroidism was not printed on the list.

The physician who administered the dose picked up the request form and the iodine-131 dosage from the Nuclear Medicine Department and went to the nursing station on the floor of the patient with the lung problem. The physician did not inform the nursing staff that he was about to administer a therapeutic dosage to one of their patients and went to the lung patient's room. There, he asked the patient his name and verified the name on the wrist band but did not cross check the patient number on the wrist band with the patient number on the request form. The physician completed the request form and returned the patient folder to the nurses' station. Within five minutes of the administration of the radiopharmaceutical, the nurses discovered the error and informed the physician and the Radiation Safety Officer. The licensee decided to administer a thyroid blocking agent of 1000 milligrams of potassium iodide immediately, with three subsequent doses of 1000 milligrams each given at four hour intervals.

The licensee determined that the thyroid of the patient received an uptake of between 80 and 100 microcuries of iodine-131 which would give a dose of between 112 and 140 rads. An NRC medical consultant, who reviewed the event, concurred with these figures. The licensee advised the NRC that no adverse effects were anticipated during the lifetime of the patient as a result of the misadministration.

Cause or Causes—The causes were attributed to failure to follow the hospital protocol of checking the

patient identification number, and failure to inform the head nurse of the floor of the therapeutic procedure, prior to administration.

Actions Taken to Prevent Recurrence

Licensee—The licensee's planned corrective action includes establishing a check list that must be completed by individuals administering therapeutic dosages. The check list will require that the person administering the dosage to check, as a minimum, the type of radiopharmaceutical to be administered, the activity of the dosage, the name of the patient, and the patient number; it will also require notification of the nursing staff that one of their patients is undergoing radiopharmaceutical therapy. Other actions include changing the computer program so that all of the information is printed out on the patient list, and reinstruction to personnel regarding patient verification procedures.

NRC—On April 1, 1991, a Region I inspector conducted a special inspection of the circumstances surrounding this misadministration. The inspection report was forwarded to the licensee on April 17, 1991 (Ref. 7). No violations of regulatory requirements were identified. The licensee's corrective actions are considered satisfactory.

This item is considered closed for the purposes of this report.

Agreement State Licensees

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. The Agreement State of Arizona reported the following event as an abnormal occurrence. The writeup is based on information provided to the NRC during late 1990.

AS91-1 Medical Therapy Misadministration at Good Samaritan Medical Center in Phoenix, Arizona

Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—February-June 1989; Good Samaritan Medical Center; Phoenix, Arizona.

Nature and Probable Consequences—On July 26, 1989, the licensee reported to the Arizona Radiation Regulatory Agency (State Agency) a series of three misadministrations involving the use of a cobalt-60 teletherapy unit in the licensee's Radiation Oncology Department.

The three patients received exposures of approximately 14%, 11%, and 12% greater than the prescribed doses of 6200 rads, 6480 rads, and 5000 rads, respectively, from an AECL Theratron-80 unit containing 5529 curies of cobalt-60 assayed on September 16, 1988. A beam correcting wedge had been used along with a treatment planning computer. Although the computer already contained a wedge correction factor, the technologist and dosimetrist added a second wedge correction factor after checking with the consulting physicist and being told that a wedge factor would be required.

While preparing to treat a fifth patient assigned the same treatment protocol, a point hand calculation indicated a wide discrepancy when compared to the computer generated treatment time. This discrepancy led to a comprehensive search of past cases which revealed the three overexposures out of four possible cases.

All three patients showed signs of skin erythema (reddening) and the first two patients (who had received radiation to the larynx region) reported hoarseness and pain on swallowing. The licensee stated that these symptoms are not unusual for patients undergoing radiotherapy, and in fact, these same symptoms were mentioned to the patients as possible side effects of the treatment.

Cause or Causes--A consulting physicist was retained to review patient records and the hospital's handling of this case. Among the findings were:

a. The hospital staffing level was inadequate for the patient load.

b. There was a loss of continuity in physics services with the departure of one physicist and the hiring of another physicist.

c. There was poor communication (documentation) regarding the use of the computer generated treatment plans.

Actions Taken to Prevent Recurrence

Licensee—The licensee has hired a full time qualified therapy physicist and a technical administrator. These individuals will not have responsibilities outside of the therapy department.

In addition, the bed of the truck, from which the shipping container fell, was a flat steel deck with no obstructions at the rear of the truck except for a canvas cover held in place with four elastic straps. During transportation, several shipping containers were fastened on the truck bed by locks attached to the containers and to the 3/8-inch diameter links of a slack steel chain, which was attached to structural members of the truck. The chain did not surround the shipping containers, freeing them to move on the truck bed. Apparently, the slack allowed the shipping containers to accelerate when the vehicle turned corners, breaking a lock and allowing the subject shipping container to fall off the back of the truck.

The police officer who held the source received an estimated exposure of approximately 5 rem to his fingers. The individual who retrieved the source received an estimated exposure of approximately 150 millirem to his fingers.

Cause or Causes—The event was attributed to human error. Licensee personnel did not follow the licensee's procedures or management instructions in correcting shipping container deficiencies and in properly securing the shipping containers to the transporting vehicle.

Actions Taken to Prevent Recurrence

Licensee—On September 6, 1991, the day after the incident, the licensee issued a memorandum to all their North American facilities. This memorandum concerned corrective measures that were effective immediately. Subsequently, the licensee took additional corrective actions to prevent such losses.

NRC—On September 6, 7, and 11, 1991, NRC Region IV inspectors conducted a special, announced radiation safety inspection of the licensee's byproduct material program (Ref. 1). The inspection included the review of organization, management, training, radiation protection, independent measurements, notification, and transportation activities. Seven apparent violations of NRC regulations were identified. Escalated enforcement action is under consideration.

Future reports will be made as appropriate.

91-9 Medical Diagnostic Misadministration at St. John's Mercy Medical Center in St. Louis, Missouri

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—September 9, 1991; St. John's Mercy Medical Center in St. Louis, Missouri.

Nature and Probable Consequences—A bone scan diagnostic study was scheduled for September 9, 1991, for a 15-month-old male child with possible osteomyelitis (bone inflammation) of the ankle. The child was given an adult dose of technetium-99m MDP, the radioactive pharmaceutical used for a bone scan. The normal dose for a child of his weight would be 1.91 millicuries. The standard adult dosage used for the diagnostic study was about 21.96 millicuries, more than 10 times the intended dosage to the child.

The licensee uses a computer system as an aid to determine the appropriate amounts of the radiopharmaceutical to use in the bone scan. For adult patients, there are standardized dosages; for patients under 18 years old, the dosages are calculated on the basis of body weight. The pediatric patients are identified on the licensee's treatment list with an asterisk, accompanied by a handwritten notation of the patient's body weight.

The radiopharmacist who prepared the technetium-99m MDP for the bone scan failed to note the asterisk and handwritten body weight on the computer printout of scheduled diagnostic studies. As a result, he prepared the standard adult dosage.

The nuclear medicine technician did not detect the error prior to administering the radiopharmaceutical to the patient. The technician checked the patient's name on the dose ticket accompanying the syringe, but did not verify the radiopharmaceutical and dosage, as required by hospital policy. After the administration, the technician noted the volume of the technetium-99m MDP was greater than expected, rechecked the dose ticket, and discovered the error.

The error did not negate the results of the diagnostic study and the bone scan was completed. Although the amount of radiation the child received was greater than intended, the licensee determined the increased risk of biologic effects was not significant. The calculated radiation dose for the study was about 4.4 rads to the bone and 1.3 rads to the total body. This compares to about 0.38 rads to the bone and 0.11 rads to the whole body had the correct dosage been administered.

Cause or Causes—The cause is attributed to human error on the part of the radiopharmacist and the nuclear medicine technician.

Actions Taken to Prevent Recurrence

Licensee—The hospital has counseled the two employees involved in the error. Hospital management met with the nuclear medicine department staff on September 17, 1991, to review the impact of the errors in this incident, to stress the importance of checking one's own work as well as the work of others, and to point out the need to follow department policies.

NRC—The NRC staff has reviewed the circumstance of the misadministration and will evaluate the licensee's corrective actions in a routine inspection to be conducted in the next several months.

This item is considered closed for the purposes of this report.

Agreement State Licensees

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in these quarterly reports to Congress. For this period, the Agreement States reported no events as abnormal occurrences.

of the drum. Rather than question why he did not register any reading, he assumed that all items inside the package had been properly secured and he allowed it to continue on to its destination.

The package arrived at Therapeutic Nuclides on Monday, November 5, 1990, but it was not opened until the following day. When the package was opened and discovered empty, the Radiation Safety Officer for Therapeutic Nuclides immediately notified the Los Angeles County Radiation Control office (Agency) and an investigation was begun. An Agency inspector contacted Federal Express in an attempt to backtrack the route the package took from the time it was picked up at the hospital. She was able to focus her search on the Hub facility at LAX and discovered the sources there as soon as she entered the facility.

All seven sources were located in various places throughout the facility by the inspector. Federal Express personnel who came in contact or worked near where the sources were found were interviewed. Those individuals who came in close contact with the sources were sent for medical evaluation and followup. Dose estimates were established for all workers and all were notified of their estimated doses. Individual dose estimates for the 24 employees involved ranged from 10 mrem to 1810 mrem whole body. Also, three individuals who said they touched the sources had estimated extremity doses that ranged from 90 to 260 rem.

The U.S. Department of Transportation (DOT) investigated whether the package of sources was properly secured prior to pick-up by Federal Express. There is strong evidence that the package was not properly sealed; therefore, when it fell down the conveyor belt it easily spilled open. The hospital staff supplied sworn statements to Radiation Control Program staff that they had followed all procedures when they packaged the sources; however, DOT has run extensive tests on the container and has concluded that if it had been sealed properly, it would not have spilled its contents.

Actions Taken to Prevent Recurrence

Hospital—After long delays, the hospital complied with the dose notification requirements.

State Agency—A Notice of Violation was issued to the hospital for failure to report the incident and also for the exposures to personnel in excess of permissible levels. The case was closed on November 13, 1991.

Other—Therapeutic Nuclides has redesigned their container to prevent this type of spill in the future.

Unless new, significant information becomes available, this item is considered closed for the purposes of this report.

AS91-7 Medical Therapy Misadministration at Northridge Hospital Medical Center in Northridge, California

Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

This writeup is based on information provided to the NRC in December 1991 by the Agreement State of California for inclusion in this report.

Date and Place—May 3, 1991; Northridge Hospital Medical Center in Northridge, California.

Nature and Probable Consequences—On May 3, 1991, 15 mCi of iodine-131 intended for patient "A" was administered in error to patient "B" who had the same first and last names as patient "A." The administration was made by the hospital's Certified Nuclear Medicine Technologist without the responsible physician present, which is a violation of the California Radiation Control Regulations. Patient "B" had reported to the hospital's Outpatient Department for a preoperational chest x-ray instead of reporting to her doctor's private office as she was instructed. Patient "A" was scheduled to receive a hyperthyroidism treatment that same morning.

When her name was called, patient "B" answered and signed the consent form. She asked questions of her technologist about thyroid disorders and was given answers. The dose of 15 mCi was administered.

Later that same day, patient "A" presented herself for the treatment. It was then that the hospital discovered that they had administered the dose to the wrong patient. Patient "B's" doctor was contacted and consulted with the Chief Nuclear Medicine physician. They decided to give patient "B" 15 drops of a potassium iodine solution three times daily for three days plus forced fluids to reduce the uptake of the radioactive iodine. She underwent the previously scheduled surgical procedure three days after the dose was administered without any regard for the possible exposure of surgical room staff from the patient.

This incident was reported to the wrong unit of California's Department of Health Services by the

hospital five days after it occurred. Not realizing the significance of the error, Radiologic Health was not contacted until May 31, 1991, 28 days after it occurred. An investigation was begun by the Radiologic Health Unit of the Los Angeles County Health Department, the inspection agency for this licensee. The inspector discovered that the hospital had originally estimated the patient's thyroid dose to be much lower than it actually was. The agency retained a consultant who performed a complete workup of the patient. The patient's dose was established at 3000 rem to the thyroid and she was informed of this in writing by the hospital. She was placed into a treatment followup program.

An evaluation of exposures to the surgical room staff was also made by the consultant. Their exposures were determined to be minimal and they were also notified by the hospital.

Cause or Causes—The administration was made by the hospital's Certified Nuclear Medicine Technologist without the responsible physician present.

Actions Taken to Prevent Recurrence

Licensee—An enforcement conference was held at the Los Angeles County Health Department between members of the hospital administrative staff and representatives of the County and State Radiation Control Program staff. The hospital presented an extensive corrective action plan and explained new controls that would be put in place.

Agency—Representatives of the Radiologic Health Branch accepted the plan and the case was referred to the city attorney's office for determination if charges should be filed.

This item is considered closed for the purposes of this report.

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES OCTOBER–DECEMBER 1991

Nuclear Power Plants

The NRC is reviewing events reported at the nuclear power plants licensed to operate. For this report, the NRC has not determined that any events were abnormal occurrences.

Fuel Cycle Facilities
(Other Than Nuclear Power Plants)

The NRC is reviewing events reported by these licensees. For this report, the NRC has not determined that any events were abnormal occurrences.

Other NRC Licensees
(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are currently over 8000 NRC nuclear material licenses in effect in the United States, principally for use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category from licensees such as radiographers, medical institutions, and byproduct material users. The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that the following events were abnormal occurrences.

91-10 Medical Diagnostic Misadministration at I. Gonzalez Martinez Oncologic Hospital in Hato Rey, Puerto Rico

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—June 17, 1991; I. Gonzalez Martinez Oncologic Hospital; Hato Rey, Puerto Rico.

Nature and Probable Consequences—On June 17, 1991, a patient scheduled to receive a diagnostic dose of iodine-131 (I-131), was mistakenly administered a dose of I-131 in the therapeutic range. The misadministration occurred when a nuclear medicine technologist misread the dose calibrator and administered 6.2 millicuries rather than 6.2 microcuries. The technologist realized the error nine minutes after the dose was administered when the printed dose label from the dose calibrator was checked. The physician-in-charge promptly administered potassium iodide solution to the patient to reduce the uptake of the radioactive iodine. The licensee estimated, based on 24-hour uptake measurements, that the uptake of radioactive iodine in the thyroid was approximately five percent resulting in an estimated dose to the thyroid of 1612 rem. The misadministration was promptly reported to the NRC.

The licensee continues to follow the patient's condition and has advised the NRC that the patient has not experienced any adverse effects because of the misadministration.

Cause or Causes—The cause is attributed to human error by the nuclear medicine technologist. The technologist did not verify the dose by reviewing the printed dose label before administering the dose.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions included taking disciplinary action against the technologist and requiring that the nuclear medicine supervisor check each dose before the dose is administered to a patient.

NRC—NRC Region II conducted an inspection to review the circumstances associated with the misadministration, and to review the licensee's correc

tive actions. No violations of NRC requirements were identified during the inspection.

This item is considered closed for the purposes of this report.

91-11 Medical Therapy Misadministration at William Beaumont Army Medical Center in El Paso, Texas

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see the overall criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place—August 30, 1991; William Beaumont Army Medical Center; El Paso, Texas.

Nature and Probable Consequences—On August 30, 1991, a patient referred to the Medical Center for therapeutic radioiodine treatment of Graves' disease, mistakenly received a 28.6 millicurie (mCi) oral dosage of iodine-131 (I-131) instead of the prescribed oral dosage of 15.0 mCi I-131. As a result, the patient's thyroid received about 31,900 rads instead of the 16,700 rads intended.

Prior to the administration, the radiopharmacist involved was informed that a radioiodine treatment for Graves' disease had been requested. He assumed that it was a 29 mCi treatment rather than a 15 mCi treatment. [At the Medical Center, a 15.0 mCi dose is routinely used for Graves' disease while a 29.0 mCi dosage is used for thyroid disorders such as multinodular toxic goiters.] He then requested a 29.0 mCi dose from Syncor, the commercial radiopharmacy. The actual dose received from Syncor was 28.6 mCi, and was labeled as such. When the radiopharmacist logged the dosage into the computer, after it had been measured by the dose calibrator, he failed to take note of the intended therapy dose as reflected in the referring physician's prescription. In addition, the counseling nuclear medicine physician did not verify the dosage to be administered with the intended dosage. The 28.6 mCi incorrect dosage was then administered to the patient.

The referring physician was notified on the day of the misadministration. The licensee stated that no adverse effects on the patient were noted. The patient's condition will be appropriately followed in the licensee's Endocrine Clinic.

Cause or Causes—The event was attributed to human error as a result of the radiopharmacist's and consulting nuclear medicine physician's inattentiveness and short experience at this facility. Although the prescribing physician's written request was available at the time the dosage was ordered and administered, both individuals failed to compare the prescribed dosage with the dose calibrator assay result or the radiopharmaceutical package label. Additionally, both the radiopharmacist and consulting nuclear medicine physician had only been working at the facility for a short time and were unfamiliar with the use of radioiodine dosages as low as 15 millicuries for the treatment of Graves' disease. The physician's previous experience and personal preference involved a routine dosage of 25-30 millicuries for a hyperthyroid disorder, and the radiopharmacist had dispensed only a few therapeutic radioiodine dosages, involving higher dosages, prior to this particular case. The licensee also acknowledged that the consulting nuclear medicine physician may not have realized that the patient was receiving treatment for Graves' disease rather than a multinodular toxic goiter at the time the dosage was administered.

Actions Taken to Prevent Recurrence

Licensee—The radiopharmacist and consulting nuclear medicine physician were counseled and reinstructed as to the proper dose verification techniques and safeguards. For future therapies using radiopharmaceuticals, the counseling nuclear medicine physician must visually check the activity of the radiopharmaceutical dosage, as measured by the radiopharmacist or technologist, with the written physician prescription. The licensee also intends to require that the consulting nuclear medicine physician be familiar with the patient's case history prior to administering a therapeutic radiopharmaceutical dosage.

Also, the licensee's Radiation Safety Officer will conduct a training session in which all nuclear medicine personnel will be required to review the videotape entitled, "Good Practices in Preparing and Administering Radiopharmaceuticals," prepared by the NRC's Office for Analysis and Evaluation of Operational Data.

NRC—NRC Region IV conducted an inspection to review the circumstances associated with this misadministration and the licensee's corrective actions as described above (Ref. 1). The inspection revealed no violations of regulatory requirements regarding this misadministration, and the licensee's determination of the cause of the event was considered accurate based upon interviews of the individuals involved. The licensee had implemented

rads based on an uptake of 66 percent and the dose to the whole body to be approximately 6.25 rads.

Cause or Causes—It was determined that one of the causes of the misadministration was a miscommunication between staff at both the referring endocrine clinic and Baystate. Other causes were failure of the staff at Baystate to follow regulatory procedures involving radioiodine doses greater than 30 microcuries which require that an authorized user prepare a written directive prior to the administration. Nuclear Medicine Departmental procedures also require that when an order for a requested study is unclear or illegible, the referring physician be contacted prior to the performance of the study.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions included: (1) instruction of nuclear medicine staff in the department procedures and regulatory requirements for radioiodine studies; (2) preparation, prior to the administration, of a written directive by the Director of Endocrine (an authorized user), or a designated authorized user before any iodine study using greater than 30 microcuries is performed; (3) prompt transmittal of written requests for nuclear medicine studies from the clinics to the Baystate Medical Center, Nuclear Medicine Division, in order to compare the request to the computer entry prior to the administration; and (4) review of this patient's progress once every six weeks for three months.

NRC—An NRC Region I inspector conducted an inspection on May 27 and 28, 1992, to determine the circumstances associated with the misadministration (Ref. 9). An NRC medical consultant worked with the licensee to provide a clinical assessment of the misadministration. Although the medical consultant calculated the thyroid dose to be considerably less than the licensee's estimate, his evaluation of the event and consequences to the patient were similar to the licensee's evaluation. They were in agreement that because the patient was diagnosed as having Graves' disease, the ultimate therapy would be treatment with about 10 millicuries of iodine-131 (compared to about 4 millicuries that were mistakenly administered). Therefore, the patient did not suffer adverse health effects from the misadministration worse than those normally associated with treatment of Graves' disease.

The NRC inspection identified two apparent violations of NRC requirements: (1) failure of authorized user to prepare a written directive, and (2) failure to follow procedures. An enforcement conference was held on June 23, 1992. Enforcement action is pending.

Future reports will be made as appropriate.

92-8 Medical Therapy Misadministration at The Christ Hospital in Cincinnati, Ohio

The following information pertaining to this event as also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is less then 0.5 times the prescribed dose can be considered an abnormal occurrence. In addition, some tissue received considerably more radiation than it would have had the treatment been as prescribed.

Date and Place—May 29, 1992; The Christ Hospital; Cincinnati, Ohio.

Nature and Probable Consequences—On May 29, 1992, the licensee performed an implant of radiation seeds for treatment of a patient's prostate cancer. The patient had previously received radiation treatment to the prostate using a linear accelerator. The implant treatment plan called for placement of 58 seeds, each containing 0.31 millicuries of iodine-125. The seeds were to be implanted in the prostate using needles guided by an ultrasound image. The implanted seeds were to deliver a dose of 12,000 rads to the prostate.

The 58 seeds were implanted, but a subsequent computerized tomographic scan showed that 21 seeds were implanted in tissue surrounding the prostate rather than the intended sites. Two seeds were eliminated with the patient's urine. The licensee calculated that the mispositioning of the seeds resulted in the patient receiving a 5,000 rad dose to the prostate rather than the intended 12,000 rad dose.

The principal consequence of this misadministration is the potential effects of the underdosage to the prostate. In addition, tissue surrounding the prostate received a greater radiation dose than intended. The prescribing physician concluded that the delivered dose from the implanted seeds and from the previous linear accelerator treatment was sufficient. An NRC medical consultant, retained to evaluate the circumstances and response to the misadministration, noted: "Tumor recurrence is the greatest risk, and it will be monitored closely." The consultant also concluded that there was not a high probability of radiation damage to the rectum, which would be the area of principal concern.

Cause or Causes—The misadministration resulted from the difficulties in the ultrasound placement technique. The ultrasound image is difficult to interpret in guiding the placement of the seeds with the implanting needles. The prescribing physician, who is the Authorized User in the NRC license, had been trained and certified in the ultrasound guided implant technique, but had not actually performed the procedure.

brachytherapy applicator and administered to the patient. Because all the sources were smaller in diameter than the intended sources, they slipped from the prescribed position and irradiated normal tissue not intended to be irradiated. The applicator was loaded by a technologist who had never performed the procedure. The technologist was supervised by a technologist who had not performed the procedure in eight years, when the incorrect sources were in active use. The incorrect sources were discovered at the midpoint of the treatment by the licensee's medical physicist during an unplanned training session for a new physicist. The incorrect sources were promptly removed from the patient and the treatment restarted and completed as directed by the authorized user.

The licensee estimated the dose to normal tissue was approximately 400–500 rads. The licensee advised the NRC that no adverse effects to the patient are anticipated as a result of the misadministration.

Cause or Causes—The causes are attributed to the licensee's failure to: (1) properly train individuals handling brachytherapy sources, (2) adequately implement a Quality Management Program (QMP), (3) develop and implement adequate QMP procedures, and (4) properly label the storage vault for the brachytherapy sources.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions included revision of the QMP policies and procedures, training all supervised individuals on brachytherapy procedures and in the revised QMP, arranging safe storage for the sources no longer in use, posting a map of the source storage vault indicating the type of source at each storage point, and enhancing source accountability practices.

NRC—Region II reviewed the circumstances associated with the misadministration and the licensee's immediate corrective actions during a reactive inspection on April 10, 1992, and a follow-up inspection on April 22 and 23, 1992, which included NRC consultants in the areas of medical physics, oncology, and risk assessment (Ref. 6). NRC Region II conducted an Enforcement Conference with the licensee on May 20, 1992, to discuss the event (Ref. 7). A notice of Violation and Proposed Imposition of Civil Penalty in the amount of $2,500 was issued on June 26, 1992 (Ref. 8).

This action was based on two violations that contributed to the brachytherapy misadministration: (1) failure of the QMP to include written policies and procedures to verify the use of correct brachytherapy sources and identify any unintended deviations, and (2) failure to instruct supervised individuals in the principles of radiation safety and the QMP. Each violation was categorized at Severity Level III on a scale in which Severity Levels I through V are the most significant and least significant, respectively. Each violation was assessed a proposed civil penalty of $1,250. Six other violations (including the failure to notify the NRC within 24 hours after discovery of a therapy misadministration) were also cited at either Severity Level IV or V and involved the licensee's radiation safety program.

Unless new, significant information becomes available, the item is considered closed for the purposes of this report.

92–7 Medical Diagnostic Misadministration at Baystate Medical Center, Incorporated, in Springfield, Massachusetts

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 4 in Table A–1) of this report notes that administering a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose can be considered an abnormal occurrence.

Date and Place—May 19, 1992; Baystate Medical Center, Incorporated (Baystate); Springfield, Massachusetts.

Nature and Probable Consequences—On May 20, 1992, the licensee notified the NRC by telephone that a medical misadministration involving iodine-131 (I–131) radiopharmaceuticals had occurred at the licensee's facility the previous day. A diagnostic dose was intended; however, a therapeutic dose was administered. The details of the event are described below.

A nurse from the referring endocrine clinic called Baystate to make an appointment for a patient for a thyroid scan and I–131 uptake study. Baystate's departmental procedure for a thyroid scan and I–131 uptake is to perform the study using 16 microcuries of I–131 and 10 millicuries of technetium-99m. A whole body scan requires that approximately 4 millicuries of I–131 be given to the patient. Apparently, the order was entered in the patient's scheduling chart as a whole body scan rather than the thyroid scan and I–131 uptake study which was intended. Questions were raised on several occasions by licensee personnel because the patient was diagnosed with an enlarged thyroid and generally an I–131 whole body scan is not indicated for this diagnosis. Also, an authorized user was not consulted to review the study and prepare a written directive prior to the administration of greater than 30 microcuries of I–131 as required by 10 CFR 35.32. A nuclear medicine technologist administered 4.1 millicuries of I–131 for a whole body scan without following the department's procedures for administration of I–125 or I–131. The licensee evaluated the dose to the patient's thyroid to be approximately 14,300

MBq (5 mCi) of P-32, as an outpatient receiving radiation therapy treatment. The patient was discharged in stable condition. The mistake was caught when the Chief Technologist was reviewing the records of doses prescribed and comparing these to the doses administered. Immediate action was taken to follow-up on the discrepancy. The attending physician and patient were notified of the misadministration. The patient's blood count monitoring frequency was changed from monthly to bi-weekly and the patient was monitored for potential infections. Six weeks after the administration of P-32, the patient's blood count was normal except for a decrease in the platelet count, which remained within the range of safety and represented the expected therapeutic response.

Cause or Causes—The licensee's account of the cause is as follows: The stated package dose was 185 MBq (5 mCi), calibrated to a date 10 days after the date on which the technologist drew the dose. The technologist failed to take notice of the calibration date and assumed that the stated package dose of 185 MBq (5 mCi) was drawn for administration. Although the dose calibrator measurement of the prepared (drawn) dose indicated a significant discrepancy between the prescribed dose and the measured dose, the technologist failed to investigate the cause of this discrepancy and did not notify the physician in regard to the discrepancy. A dose of 303.4 MBq (8.2 mCi) was administered to the patient by the physician, a Board Certified Radiologist.

Actions Taken to Prevent Recurrence

Licensee—The corrective actions reported by the licensee included the implementation of a modified radiopharmaceutical therapy protocol for P-32 and iodine-131 administrations, and training for the technologists. In addition, a work sheet and check list, designed with several checks for technologists and physicians prior to administration of the dose, were developed for P-32 therapy. The physician involved in the procedure was counselled and the technologist was suspended from administration of therapy doses for a minimum period of six months. The Chief Technologist and Nuclear Medicine Physician will evaluate the technologist prior to allowing him or her to begin administering therapeutic doses again.

State Agency—The State required the licensee to submit a plan of corrective action designed to prevent recurrence. The corrective actions reported by the facility appear to be satisfactory.

This item is considered closed for purpose of this report.

AS 93-8 Medical Sodium Iodide Misadministration at Inland Imaging in Spokane, Washington

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences," July-September 1993. The abnormal occurrence is updated as follows:

Date and Place—December 14, 1992; Inland Imaging: Spokane, Washington.

Nature and Probable Consequences—On December 14, 1992, a patient diagnosed as hyperthyroid was referred to the licensee by the Fairchild Air Force Base Hospital for a thyroid uptake scan of .26 megabecquerel (MBq) to 3.7 MBq (7-10 microcuries) of iodine-131 (I-131). The patient was mistakenly administered a 196 MBq (5.3 millicurie) dose of I-131, sodium iodide for a whole body scan. As a result, the patient's thyroid received a dose of approximately 7950 centigray (7950 rad).

The nuclear medicine technologist misinterpreted the orally requested procedure and failed to verify the requested procedure through review of the referring physician's written requisition. The patient's physician, an endocrinologist, was notified and did inform the patient.

The licensee reported that both a whole body scan and the requested thyroid uptake study were performed three days after the misadministration "with no patient complaints or immediate side effects." The licensee has noted that the patient will most probably be hypothyroid for the rest of his life and that future litigation remains a possibility. No NRC or State medical consultant has been contracted to review this event.

Cause or Causes—This event was attributed to human error as a result of the technologist's inattentiveness and relatively short experience at this facility. Although the referring physician's written request was available at the time the dosage was prepared and administered, the technologist failed to reconcile the dose and study prescribed with the dose and study given.

Actions Taken to Prevent Recurrence

Licensee—The technologist and the lead technologist (who was not present) were counseled and reinstructed by the authorized physician user/radiation safety officer. A review by the licensee of all such administrations for the prior 6 months revealed that the technologists were inconsistent in verifying written referrals with the study given, prior to administration. The licensee stated that all iodine studies are required to be verified against the written request slips prior to any iodine administration.

where the dosimetrist performed treatment planning. All three facilities were notified and had independent physics reviews of treatment plans. At one of the hospitals, mistakes were found in two treatments involving a wedge; however, the total dose delivered was within 10 percent of that prescribed. At that same hospital, a mistake in the calibration of an orthovoltage unit was discovered which resulted in 22 patients receiving doses in excess of 10 percent of those prescribed. That calibration was performed by the senior member of the physics consulting group. Those patients were followed up and no adverse outcomes were reported.

Cause or Causes—The dosimetrist involved lacked understanding of the computer treatment planning software and other basic methods in determining treatment times. Quality assurance of treatment planning was inadequate and no second checks of treatment plans were performed.

Actions Taken to Prevent Recurrence

Licensee—Insufficient information is available on the action(s) taken by the licensee to prevent recurrence. NRC has asked the State of New York to provide additional information regarding the licensee action(s).

State Agency—License conditions concerning the qualifications of physicists, treatment prescriptions, second checks, and misadministrations were added to all teletherapy licenses in 1988. Since that time, the State Sanitary Code has been revised to include specific requirements for quality assurance in radiation therapy for all therapy modalities. The State of New York believes that the dosimetrist involved no longer performs treatment planning in New York State. The senior physicist in the consulting group did not perform any therapy functions in New York State after the incident.

This report will be further evaluated when additional information becomes available.

AS 88-4 Multiple Medical Therapy Misadministrations by Rochester General Hospital in Monroe County, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 11, No. 4, "Report to Congress on Abnormal Occurrences," October-December 1988 and closed out at that time. It was reported that 19 patients received cobalt teletherapy misadministrations at Rochester General Hospital in Monroe County, New York, between January 1988 and August 1988.

This abnormal occurrence was reopened because the following new significant information concerning enforcement action and the status of the affected patients became available.

Enforcement action was initiated by the New York State Department of Health which included provisions that the hospital take the following actions: commit to comprehensive quality assurance reviews for radiation therapy, submit quarterly progress reports for each component of the stipulation, order of the enforcement action, implement quality assurance reviews, mandatory periodic in-service training, testing of physics staff, and perform a periodic follow-up of the affected patients for 1-year.

Reports of the patient follow-up were submitted to the State of New York, Department of Health. As of December 1990, the reported status of the patient's condition involved in the misadministration is as follows: two patients had laryngectomies; one patient had necrosis of the larynx; three patients had discomfort in the treatment area; one patient had a rib fracture; four patients had skin changes; three patients had atrophy in the breast; one patient had a radiation ulcer, one patient had radiation proctitis, and nine patients died from complications not related to the misadministration.

The State radiation control regulations have been revised to include requirements of Quality Assurance programs, audits of therapy programs, misadministration reporting and training and experience requirements for therapy physicists.

The item is considered closed for the purposes of this report.

AS 93-7 Medical Radiopharmaceutical Misadministration by "Unspecified Licensee" in Albany, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on Abnormal Occurrences," July-September 1993. The abnormal occurrence report is updated as follows:

Date and Place—October 5, 1992.

The name of the licensee has been withheld by the State of New York due to provisions in New York State Public Health law.

Nature and Probable Consequences—A patient was administered 303.4 megabecquerel (MBq) (8.2 millicurie [mCi]) of phosphorus (P-32), instead of the prescribed 185

Following the staff's review of the second occurrence on April 26, 1993, NRC issued a Civil Penalty in the amount of $10,000 and Confirmatory Order Modifying License (Effective Immediately), which confirmed the licensee's proposal to have a program assessment performed by independent experts. The program assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted their Program Assessment Report and Program Improvement Plan which was formulated in response to the program assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Program Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of $10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of $10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of $10,000.

A routine inspection was conducted of the licensee's program from September 28 through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

93-3 Medical Therapy Misadministration Involving the Use of a High Dose-Rate Remote Afterloader Brachytherapy Device at Yale-New Haven Hospital in New Haven, Connecticut

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 1, "Report to Congress on Abnormal Occurrences," January-March 1993. The abnormal occurrence report is updated as follows:

On January 21, 1993, NRC was notified by the licensee that a female patient received a 50 percent undertreatment during a brachytherapy procedure to the vagina and an unplanned 700 centigray (700 rad) exposure to her rectum when the physician mistakenly inserted the HDR applicator into the rectum instead of the vagina.

NRC Region I conducted a special inspection on January 26 and 27, 1993. The licensee was given the option of participating in an enforcement conference but declined. A medical consultant was retained to review the misadministration. On April 26, 1993, NRC proposed a Civil Penalty in the amount of $10,000 and Confirmatory Order Modifying License (Effective Immediately) which confirmed the licensee's proposal to have a Program Assessment performed by independent experts. The Program Assessment was completed on May 10 and 11, 1993. On August 24, 1993, the licensee submitted the report of the Program Assessment and their Program Improvement Plan which was formulated in response to the Program Assessment. On November 16, 1993, the licensee submitted the first of the required quarterly reports on the implementation of the Improvement Plan and stated that all actions were completed. NRC Region I has reviewed the Program Assessment Report and Program Improvement Plan and is currently preparing a response.

On June 10, 1993, the licensee responded to the Notice of Violation and Proposed Imposition of $10,000 Civil Penalty. In this response, the licensee denied one violation, took issue with the manner in which the civil penalty was determined, and requested mitigation of the civil penalty based on minimal safety significance and lack of programmatic implications. On December 27, 1993, NRC responded to the licensee's request with an Order Imposing Civil Penalties in the amount of $10,000. The licensee responded to the Order by letter dated January 26, 1994, and paid the Civil Penalty of $10,000.

A routine inspection was conducted of the licensee's program from September 28 through 30, 1993. One minor violation of regulatory requirements was identified by the inspector. This violation has since been corrected by the licensee.

This report will be updated when additional information becomes available.

93-10 Medical Sodium Iodide Misadministration at Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center in Tulsa, Oklahoma

This abnormal occurrence was originally reported in NUREG-0090, Vol. 16, No. 3, "Report to Congress on

Abnormal Occurrences: July-September 1993." The abnormal occurrence report is updated as follows:

In July 1993 the wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi]) of iodine-131 (I-131). The misadministration occurred because the licensee failed to verify patient identity.

The NRC staff retained a medical consultant to evaluate the potential medical effects to the patient as a result of the misadministration. The consultant provided a report in October 1993, which stated that the impact of the incident on the status of the patient's health should be negligible, with no expected long-term disability as a result of this misadministration.

On January 11, 1994, the NRC issued a Notice of Violation to the licensee. The licensee was cited for failing to require individuals working under the supervision of authorized users to follow the instructions of the supervising authorized user and the written radiation safety and quality management procedures established by the licensee. Because the misadministration was the result of an isolated failure to follow the quality management procedures and was of limited consequence to the patient, no escalated enforcement action was taken by the NRC.

This item is considered closed for the purpose of this report.

Agreement State Licensees

AS 87-5 Therapeutic Medical Misadministrations At Northern Westchester Hospital Center, Westchester County, New York

This abnormal occurrence was originally reported in NUREG-0090, Vol. 10, No. 3., "Report to Congress on Abnormal Occurrences," July-September 1987, and closed out at that time. It was reported that 22 patients received cobalt teletherapy misadministrations at Northern Westchester Hospital in Westchester County, New York, between 1982 and 1987.

This abnormal occurrence was reopened because the original report contained several incorrect statements. The following report was prepared by the State of New York to correct the errors.

Date and Place—On August 5, 1987, the New York State Department of Health Bureau of Environmental Radiation Protection was notified that mistakes in treatment planning had been discovered and that some cobalt teletherapy patients had received excess radiation at Northern Westchester Hospital Center.

Nature and Probable Consequences—The hospital had contracted with a physics consulting group (Radiological Physics Associates, Elmsford, New York) to provide physics services. A dosimetrist from the group, who normally prepared treatment plans, was not available and upon review of one plan by another physicist from the group, it was discovered that the dosimetrist had made errors in his calculations. The State Health Department was notified of the mistakes and the hospital was directed to discontinue therapy until treatment plans had been reviewed and verified as correct and the cobalt teletherapy unit recalibrated. Twenty-two patients were identified as having received incorrect treatments ranging from 50 percent underdose to approximately 100 percent overdose (total dose). All of the associated plans were prepared by the same dosimetrist.

An outside radiological physicist reviewed about 250 treatment plans including those of affected patients. The conclusion was that the dosimetrist made somewhat random mistakes, that is, plans were done with the correct methods in some cases and incorrectly at other times. Overall, the cases indicated a lack of understanding of the computer program used for treatment planning and the methods of calculation of timer settings from the computer output. Furthermore, there were no second checks performed which may have caught these mistakes.

Northern Westchester Hospital Center was directed by the State Health Department to follow-up on the affected patients for at least 1-year and to provide status reports to the department. At the time of the last report (May 1988), 11 of the 22 patients had died. Some of the deaths may have been from complications related to the misadministration in question. Other patients returned for further treatment. All treatment records for the affected patients were requested for review by the State's Radiological Health Advisory Committee. The committee did not have any comments that would counter the assertions by the hospital. The New York State Department of Health notified the NRC that the dosimetrist involved is no longer working at the hospital or any other facility in New York State. The physicist in charge of the consulting group stopped providing therapy services in New York State after the incident and only performed diagnostic x-ray and nuclear medicine consulting services.

The State requested the names of other facilities where physics services were performed by the same dosimetrist. Two other hospitals and a private office were identified

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Nuclear Power Plants

NRC is reviewing events reported at the nuclear power plants licensed to operate. For this report, NRC has determined that no events were abnormal occurrences.

Fuel Cycle Facilities (Other than Nuclear Power Plants)

NRC is reviewing events reported by these licensees. For this report, NRC has determined that no events were abnormal occurrences.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are currently over 7,500 NRC nuclear material licenses in effect in the United States, principally for the use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category by licensees such as radiographers, medical institutions, academic institutions, and byproduct material users. NRC is reviewing events reported by these licensees. For this report, using the criteria and guidelines given in Appendix A, NRC has identified the following events as abnormal occurrences. As noted in the Preface to this report, the guidelines for identifying medical misadministrations as abnormal occurrences are currently being revised.

93–9 Medical Sodium Iodide Misadministration at Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center in Tulsa, Oklahoma

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 1 in Table A-1) of this report notes that a diagnostic dose of a radiopharmaceutical to a part of the body receiving radiation improperly, if greater than five times the intended dose to that body part, should be considered an abnormal occurrence.[1]

Date and Place—July 27, 1993; Osteopathic Hospital Founders Association DBA (doing business as) Tulsa Regional Medical Center; Tulsa, Oklahoma.

Nature and Probable Consequences—The licensee reported that on July 27, 1993, a wrong patient was administered 0.21 gigabecquerel (GBq) (5.7 millicuries [mCi]) of iodine-131 (I-131). On July 27, 1993, diagnostic procedures were prescribed for two outpatients, patients A and B, using technetium-99m (Tc-99m) for patient A and I-131 for patient B. Prior to the administration, the technologist involved in the procedure believed that patient A was the one prescribed to receive I-131 and addressed patient A by name and requested a second form of identification. Patient A responded positively and presented a social security card as the second means of identification. The technologist copied the social security number and attached it to patient A's chart. However, the written directive was not checked for verification of the patient's name. As a result patient A was administered a 0.21 GBq (5.7 mCi) dosage of I-131 intended for patient B.

[1]The definition of a misadministration was revised in 10 CFR 35.2 and became effective on January 27, 1992. The revision defines a new type of misadministration involving sodium idodide. The existing abnormal occurrence guidelines for misadministrations do not include specific examples for these types of misadministrations but are presently under revision.

Actions Taken to Prevent Recurrence

Licensee-The licensee requested that DOE (the source manufacturer and the source lessor) manage the effort to identify the leaking capsule, develop a plan for its safe removal, manage its removal, and oversee the cleanup and recovery activities at RSI.

NRC—Following the incident, NRC reevaluated the WESF sources and determined in early 1991 that WESF sources were not appropriate for long-term use in commercial irradiator facilities and ensured that the remaining commercial users were so notified and advised to cooperate with DOE in scheduling removal of WESF sources from their facilities. As of the date of this report, WESF capsules remain in place in two licensed irradiators, one in Virginia and one in Colorado (licensed by the State of Colorado). According to DOE staff, if certain technical matters are resolved, DOE plans to begin removing the remaining WESF sources from these facilities by the end of 1993.

State Agency—The State of Georgia secured the services of an independent consultant to verify the results of decontamination efforts by the DOE contractor. Once it was verified that the facility met Federal and State regulatory standards for decontamination, the State terminated RSI's material license and returned control of the facility to its owner. Georgia will no longer license highly soluble cesium for this application.

Future reports will be made as appropriate.

AS 93-2 Medical "Sodium Iodide" Misadministration at Grenada Lake Medical Center in Grenada, Mississippi

Appendix A (see Event Type 4 in Table A1) of this report notes that administering a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose should be considered an abnormal occurrence.

This report is based on information provided to the State of Mississippi on April 3, 1992.

Date and Place—April 1, 1992; Grenada Lake Medical Center; Grenada, Mississippi.

Nature and Probable Consequences—On April 1, 1992, a patient scheduled to receive 3.7 megabecquerel (MBq) (100 microcuries [Ci]) of iodine-131 (I-131) for a thyroid uptake study was administered 218.3 MBq (5.9 millicuries [mCi]) of I-131. The 218.3 MBq (5.9 mCi) dosage of I-131 was to be administered to another patient. The technologist immediately discovered the error and notified the physician (authorized user). Vomiting was induced within 5 minutes of administering the I-131 capsule. The patient was also administered a thyroid blocking agent, 1.2 milliliters (ml) (0.04 fluid ounces [fl. oz.]) of potassium iodide. The patient was also instructed to take additional thyroid blocking agent, 0.3 ml (0.01 fl. oz.) of potassium iodide, once a day for 14 days. A thyroid uptake and scan were performed 24 hours after the incident. The thyroid uptake was 0.3 percent. The referring physician and the patient were informed of the misadministration.

Cause or Causes—The misadministration occurred because the nuclear medicine technologist failed to identify the patient prior to the administration of the radiopharmaceutical.

Actions Taken to Prevent Recurrence

Licensee—The Radiation Safety Officer has implemented new procedures for verification of patient identification and has committed to improve the supervision of personnel. The licensee also stated that patients who are prescribed radiation therapeutic procedures will no longer be included in the same schedule with patients who are prescribed diagnostic procedures.

State Agency—The state agency staff has reviewed the circumstances of the misadministration and will evaluate the licensee's corrective actions during the next inspection to be conducted in the near future.

This item is considered closed for the purposes of this report.

AS 93-3 Medical Brachytherapy Misadministration at Maine Medical Center in Portland, Maine

Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to a part of the body not scheduled to receive radiation should be considered an abnormal occurrence.

Date and Place—November 11, 1992; Maine Medical Center; Portland, Maine.

Nature and Probable Consequences—A patient was prescribed a brachytherapy treatment using 13 seeds of iridium-192 in a nylon ribbon. The catheter used for the treatment developed a kink and stopped 26 centimeters (cm) (10.24 inches [in.]) from the prescribed treatment area. This resulted in a dose to the patient's hypopharynx area of 3500 centigrays (cGy) (3500 rad), which was the prescribed dose to the lung. The intended treatment area of

The written QM Program was received by the NRC on February 11, 1993.

NRC—NRC Region I conducted an inspection on February 3, 1993 (Ref. 6). Because the misadministration resulted in an underdose to the patient and the therapy could be completed, the NRC did not contact a medical consultant to review this misadministration. A Confirmatory Action Letter (CAL) (Ref. 7) was issued to the licensee on February 5, 1993, which described the commitments made by the licensee to establish and implement a QM Program. An Enforcement Conference was held on March 1, 1993, to discuss the inspection findings and actions taken by the licensee in response to the CAL. On March 18, 1993, NRC Region I issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation and $250 Civil Penalty (Ref. 8). The licensee paid the Civil Penalty. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

This item is considered closed for the purposes of this report.

Agreement State Licensees

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in these quarterly reports to Congress. For this period, the Agreement States reported no events as abnormal occurrences.

Cause or Causes—The licensee did not confirm the treatment site before the treatment was given as required by its Quality Management (QM) Program.

Action Taken to Prevent Recurrence

Licensee—The licensee added a procedure requiring physicians to visually insert applicators. In addition, the licensee committed to a complete program assessment by an outside expert. This commitment was formalized by the NRC in a Confirmatory Order Modifying License issued on April 26, 1993 (Ref. 5).

NRC—NRC Region I conducted a special inspection at the facility on January 22, 1993 (Ref. 3). An NRC medical consultant was contacted to provide a clinical assessment of the effects of this misadministration. The licensee was offered the opportunity to participate in an Enforcement Conference but declined, believing that it would not be able to provide the NRC with any additional information. NRC recommended an enforcement action. A Notice of Violation and Proposed Imposition of Civil Penalties, and Confirmatory Order Modifying License were issued on April 26, 1993 (Ref. 5). (License modification required that the licensee's radiation safety program be improved as recommended by an outside expert.) The enforcement action was based on this event and AO 92-19, which is discussed in Appendix B. The cumulative amount of $10,000 for the violations was based on the combined events.

Future reports will be made as appropriate.

93-4 Medical Therapy Misadministration at Papastavros' Associates Medical Imaging in Wilmington, Delaware

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 in Table A-1) of this report notes that a therapeutic dose that is less than 0.5 times the prescribed dose can be considered an abnormal occurrence.

Date and Place—January 14, 1993; Papastavros' Associates Medical Imaging; Wilmington, Delaware.

Nature and Probable Consequences—On February 1, 1993, NRC Region I was notified by telephone that a therapeutic misadministration of iodine-131 occurred at the licensee's facility. In early January, the nuclear medicine technologist received a telephone call from the referring physician requesting that a patient be scheduled for a third treatment for hyperthyroidism and that 1.11 gigabecquerel (GBq) (30 millicurie [mCi]) of iodine-131 be administered. On January 13, 1993, the technologist ordered a 1.11 GBq (30 mCi) dose from the radiopharmacy. The dose was received on January 14, 1993. The technologist noted that the label on the lead container indicated 1.07 GBq (29 mCi) of iodine-131, but did not note that the label indicated that two capsules were present in the vial. A second technologist who removed the vial from the lead container and placed it in the dose calibrator for assay also failed to note that labels on both the lead container and the vial indicated the presence of two capsules. The assayed dose was consistent with the activity noted on the label. The technologist transferred the dose from the supplier's vial to a glass vial for administration to the patient. Only one of the capsules came out of the vial. The presumed empty lead container that still contained the plastic vial and remaining capsule was placed in the nuclear medicine hot laboratory for storage. The licensee discovered the remaining capsule on February 1, 1993, when the technologist was preparing lead containers for disposal. The patient was administered 0.56 GBq (15.1 mCi) of iodine-131, instead of the intended dose of 1.11 GBq (30 mCi). The misadministration was reported as required on February 1, 1993. The patient and the patient's physician were notified of the error and the patient was scheduled for follow-up therapy on February 10, 1993. The licensee's physician expected no adverse effects as a result of the misadministration. While the therapeutic dose administered was actually about 0.5 times the prescribed dose, the staff believes that this misadministration should still be considered an abnormal occurrence.

Cause or Causes—The misadministration was caused by failure of the licensee to establish and implement a Quality Management (QM) Program as required by 10 CFR 35.32(a). In particular, failure of the licensee to establish procedures to ensure that each therapy administration is in accordance with the written directive contributed to the misadministration.

Actions Taken to Prevent Recurrence

Licensee—The licensee's plan for preventing recurrence of the misadministration includes three steps: (1) to prepare and implement a written QM Program and provide training; (2) to have the radiopharmaceutical supplier indicate the number of capsules in each vial on the packing slip provided with iodine-131 therapy doses; and (3) to require the nuclear medicine technologists to read the label on the vials and lead containers to determine the number of capsules present in the vial, and then verify that the required number of capsules are administered to the patient. In addition, the vial into which the capsules are transferred after initial assay will be reassayed to ensure that all capsules are transferred.

Region III about the incident after reading about a similar case in an NRC Office of Nuclear Material Safety and Safeguards newsletter. A licensee consultant reviewed the case with NRC Region III on February 19, 1993. Following that discussion, the consultant reported the incident as a misadministration because the procedure requested by the patient's physician, a thyroid scan, would normally use a different radiopharmaceutical, technetium-99m.

Cause or Causes—The basic causes of this misadministration were a miscommunication between the referring physician's office and the licensee, and a failure of the licensee to follow its Quality Management (QM) Program for procedures using radioactive pharmaceuticals.

The licensee's QM Program, which was implemented in January 1992, requires that a written directive be prepared for procedures using more than 1.11 MBq (30 microcurie [μCi]) of iodine-131. However, no written directive was prepared for this procedure.

The licensee's procedure for a whole body iodine-131 scan required that the patient's thyroid had been removed previously. The licensee's procedures were not effective in determining if the patient had an intact thyroid.

The nuclear medicine department staff had not received training on the requirements of the licensee's QM Program which included the provision that a written directive had to be issued for a whole body scan (using more than 1.11 MBq [30 μCi] of iodine-131).

Actions Taken to Prevent a Recurrence

Licensee—The licensee has revised the procedures for thyroid cancer studies and provided training for nuclear medicine personnel in the QM Program requirements.

NRC—A special inspection was conducted from February 25 to 26, 1993, to review the circumstances surrounding the iodine-131 misadministration (Ref. 2). The NRC has also retained a medical consultant to review the case.

The NRC consultant concluded that the most probable effect of the misadministration would be permanent hypothyroidism, and he noted that evidence suggested that this condition had already occurred. No other health effects would be expected as a result of the misadministration.

Several violations of NRC requirements were identified in the inspection. These violations and the implementation of the licensee's QM Program are still under review by the NRC for possible enforcement action.

On March 2, 1993, NRC Region III issued a Confirmatory Action Letter to the licensee documenting its agreement to provide training to the nuclear medicine staff on the requirements of the QM Program, NRC regulations, and NRC licensee requirements (Ref. 3). No procedures using more than 1.11 MBq (30 μCi) of iodine-131 were to be performed before the training was completed. The licensee also agreed to make certain that its procedures for iodine-131 studies are consistent with the QM Program.

Future reports will be made as appropriate.

93-3 Medical Therapy Misadministration Involving the Use of a High Dose-Rate Remote Afterloader Brachytherapy Device at Yale-New Haven Hospital in New Haven, Connecticut

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 3 in Table A-1) of this report notes that for a therapeutic exposure, if parts of the body receiving radiation improperly would have normally received radiation anyway, had the proper administration been used, and the actual dose is greater than 1.5 times that intended to the above described body part, the event can be considered an abnormal occurrence.

Date and Place—January 21, 1993; Yale-New Haven Hospital; New Haven, Connecticut.

Nature and Probable Consequences—A patient was prescribed to receive three treatments of 700 centigray (cGy) (700 rad) per treatment to the vagina using a Gamma Med high dose-rate remote afterloader brachytherapy device (HDR). During the first treatment on January 21, 1993, the physician mistakenly inserted the HDR applicator into the patient's rectum instead of the vagina, as prescribed. The licensee discovered the error immediately after the treatment was completed and the patient was immediately notified. The licensee estimated that the patient received approximately 350 cGy (350 rad) to the vagina and 700 cGy (700 rad) to the rectum. At the time of the NRC inspection on January 22, 1993, the licensee had planned to make up the dose to the vagina during the remaining two treatments and to add shielding to the applicator to prevent significant additional dose to the rectum.

The patient's physician, the physician who delivered the therapy, and an NRC Medical Consultant are presently evaluating the probable consequences of this misadministration.

NRC—The event is still under staff review. The NRC will review the AIT's findings and those of the licensee, and will take appropriate actions.

Future reports will be made as appropriate.

Fuel Cycle Facilities
(Other than Nuclear Power Plants)

The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that no events were abnormal occurrences.

Other NRC Licensees
(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are currently over 7,500 NRC nuclear material licenses in effect in the United States, principally for the use of radioisotopes in the medical, industrial, and academic fields. Incidents were reported in this category from licensees such as radiographers, medical institutions, and byproduct material users. The NRC is reviewing events reported by these licensees. For this report, the NRC has determined that the following events were abnormal occurrences using the criteria and guidelines given in Appendix A. As noted in the Preface to this report, the guidelines for identifying medical misadministrations as abnormal occurrences are currently being revised.

93-2 Medical "Sodium Iodide" Misadministration at Ingham Medical Center in Lansing, Michigan

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 4 in Table A-1) of this report notes that a diagnostic dose of a radiopharmaceutical that is greater than five times the prescribed dose can be considered an abnormal occurrence.[1]

Date and Place—May 11, 1992; Ingham Medical Center; Lansing, Michigan.

Nature and Probable Consequences—The referring physician's staff telephoned the licensee's nuclear medicine department on May 5, 1992, to schedule a thyroid scan to detect or rule out thyroid cancer. There was a miscommunication between members of the support staff. The technologist who received the call understood that the referring physician wanted a whole body scan to rule out thyroid metastasis and to look at a thyroid nodule. The medical technologist entered a whole body scan into the scheduling record.

On May 11, 1992, a 47-year old patient received 366.3 megabecquerel (MBq) (9.9 millicurie [mCi]) of iodine-131 in capsule form as preparation for a whole body scan. This procedure is normally used after a patient with thyroid cancer has had the thyroid removed or ablated to determine if the cancer originating in the thyroid has spread elsewhere in the patient's body. The patient still had an active thyroid and the patient's physician intended that the patient receive a thyroid scan to help determine if a thyroid nodule was cancerous. The thyroid scan is a different procedure from a whole body scan and as performed at the licensee's facility uses 370 MBq (10 mCi) technetium-99m, a different radiopharmaceutical than iodine-131.

On May 12, 1992, the patient returned to the licensee's nuclear medicine department for the scan. The image of the initial scan showed that the patient's thyroid was intact and that an error had been made. The technologist performing the scan immediately reported the situation to the supervising physicians. The licensee's procedures for an iodine-131 whole body scan specified that this diagnostic procedure be used only on individuals whose thyroid had been removed.

The referring physician and the patient were notified of the misadministration. The licensee has been monitoring the patient and has observed decreased thyroid function.

Initially, the licensee determined that the incident was not a misadministration and did not report it to the NRC. This was because the correct dosage and procedure were used for the study, as understood by the technologist to have been requested. The licensee contacted NRC

[1]The definition of misadministration was revised. The revision 10 CFR 35.2 became effective on January 27, 1992. The revision defines a new type of misadminstration "Sodium Iodide." The current abnormal occurrence guidelines for misadministrations do not include specific examples for sodium iodide misadministrations. For these types of misadministrations the staff is currently using the abnormal occurrence guidelines (currently under revision).

This item is considered closed for the purpose of this report.

94-11 Medical Brachytherapy Misadministration at the Queen's Medical Center in Honolulu, Hawaii

This AO was originally reported in NUREG-0090, Vol.17, No.2, "Report to Congress on Abnormal Occurrence, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this—Administering a therapeutic dose greater than 1.5 times the prescribed dose can be considered an AO.

At that time, it was reported that on May 2, 1994, a patient received 1778 centigray (cGy) (1778 rads) to the right eye during the second of a two-part treatment, rather than the prescribed 1000 cGy (1000 rads), because of an error in timing a strontium-90 (Sr-90) eye treatment.

The AO report is updated and closed out as follows:

An NRC inspection was conducted from May 1 to July 13, 1994. Consequently it was concluded that the licensee's Quality Management Program (QMP) lacked appropriate procedures for use of Sr-90 eye applicators, as required by Title 10 of the *Code of Federal Regulations*, Part 35.32, "Quality Management Program." However, based on additional information provided by the licensee during an Enforcement Conference on August 4, 1994, NRC concluded that the licensee's QMP, although marginal, was adequate and that the QMP was violated in this specific instance by the involved physician. Accordingly, a Severity Level IV violation with no civil penalty was issued on August 11, 1994.

The licensee responded to the violation on August 22, 1994, by identifying several corrective actions to preclude recurrence. This included additional clarification of the QMP and Sr-90 procedure, additional training of nurses and physicians, and additional independent auditing of Sr-90 procedures.

NRC accepted the licensee's response to this item in a letter dated September 16, 1994.

This item event is considered closed for the purpose of this report.

94-12 Medical Sodium Iodide Misadministration at Stamford Hospital in Stamford, Connecticut

This AO was originally reported as AO 94-12 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

The AO criterion used was Event Type 1 in Table A-1 of Appendix A of this report—Administering a diagnostic radiopharmaceutical other than the one prescribed that result in a wrong part of the body receiving five times the upper limit of the normal range of exposure prescribed for diagnostic procedures involving that body part can be considered an AO.

At the time, it was reported that on May 17, 1994, a patient was administered 37 megabecquerel (1 millicurie) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed. It was estimated that the patient received a whole body dose equivalent of 4.7 millisievert (470 millirems) and a thyroid absorbed dose of 800 centigray (800 rads).

The AO report is updated and closed out as follows:

In a letter (Ref. 11) dated November 17, 1994, NRC rescinded the proposed civil penalty based on a reconsideration of the licensee's good performance on previous NRC inspections.

This item is considered closed for the purpose of this report.

94-14 Medical Brachytherapy Misadministration that Required Medical Intervention at The William W. Backus Hospital in Norwich, Connecticut

This AO was originally reported as AO 94-14 in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences, April-June 1994."

APPENDIX B

UPDATE OF PREVIOUSLY REPORTED ABNORMAL OCCURRENCES

During July through September 1994, NRC licensees, Agreement States, Agreement State licensees, and other involved parties, such as reactor vendors and architect-engineering firms, continued with the implementation of actions necessary to prevent recurrence of previously reported abnormal occurrences (AO). The AOs discussed below contain a summary of information presented in previous reports and any subsequent updated information provided during the reporting period. Those updated events which still require additional information will be discussed in future reports.

Other NRC Licensees

92-17 Medical Therapy Misadministration at Indiana University Medical Center in Indianapolis, Indiana

This AO was originally reported in NUREG-0090 Vol. 15, No.4, "Report to Congress on Abnormal Occurrences, October-December 1992."

The AO criterion used was Event Type 5 in Table A-1 of Appendix A of this report—Administering a therapeutic dose greater than 1.5 times the prescribed dose.

At the time, it was reported that a 31-month-old patient was prescribed two cobalt-60 teletherapy treatments of 150 centigray (cGy) (150 rads) each to treat a brain tumor. Due to an error by the dosimetrist, two treatments of 300 cGy (300 rads) each were delivered.

The AO report is updated and closed out as follows:

On October 7, 1993, NRC issued to the licensee a Notice of Violation and Proposed Imposition of Civil Penalty for $5,000 (Ref. 1). On January 18, 1994, an Order Imposing Civil Monetary Penalty was issued to the licensee. The licensee requested (Ref. 2) a hearing on the Order and denied that it had violated the NRC's requirements as stated in the Order.

On September 29, 1994, a settlement agreement between the NRC and the licensee was approved by the Atomic Safety and Licensing Board. The settlement agreement provisions included: payment of $2,500 by the licensee to NRC; submission by NRC to the licensee of a list of deficiencies in the licensee's written Quality Management Program; resolution by the licensee of the deficiencies; and retention by the licensee of an independent contractor to audit the implementation of its Quality Management Program.

This item is considered closed for the purpose of this report.

94-07 Medical Brachytherapy Misadministration at Alexandria Hospital in Alexandria, Virginia

This AO was originally reported in NUREG-0090, Vol. 17, No. 1, "Report to Congress on Abnormal Occurrences, January-March 1994."

The AO criterion used was Event Type 3 in Table A-1 of Appendix A of this report — A therapeutic exposure to a part of the body not scheduled to receive radiation.

At the time, it was reported that a patient was scheduled to receive a 500 centigray (cGy) (500 rads) brachytherapy treatment to the trachea using a Nucletron high-dose-rate (HDR) remote afterloader system. Because the HDR was not properly programmed for the correct treatment site, the prescribed 500 cGy (500 rads) dose was delivered to the left lung instead of the trachea target site.

The AO report is updated and closed out as follows:

NRC held an Enforcement Conference on July 21, 1994, to discuss the inspection findings with the

procedures for verifying a radiopharmaceutical dose prior to administration to a patient. The violation was categorized as a Severity level IV violation.

This item is considered closed for the purpose of this report.

94-23 Medical Brachytherapy Misadministration at North Memorial Medical Center in Robbinsdale, Minnesota

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 in Table A-1) of this report indicates that a therapeutic exposure to any part of a body not scheduled to receive radiation can be considered an AO.

Date and Place—August 3, 1994; North Memorial Medical Center; Robbinsdale, Minnesota.

Nature and Probable Consequences—On August 15, 1994, a licensee informed NRC that a patient received 1380 centigray (cGy) (1380 rads) to a wrong treatment site during a brachytherapy treatment for metastatic lung cancer.

On August 3, 1994, a catheter was inserted into the patient's bronchus and a ribbon containing 20 seeds of iridium-192 having a total activity of 673.4 megabecquerel (18.2 millicuries) was then inserted into the catheter and moved to the proper treatment location. The treatment plan was intended to deliver a prescribed dose of 2000 cGy (2000 rads) to the intended target. The treatment began at 11:15 a.m. on August 3, 1994, and continued until its scheduled completion at 10:15 a.m. on August 4, 1994.

At about 7:00 p.m. on August 3, 1994, a nurse informed the physician that the visible portion of the catheter appeared to be protruding approximately 25.4 to 30.5 centimeters (10 to 12 inches) from the patient's nose. This was a significantly greater protrusion than previously observed, indicating that the catheter had moved from its initial placement. The nurse secured the catheter in place with additional tape. The physician stated that, based on the information available to him at that time, he determined that the catheter and ribbon had moved; but that the tumor was receiving some radiation dose and therefore he continued the treatment. The iridium-192 seeds were removed on August 4 as planned. On August 4, 1994, a staff radiologist read the portable x-ray film taken on August 3, 1994, and indicated that the iridium implant was not seen.

Due to catheter displacement, the tumor dose was significantly reduced and estimated to be 620 cGy (620 rads) or 31 percent of the intended dose. The remaining dose of 1380 cGy (1380 rads) was delivered to an unintended site.

The patient was notified of the event by the treating physician on August 4, 1994, and again by another physician on August 17, 1994. The referring physician was informed by the treating physician on August 4, 1994.

An NRC medical consultant was retained to perform a clinical assessment of this misadministration. The medical consultant concluded that it is improbable that the patient will experience any long term consequences as a result of the exposure to the unintended treatment site.

Cause or Causes—The licensee has determined that the catheter movement caused a misadministration of the intended dose. Two possible explanations for the catheter movement could be the following: (1) failure to properly secure the catheter in place with tape; or (2) nasal discharge decreasing the adhesive capability of the tape.

Action Taken To Prevent Recurrence

Licensee—The licensee's corrective actions include: amending the nursing staff procedure so that the attending physician will be contacted if there are further questions; directing nurses to follow the standing protocol for obtaining an administrative consult; providing additional inservice training; documenting the final length of the catheter in the patient chart; and documenting the catheter position on each visit to the patient's room.

NRC - NRC conducted a safety inspection from August 15 through September 7, 1994 (Ref. 16), to review the circumstances of the misadministration. One apparent violation and one area of concern were identified. An Enforcement Conference was held with the licensee on October 11, 1994. Enforcement action is pending. NRC is continuing its review.

94-22 Medical Therapy Misadministration at Veterans Affairs Medical Center in Long Beach, California

The following information pertaining to this event is also being reported in the *Federal Register*. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

Date and Place—August 9, 1994; Veterans Affairs Medical Center; Long Beach, California.

Nature and Probable Consequence—On August 9, 1994, the licensee's radiation safety officer (RSO) notified NRC of a misadministration involving a therapeutic dose of strontium-89 (Sr-89) (Ref. 12).

The RSO reported that a patient scheduled to receive 185 megabecquerel (MBq) (5 millicurie [mCi]) of thallium-201 (a radiopharmaceutical not regulated by NRC) for a myocardial perfusion study was mistakenly administered 148 MBq (4 mCi) of Sr-89 (which is regulated by NRC). Based on the misadministration of the Sr-89, the licensee estimated that the patient received 250 centigray (250 rads) to the surface of the bone. The RSO reported that no action was taken to mitigate the consequences of the dose (i.e., administration of calcium as a blocking agent) because the patient had a preexisting heart condition which could have been exacerbated by administering calcium. The licensee also stated that medical experts were contacted to assist in an assessment of potential health effects to the patient. In addition, the licensee reported that with the exception of emergency procedures, it had voluntarily suspended all nuclear medicine procedures involving the intravenous administration of radiopharmaceuticals and had initiated an internal review of the misadministration.

On August 10, 1994, NRC issued a Confirmatory Action Letter (Ref. 13) to confirm the licensee's actions as stated above.

Cause or Causes—The cause of the misadministration was attributed to the administering technologist's failure to verify the isotope as well as dosage (by reading the label on the syringe) prior to injection.

Actions Taken To Prevent Recurrence

Licensee—Corrective actions initially proposed by the licensee included the following: (1) physically separating diagnostic unit dosages from therapeutic radiopharmaceutical dosages in the licensee's hot lab; (2) packaging unit dosages received from a local radiopharmacy in different containers, according to isotopes; and (3) retraining technologists in requirements for identifying radiopharmaceuticals prior to injection.

NRC - Two NRC inspectors conducted a special safety inspection on August 10-12 and 17-19, 1994, to review the circumstances associated with the misadministration and to review the licensee's corrective actions (Ref. 14). In addition, NRC contracted a medical physician consultant to assist in its evaluation of the potential consequences of the patient's radiation exposure. The consultant stated that there were no adverse health effects to the patient.

An Enforcement Conference was held with the licensee on November 30, 1994, to discuss an apparent violation involving the failure of an individual working under the supervision of an authorized user physician to follow the licensee's written radiation safety procedures. Additional concerns discussed during the conference included the licensee's use of an informal labeling system for unit radiopharmaceuticals which was identified as a potential programmatic weakness. The licensee presented information during the conference which supported its view that the error which led to the August 9, 1994, misadministration was an isolated failure rather than a programmatic problem.

Based on its review of information developed during the inspection and information provided during the Enforcement Conference, NRC concluded that the misadministration was the result of an isolated failure. A Notice of Violation (Ref. 15) was issued on December 29, 1994, for a violation involving the failure of an individual working under the supervision of a physician authorized user to follow the licensee's written

that a serious deficiency in management or procedural controls in a major area can be considered an AO.

Due to the nature of this occurrence, NRC performed an extensive review requiring interviews and an historical review of licensee records. This detailed review resulted in a delay in the prompt reporting of this information.

Date and Place—October 1988 through June 1993; Ball Memorial Hospital; Muncie, Indiana.

Nature and Probable Consequences—On July 19, 1993, NRC was notified that nuclear medicine technologists employed by the licensee had increased the dosages of radiopharmaceuticals used in diagnostic studies. NRC was also informed that the technologists had falsified the required records of the dosages administered.

On July 21 through August 9, 1993, NRC conducted an inspection of the licensed facility. The inspection revealed that since 1988, nuclear medicine technologists employed by the licensee have been administering radiopharmaceutical dosages above the approved dose ranges for diagnostic image studies by as much as 40 percent. The inspection also verified that subsequent to administering high doses, the technologists entered false information in NRC-required records. The doses were increased for imaging studies of the lung, liver, bone, and gastrointestinal tract using technetium-99m and xenon-133.

NRC inspectors did not identify any medical misadministrations, as defined in 10 CFR 35.2, as a result of this practice of administering higher than approved doses for diagnostic imaging.

Cause or Causes—According to the licensee, one technologist told licensee officials that dosages were increased to minimize patient discomfort, to reduce imaging time for critically ill patients and to enhance the clarity of images for studies performed on obese patients.

Action Taken To Prevent Recurrence

Licensee—The licensee conducted an internal review. Based on the findings from this review, the licensee initially suspended two nuclear medicine technologists from all NRC-licensed activities. Subsequently, the licensee terminated one of the two individuals and the other individual was allowed to continue to perform duties that do not involve NRC-licensed activities.

The licensee also committed to a number of corrective actions. Some of the corrective actions include: assigning a pharmacist or a radiologist to verify all radioisotope dosages; implementing a unit dose system; obtaining the services of an assistant radiation safety officer; and conducting monthly and quarterly audits of the Nuclear Medicine Section for at least one year.

NRC—A special safety inspection was conducted by NRC from July 21 to August 9, 1993. Subsequent to that inspection, NRC conducted a followup review .

NRC issued a Confirmatory Action Letter (Ref. 9) on July 26, 1993, and Confirmatory Order Modifying License (Ref. 10) on October 20, 1993. These documented specific procedures and verifications to prevent any further unauthorized increases in patient doses.

On May 23, 1994, NRC issued an Order against a former nuclear medicine technologist of the licensee. The Order required the following: (1) prohibited the technologist from involvement in NRC-licensed activities for a period of one year; (2) required the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities for a three-year period; and (3) required the technologist to notify NRC within 20 days of accepting employment involving NRC-licensed activities.

On May 27, 1994, the technologist requested a hearing and on September 26, 1994, a settlement agreement was reached. The settlement was reviewed and approved by the Atomic Safety and Licensing Board on October 3, 1994 (Ref. 11). The agreement resulted in the withdrawal of the requirement for the technologist to provide a copy of the Order to any prospective employer who engages in NRC-licensed activities. The settlement retained provisions (1) and (3) of the Order.

This item is considered closed for the purpose of this report.

Due to the location and the extent of the cracking recently found, NRC and the BWROG agreed that additional attention to this issue was warranted. BWROG met with NRC on June 28, 1994, to announce the formation of BWRVIP, which is headed by several high level utility executives to direct its efforts. BWRVIP has since submitted documents (Ref. 5 and Ref. 6) which addressed an integrated safety assessment of the issue, inspection plans for the reactor internals, and generic criteria for repairs and flaw acceptance.

NRC has reviewed these documents (Ref. 7 and Ref. 8) and concurs with the BWRVIP recommended generic repair criteria and flaw assessment methodology. Inspection scope and methodology are still under consideration.

In addition to the above actions, in order to verify compliance with the structural integrity requirements of 10 CFR 50.55a and to assure that the risk associated with core shroud cracking remains low, NRC concluded that it is appropriate for BWR licensees to implement timely inspections and/or repairs, as appropriate, at their plants. To implement this position, NRC issued GL 94-03 (July 25, 1994) which requested BWR licensees to inspect their core shrouds by the next outage and to justify continued safe operation until all appropriate corrective actions have been implemented.

This item is considered closed for the purpose of this report.

There are 41 active licenses for the milling, processing, and fabrication of nuclear fuel in the U.S. NRC has reviewed all incident and event reports received from these licensees through the fourth quarter of 1994. Using the criteria and guidelines in Appendix A of this report, none of the occurrences reviewed for this reporting period were determined to be significant enough to be reported as an AO.

Fuel Cycle Facilities (Other than Nuclear Power Plants)

There are 41 active licenses for milling, processing, and fabrication of nuclear fuel in the U.S. NRC has reviewed all incident and event reports received from these licensees through the fourth quarter of 1994. Using criteria and guidelines in Appendix A of this report, none of the occurences reviewed for this reporting period were determined to be significant enough to be reported as an AO.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are approximately 22,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications in the U.S. Twenty-nine States, known as Agreement States, have entered into agreements with NRC to assume regulatory authority for approximately 15,000 of these licensees within their States. NRC is responsible for regulating approximately 7000 licensees located in the remaining 21 States, the District of Columbia, and all U.S. territories. NRC has reviewed all incident and event reports received from NRC licensees through the fourth quarter of 1994. Using the criteria and guidelines in Appendix A of this report, the following occurrences have been determined to be significant enough to be reported as AOs.

94-21 Recurring Incidents of Administering Higher Doses than Procedurally Allowed for Diagnostic Imaging at Ball Memorial Hospital in Muncie, Indiana

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 11 from Examples For All Licensees) of this report notes

On May 16, 1994, NRC Region III issued a Notice of Violation (Ref. 3) to the hospital, citing it for failing to provide written notification to the patient of the misadministration within 15 days, as required. The patient was informed orally of the misadministration at the time it was discovered, but was not provided with written notification until April 27, 1994. No fine was assessed.

This event is closed for the purpose of this report.

94-12 Medical Sodium Iodide Misadministration at Stamford Hospital in Stamford, Connecticut

This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences," April-June 1994.

The AO criterion used was Event Type 1 in Table A-1—Administering a radiopharmaceutical other than the one intended which results in any part of the body receiving unscheduled diagnostic radiation, and the actual dose to the wrong body part is five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part.

At the time, it was reported that on May 17, 1994, a patient was administered 37 megabecquerel (MBq) (1 millicurie [mCi]) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed.

The AO report is updated as follows:

The licensee responded to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties in a letter dated August 10, 1994, contesting a number of the violations and the civil penalty. NRC is evaluating the licensee's response.

This event will be updated when additional information becomes available.

94-14 Medical Brachytherapy Misadministration at The William W. Backus Hospital in Norwich, Connecticut

This abnormal occurrence (AO) was originally reported in NUREG-0090, Vol. 17, No. 2, "Report to Congress on Abnormal Occurrences," April-June 19

The AO criterion used was Event Type 5 in Table A-1—A therapeutic dose that is greater than 1.5 times the prescribed dose.

At the time, it was reported that on June 21, 1994, a patient was implanted with 112 iodine-125 (I-125) seeds having an activity of 166 megabecquerel (MBq) (4.49 millicurie [mCi]) each, rather than the prescribed 112 I-125 seeds having an activity of between 15.9 and 17.0 MBq (0.43 and 0.46 mCi) each.

The AO report is updated as follows:

The license submitted its 15-day report on the misadministration by letter dated July 6, 1994 (Ref. 4). The report stated that in addition to the prostatectomy performed during the initial surgery on June 21, 1994, the patient's bowel was diverted via a colostomy. The initial dose was intended to deliver a peripheral target dose of 16,000 centigray (cGy) (16,000 rad). A conservative estimate of the final dose is 55,137 cGy (55,137 rad) based on the remaining residual seeds. The NRC medical consultant's final report was in agreement with the licensee's report. The consultant indicated that the misadministration, and subsequent multiple surgical procedures to remove the isotope, predisposes the patient to a variety of future medical problems. The licensee agreed to provide monthly updates on the patient's condition to NRC for at least one year.

At the Enforcement Conference held on August 24, 1994, the licensee presented corrective actions that included: (1) requiring nuclear medicine technologists to verify all information contained in the packing slip, certificate of activity, vial label, and written directive at the time the package is received, as well as requiring the Radiation Safety Officer to be notified if any discrepancy is identified; (2) confirming all orders in writing with the supplier prior to implantation; (3) providing training to the nuclear medicine staff; (4) revising procedures to require verification in accordance with the written directive prior to administration of doses; (5) revising the Quality Management program; and (6) creating the staff position of Brachytherapy Safety Nurse Coordinator to provide increased control over these activities.

NRC is evaluating the licensee's corrective actions, and is reviewing its enforcement options as a result of the Enforcement Conference held on August 24, 1994.

NRC performed an inspection on September 19, 1994, and observed that all of the corrective actions had not yet been fully implemented. The licensee agreed to notify NRC Region I in writing when implementation of the corrective actions was completed.

This event will be updated when additional information becomes available.

NRC—NRC Region III conducted an inspection on August 1, 1994, to review the misadministration (Ref. 3). A Confirmatory Action Letter (CAL) was issued to the licensee on August 2, 1994, which described the commitments made by the licensee as to which actions will be taken prior to the administration of I-131. An Enforcement Conference was held on August 24, 1994, to discuss the inspection findings and actions taken by the licensee in response to the CAL.

In October 1994, NRC proposed an $8,000 fine against the licensee for violations of NRC requirements involved in a diagnostic procedure using radioactive iodine at the hospital. The violations involve: (1) failure to have signed written directives by an authorized user prior to administration of I-131 in quantities greater than 1.11 MBq (0.03 mCi) on July 26, and in two previous instances where the I-131 was the intended radiopharmaceutical; (2) failure to have a clinical procedure for the proper administration of I-131 for whole body scans; and (3) failure to provide proper instruction to the nuclear medicine staff. The licensee paid the civil penalty.

This event is closed for the purpose of this report.

94-18 Multiple Teletherapy Misadministrations at Sinai Hospital in Detroit, Michigan

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—July 28 and August 3, 1994; Sinai Hospital; Detroit, Michigan.

Nature and Probable Consequences—On July 28, 1994, and August 3, 1994, misadministrations occurred on two separate patients when the licensee's therapists failed to verify correct teletherapy machine parameters prior to treatment.

Beginning on July 19, 1994, a patient was to receive 4500 centigray (cGy) (4500 rad) in a series of 25 treatments to the left neck area. The first seven treatments were completed without incident. However, on the eighth treatment on July 28, one fraction was set up using the wrong treatment angle. This resulted in a radiation dose of 90 cGy (90 rad) being received by the right shoulder and neck area instead of the left neck area.

Beginning July 5, 1994, another patient was to receive 5000 cGy (5000 rad) in a series of 25 treatments to the right shoulder area. The first 21 treatments were completed without incident. However, on the 21st treatment on August 3, the teletherapy unit was positioned using the wrong treatment angle. This resulted in a radiation dose of 100 cGy (100 rad) being received by the right lung area instead of the right shoulder area.

An NRC medical consultant reviewed both cases and concluded that no significant adverse side effects or tissue injury are expected.

Cause or Causes—The cause of both misadministrations was human errors by several of the licensee's therapists. The therapists failed to verify the collimator angle, the wedge setting, and the treatment site before administering the teletherapy dose to the patients.

Action Taken To Prevent Recurrence

Licensee—The corrective actions taken included: (1) suspending all teletherapy treatments pending an internal investigation, and identification of appropriate corrective actions prior to re-start of the teletherapy treatments; (2) developing procedures which require independent verification of proper treatment parameters during patient set-up; and (3) installing a record-and-verify system on the teletherapy unit to ensure that all major treatment parameters are checked prior to a treatment.

NRC—NRC Region III conducted an inspection July through August 12, 1994, to review the circumstances surrounding the two misadministrations (Ref. 4). NRC retained a medical consultant to review the case. An Enforcement Conference was held on September 8, 1994, to discuss the inspection findings and actions taken by the licensee. On September 21, 1994, NRC Region III issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation with no civil penalty assessed. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensee program.

As required by 10 CFR 35.33(a), the licensee, for each misadministration, notified the referring physician and the patient after the discovery of the incident and submitted a written report to the patient, including a statement that the report submitted to NRC Region III will be made available upon request.

This event is closed for the purpose of this report.

94-19 Brachytherapy Misadministration Involving the Use of a Strontium-90 Applicator at the University of Massachusetts Medical Center in Worcester, Massachusetts

Conference. The causes appeared to be the following: (1) written procedures were not developed to address gantry angle conversions; (2) the technologists did not have an adequate understanding of the informal gantry angle conversion procedures; (3) the informal gantry angle conversion procedure was not part of the licensee's annual refresher training program; (4) technologists did not fully understand their responsibilities to resolve discrepancies in a treatment plan; and (5) gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

Action Taken To Prevent Recurrence

Licensee—The licensee's corrective actions included: (1) revising the simulation data form to include a specific location to document the converted gantry angles; (2) initialing all angle conversions by the person performing the conversion, and having a second individual independently verify the conversions prior to treatment; (3) instructing the technologists to review all treatment information and to resolve any discrepancy prior to continuing treatment; (4) performing all future gantry angle conversions by the licensee rather than by the licensee's simulation contractor; and (5) conducting a review of past treatment plans back to 1988, with emphasis on those which did not identify any additional errors.

NRC—NRC Region III conducted an inspection on August 1, 1994, to review the circumstances surrounding the misadministration (Ref. 2). NRC also retained a medical consultant to review the case. An Enforcement Conference was held on September 1, 1994, to discuss the inspection findings and actions taken by the licensee. On September 20, 1994, NRC Region III issued a Notice of Violation with a Severity Level III (Severity Levels I through V range from the most significant to the least significant) violation with no civil penalty assessed. The licensee's corrective and preventive actions will be reviewed during the next NRC inspection of the licensed program.

This event is closed for the purpose of this report.

94-17 Sodium Iodide Misadministration at St. Joseph Mercy Hospital in Pontiac, Michigan

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A of this report notes that administering a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent in which the event results in adverse health effects worse than expected for the normal range of exposures prescribed for the diagnostic procedure can be considered an abnormal occurrence.

Date and Place—July 26, 1994; St. Joseph Mercy Hospital; Pontiac, Michigan.

Nature and Probable Consequences—On July 27, 1994, the licensee reported to NRC that a misadministration occurred involving a patient receiving the wrong radiopharmaceutical for a diagnostic procedure.

The patient's referring physician requested a thyroid scan which involves administration of a standard prescription at St. Joseph Mercy Hospital of a 9.25 megabecquerel (MBq) (0.25 millicurie [mCi]) sodium iodide-123 (I-123) capsule. However, the licensee administered a 92.5 MBq (2.5 mCi) I-131 capsule. The amount of activity that was administered is normally used following removal of the thyroid to examine a patient for the spread of cancer from the thyroid through the body.

NRC retained a medical consultant to review the case. The medical consultant concluded that the resultant unnecessary dose to the patient's thyroid would result in a low, but finite, probability of hypothyroidism developing in the future. Also, there is a lifetime probability of developing radiation-induced thyroid cancer of 10 percent, including a risk of fatal thyroid carcinoma of approximately 1 percent. The licensee has arranged for the patient to be seen by a endocrinologist, and for repeat thyroid imaging with I-123 to be performed several months after the misadministration.

The patient was notified in person by the Radiation Safety Officer on July 27, 1994. Subsequently, the patient was also given a written report that was dated August 5, 1994.

Cause or Causes—Part of the cause of the misadministration was the lack of the treating physician's involvement in the patient's examination prior to the I-131 administration. The administrative staff and technologists failed to have the examination clarified by a treating physician with the referring physician prior to administration of the I-131. Causal factors for this event also included the failure of licensee management to ensure implementation of the licensee's written Quality Management Program. Contributing factors also appear to include deficiencies in training, and a failure to follow through on matters.

Action Taken To Prevent Recurrence

Licensee—The licensee took the following corrective actions: (1) held a training session which included the Radiation Safety Officer, treating physicians and technologists; (2) instituted a limit on the number of individuals who will be involved in the use of I-131; and (3) required a written directive to be filled out and signed by a treating physician.

fetal whole body dose was calculated as 0.55 cGy (0.55 rad). Based on the calculated fetal dose there are a range of possible consequences, the most likely being no significant harm to the fetus. At NRC request, the Radiation Emergency Assistance Center/Training Site in Oak Ridge, Tennessee, contacted the licensee to discuss the dose assessment and potential fetal effects.

On May 10, 1994, a physician specializing in maternal fetal medicine, not affiliated with the licensee, discussed the incident with the licensee. The patient was informed of the exposure and possible consequences to the fetus by the maternal fetal specialist.

Cause or Causes—The principal cause for the event was licensee reliance on the patient's assurance of non-pregnancy. Licensee procedures do not require determination of pregnancy status through serum testing, or other appropriately documented means, for all female patients of child bearing age. The patient was apparently unaware of her pregnancy status at the time of I-131 administration on March 9, 1994.

Action Taken To Prevent Recurrence

Licensee—The licensee is in the process of developing internal policies which will address options for pregnancy status determination including serum pregnancy testing or suitable written proof, such as evidence of a hysterectomy. The legal implications and options for written proof of non-pregnancy are being evaluated by the licensee. Until policies have been finalized, the licensee plans to administer pregnancy tests to all female patients of child bearing age, unless appropriate proof of non-pregnancy is available as determined by the authorized user. For patients unwilling to undergo pregnancy testing, radiopharmaceuticals will not be administered and the authorized user will be consulted for the appropriate course of action.

NRC—NRC Region III conducted a safety inspection from May 18 through June 8, 1994, to review the circumstances surrounding the event and to evaluate aspects of the licensee's radiopharmaceutical Quality Management Program (Ref. 1). No regulatory violations associated with the event were identified. The licensee's procedure appears to have been followed in this specific case. NRC regulations do not include requirements for patient pregnancy verification prior to administration of radiopharmaceuticals. However, NRC is in the process of developing regulations which will address the administration of radiopharmaceuticals to breast feeding and pregnant patients.

This event is closed for the purpose of this report.

94-16 Teletherapy Misadministration at Medical Center Hospital in Chillicothe, Ohio

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A of this report notes that a therapeutic dose that results in any part of the body receiving unscheduled radiation can be considered an abnormal occurrence.

Date and Place—July 21 and 22, 1994; Medical Center Hospital; Chillicothe, Ohio.

Nature and Probable Consequences—On July 27, 1994, the licensee reported that a patient received a radiation dose of approximately 300 centigray (cGy) (300 rad) to an unintended treatment site using a cobalt-60 teletherapy unit.

A patient was scheduled to receive 1400 cGy (1400 rad) in a series of seven treatments for cancer of the esophagus. Each of the treatments was to consist of two radiation exposures of 100 cGy (100 rad) each delivered from different angles. The first treatment was performed on July 21. Following the first of the two exposures during the second treatment on July 22, the technologist found inconsistencies in the angles of treatment documented in the written directive and in the patient simulation sheet. Upon further review, the licensee determined that the wrong treatment angles had been used during the first treatment and part of the second treatment.

As a result of the incorrect angles of exposure, the treatment site received only part of the prescribed dose and adjacent tissue received a higher dose than intended. The licensee estimates a dose of 300 cGy (300 rad) to the unintended site. Under normal conditions, the unintended site would have received approximately 20-50 cGy (20-50 rad).

The treatment angles were corrected on the patient's chart, and the radiation dose was modified to compensate for the reduced dosage delivered in the initial treatments. The patient was informed and no adverse medical effects are expected.

The patient was notified verbally on July 26, 1994 and in writing as required by 10 CFR 35.33. According to the medical consultant, there will be no medical consequences as a result of the misadministration.

Cause or Causes—The error occurred because the simulated gantry angles had not been converted to the treatment unit gantry angles, and gantry angle conversion factors were not included in the licensee's treatment chart checks conducted by the technologists.

The root causes of the problem were discussed with the licensee on September 1, 1994, during an Enforcement

REPORT TO CONGRESS ON ABNORMAL OCCURRENCES JULY-SEPTEMBER, 1994

Nuclear Power Plants

There are 109 operating nuclear power plants in the United States (U.S.). NRC has reviewed all event reports received from these licensees through the third quarter of 1994. Using the criteria and guidelines in Appendix A of this report, none of the events reviewed for this reporting period was determined to be significant enough to be reported as an abnormal occurrence (AO).

Fuel Cycle Facilities (Other than Nuclear Power Plants)

There are 41 active licenses for the milling, processing, and fabrication of nuclear fuel in the U.S. NRC has reviewed all event reports received from these licensees during the third quarter of 1994. Using the criteria and guidelines in Appendix A of this report, none of the events reviewed for this reporting period was determined to be significant enough to be reported as an abnormal occurrence.

Other NRC Licensees (Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

There are approximately 22,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications in the U.S. Twenty-nine States, known as Agreement States, have entered into agreements with NRC to assume regulatory authority for the use of byproduct materials. NRC is responsible for regulating approximately 7000 of these licensees located in 21 States, the District of Columbia, and all U.S. territories. NRC has reviewed all events received from these licensees through the third quarter of 1994. Using the criteria and guidelines in Appendix A of this report, the following events have been determined to be significant enough to be reported as AOs.

94-15 Sodium Iodide Event at Welborn Memorial Baptist Hospital in Evansville, Indiana

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see General Criterion 1) of this report notes that a moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission can be an abnormal occurrence.

Date and Place—March 9, 1994; Welborn Memorial Baptist Hospital, Inc.; Evansville, Indiana.

Nature and Probable Consequences—On May 16, 1994, [illegible] reported to NRC that a pregnant patient was administered 185 megabecquerel (MBq) (5 millicurie [mCi]) of sodium iodide-131 (I-131) on March 9, 1994, as prescribed in the written directive for the treatment of Graves' disease (hyperthyroidism). The licensee did not know that the patient was pregnant at the time of the administration. On May 10, 1994, the licensee was informed by a private practice physician that the patient was 22-weeks pregnant at the time of treatment. As a result, the patient's fetus received an unintended radiation dose.

The patient was referred to the licensee with possible hyperthyroidism. To confirm the suspect condition, the licensee administered a 440.3 kilobecquerel (11.9 microcurie) I-131 capsule to the patient on March 7, 1994, and measured an 82-percent thyroid uptake over the ensuing 25 hours. The licensee stated that prior to administering the I-131 diagnostic capsule on March 7, 1994, the patient was questioned and informed both the treating physician and the nuclear medicine technologist administering the capsule that she was not pregnant. The licensee diagnosed the patient's condition as Graves' disease and the treating physician prescribed a 185 MBq (5 mCi) I-131 therapy treatment. On March 9, 1994, a 185 MBq (5 mCi) I-131 capsule was orally administered by one of the licensee's nuclear medicine technologists, as prescribed. Prior to the treatment on March 9, 1994, the technologist questioned the patient once more and was again informed by the patient that she was not pregnant.

Oak Ridge Institute for Science and Education calculated the fetal whole body and thyroid doses at NRC request. The fetal dose to the thyroid was calculated a 7,000–12,000 centigray (cGy) (7,000–12,000 rad), and the

Nature and Probable Consequences—On May 19, 1994, the licensee notified the NRC Operations Center that on May 17, 1994, a patient was administered 37 megabecquerel (MBq) (1 millicurie [mCi]) of sodium iodide iodine-131 (I-131) for a whole body scan when no such study was prescribed. The licensee identified this misadministration during review of the scan by the authorized user.

A patient was scheduled by a referring physician to have a "whole blood red cell mass" test, correctly known as a "red blood cell volume" test. This test involves withdrawing an amount of blood from the patient, and labeling the patient's red blood cells in vitro with the radionuclide chromium-51 having a nominal activity of 1.02 to 3.7 MBq (30-100 microcurie [μCi]). This is followed by reinjection of the labeled red blood cells into the patient, and measurement of radioactivity in blood samples withdrawn from the patient 10 to 30 minutes later. The referring physician contacted the patients's Health Maintenance Organization (HMO), as the HMO requires that it place the order with Stamford Hospital. The HMO wrongly contacted the central booking area for Nuclear Medicine at Stamford Hospital, rather than the Clinical Laboratory which performs this test as authorized in Part 35.100 of Title 10 of the *Code of Federal Regulations*. The central booking secretary, and the HMO secretary, in an attempt to fit the procedure into one of those listed under Nuclear Medicine, converted the prescribed "Whole Blood Red Cell Mass" test into "Whole Body I-131 Scan," a scan that uses 37 MBq (1 mCi) of I-131. The central booking secretary then printed the name of the referring physician at the bottom of the form for "Consultation for Nuclear Medicine," and sent it to the Nuclear Medicine Department where it was received on May 13, 1994. A nuclear medicine technologist (NMT) looked at the form and saw that it was for "total red cell mass," but since the NMT knew the referring physician, the NMT assumed that this was a new test using I-131 to determine "total red cell mass." The NMT ordered the requested 37 MBq (1 mCi) I-131 capsule, which was administered on May 16, 1994. The patient was scanned on May 17, 1994, and May 18, 1994, the authorized user (AU), who is also the Radiation Safety Officer (RSO), read the films. The AU immediately noticed the error and notified the referring physician, who notified the patient.

The licensee estimated that the patient received a whole body dose equivalent of 4.7 millisievert (470 millirem) and a thyroid absorbed dose of 800 centigray [cGy] (800 rad). NRC was notified within 24 hours of the discovery of the misadministration. The licensee submitted a written report of the misadministration to NRC Region I on May 31, 1994.

Cause or Causes—The licensee had failed to establish a quality management program (QMP) for administering quantities of I-131 and iodine-125 (I-125) greater than 1.11 MBq (30 μCi) which would require written directives and failed to instruct supervised individuals in NRC requirements of a QMP.

Actions Taken to Prevent Recurrence

Licensee—The licensee now requires that (1) all requests for diagnostic or therapeutic procedures be in writing and sent via facsimile transmission from the referring physician's office; (2) all administrations above 1.11 MBq (30 μCi) of I-131 be done only by written order from the AU/RSO or other AU's authorized to do so; (3) all diagnostic and therapy requisitions will be reviewed by a radiologist, and designated as approved or not approved; (4) all technologists will be trained in regard to the clinical diagnosis for which each test is applicable; (5) the central booking staff will meet with the RSO and will be informed that the clinical diagnosis must match the test being requested, and that any deviation from the match or any diagnosis that they don't understand must be challenged and brought to the attention of the radiologist; and (6) the RSO and physicist will review the QMP annually and discuss it at the Radiation Safety Committee meeting and with the entire nuclear medicine staff.

NRC—NRC Region I conducted a special inspection on May 23 and 24, and June 1 and 6, 1994, to investigate the circumstances of the misadministration. An NRC inspection report (Ref. 8) was issued June 15, 1994, and identified the following five apparent violations: (1) failure to establish a QMP for amounts of I-125 and I-131 greater than 1.11 MBq (30 μCi); (2) failure to conduct annual reviews of the QMP; (3) failure to have records specifying the methods used to verify patient identity which can be audited; (4) failure to have written directives signed by the authorized user; and (5) failure to instruct individuals in the QMP. An NRC medical consultant reviewed the information in the NRC's inspection report, the licensee's 15-day misadministration report, and the preliminary notification, and conducted telephone interviews with the RSO/AU. The medical consultant concluded that without an actual measurement of the thyroid uptake of I-131 there was a moderate uncertainty in the estimate of the radiation dose to the thyroid, and estimated a radiation absorbed dose of approximately 530-to-1600 cGy (530-to-1600 rad). The medical consultant further stated that it is unlikely that the misadministration will result in a clinically detectable effect on the patient's thyroid. The impact on the patient's health should be negligible, with no expected long-term disability.

An enforcement conference was held with the licensee on June 24, 1994. The five violations were classified as a Severity Level III problem and a Notice of Violation and Proposed Imposition of Civil Penalty (Ref. 9) for $1,250 was issued on July 11, 1994.

Queen's Medical Center in Honolulu, Hawaii

The following information pertaining to this event is also being reported in the *Federal Register*. Appendix A (see Event Type 1[a] in Table A-1) of this report notes that administering a therapeutic radiation dose greater than 1.5 times that intended from a sealed source should be considered an abnormal occurrence.

Date and Place—May 2, 1994; The Queen's Medical Center; Honolulu, Hawaii.

Nature and Probable Consequences—A patient was prescribed to receive two treatments of 1000 centigray (cGy) (1000 rad) to the patient's right eye using a strontium-90 (Sr-90) eye applicator. The treatment plan called for the two treatments to be scheduled one week apart. The first treatment was properly delivered on April 25, 1994, by keeping the source in contact with the patient's right eye for 18 seconds. On May 2, 1994, when the patient returned for the second treatment, the same physician treated the patient, but a different oncology nurse assisted. The physician did not refer to the written directive or to the dose-rate information available with the eye applicator, although he had used other applicators in the past. He also did not discuss the procedure with the oncology nurse prior to the second treatment. At the end of the desired 18-second period, the nurse raised her voice and paused at the count of "18" (as she had been trained) without saying "stop" as the physician expected. As a result, the treatment continued until 32 seconds had passed, when the physician realized that the desired time must have elapsed. As a result, the patient received 1778 cGy (1778 rad) to the right eye during the second treatment, rather than the prescribed 1000 cGy (1000 rad).

The Radiation Safety Officer reported the misadministration to the NRC Operations Center at 8:37 p.m. on May 2, 1994. The referring physician was also notified on the same day. The patient was notified of the event during follow-up examinations by the referring physician on May 5 and May 14, 1994. No clinical damage was observed by the referring physician, and none is expected. The patient will be examined during subsequent follow-up visits to the medical center.

The NRC staff retained a medical consultant to evaluate the potential medical effects on the patient as a result of the misadministration. The medical consultant stated that dosimetry for Sr-90 eye applicators is difficult, due to calibration factors, clinical factors, and treatment technique. The consultant will send an update on the dosimetry and calibration in the near future. The medical consultant stated that the increased unintended dose is within the range of normal treatments. He indicated that the medical consequences of the misadministration would be negligible.

Cause or Causes—Part 35 of Title 10 of the *Code of Federal Regulations* states that licensees must establish and maintain a written quality management program (QMP) to provide high confidence that each administration is in accordance with the written directive. However, at the time of the treatment, the licensee did not have a written procedure to require that staff members confirm that the planned administration will be as specified in the written directive. Consequently, neither the physician nor the oncology nurse referred to the written directive, nor did they discuss the procedure before it took place. Inconsistent training given to the oncology nurses in the method of timing treatments was also a contributing factor.

Actions Taken to Prevent Recurrence

Licensee—The licensee revised the QMP procedures to prevent recurrence of similar misadministrations. The new procedure specifies that prior to the procedure, the staff will determine that the eye applicator is as specified in the written directive. It also states that the staff must seek guidance prior to continuing if they do not understand any aspect of the written directive.

NRC—NRC Region IV conducted an inspection at The Queen's Medical Center on May 16-17, 1994, to review the circumstances associated with the misadministration and its probable cause(s). The NRC staff is currently reviewing the inspection results for possible violations, and enforcement action is pending.

Future reports will be made as appropriate.

94-12 Medical Sodium Iodide Misadministration at Stamford Hospital in Stamford, Connecticut

The following information pertaining to the event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 1 in Table A-1) of this report notes that administering a radiopharmaceutical other than the one intended which results in any part of the body receiving unscheduled diagnostic radiation, and the actual dose to the wrong body part, is five times the upper limit of the normal range of exposures prescribed for diagnostic procedures involving that body part, can be considered an abnormal occurrence.

Date and Place—May 17, 1994; Stamford Hospital; Stamford, Connecticut.

Cause or Causes—The licensee's radiation therapy staff failed to follow the licensee's normal protocol for treatment with the HDR remote afterloader. The failure to administer the treatment as prescribed resulted from performing the treatment planning and independent verification in the vicinity of the HDR console, where there were a number of distractions.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective actions included immediate retraining of all personnel involved in brachytherapy treatments and the addition of a checklist for each step in the treatment process. The licensee also added steps to its Quality Management program for HDR brachytherapy. These steps now require the use of the treatment planning computer with manual verification of the input parameter and the use of the treatment parameter card generated by the planning computer to program the HDR rather than programming the HDR treatment parameters manually.

NRC—NRC conducted a special inspection from February 2 to 4, 1994, to review the circumstances associated with the misadministration, the licensee's Quality Management program, and the licensee's immediate corrective actions. In addition, on February 25, 1994, NRC employed a medical consultant to provide an assessment of the potential clinical effects of this misadministration and the events that led to it.

The inspection report, medical consultant's assessment, and enforcement actions for the misadministration are being completed. This report will be updated when additional information becomes available.

Agreement State Licensees

The 29 Agreement States have approximately 15,000 active material licenses for the use of byproduct materials in industrial, medical, and academic applications. Procedures have been developed for Agreement States to screen events using the same criteria and guidelines as NRC, and to report those events that have been determined to be significant enough to be considered as abnormal occurrences. During this period, the Agreement States reported one abnormal occurrence, and information relating to this occurrence provided by April 25, 1994, has been included in this report.

AS 94-1 Therapeutic Radiopharmaceutical Misadministration at North Carolina Baptist Hospital in Winston Salem, North Carolina

Appendix A (see Event Type 2 in Table A-1) of this report notes that administering any therapeutic dose to the wrong patient should be considered an abnormal occurrence.

Date and Place—June 17, 1993; North Carolina Baptist Hospital in Winston Salem, North Carolina.

Nature and Probable Consequences—The nuclear medicine technologist had prepared dosages for two different patients and then prepared both patients for injection. The technologist was temporarily sidetracked and then returned to complete administration of the prepared dosages. The first patient received a 592 megabecquerel (MBq) (16 millicurie [mCi]) therapeutic dose of iodine-131 instead of the prescribed 37 MBq (1 mCi) diagnostic dose of thallium-201 for a myocardial perfusion scan. Upon entering the next room to administer the dosage to the second patient, the technologist discovered the error.

NRC was notified of this event on August 10, 1993. Immediate action taken by the licensee included notifying the referring physician and patient. An approved iodine contrast agent was injected into the patient, hemodialysis was initiated, and daily doses of potassium iodine were started and continued for 2 weeks. The patient was also held overnight for observation. No thyroid uptake was performed.

The Radiation Safety Officer concluded that without uptake data only rough estimates of the patient's exposure can be made. According to the International Commission on Radiological Protection, publication 53, "Radiation Dose to Patients from Radiopharmaceuticals," 100 percent blocking of the thyroid would result in all organ doses being less than 50 millisievert (mSv) (5 rem), and the effective dose equivalent would be approximately 43 mSv (4.3 rem). Assuming incomplete blockage, some parts of the gastrointestinal (GI) tract, the bladder wall, and the thyroid would have significantly higher doses.

In addition, the National Council on Radiation Protection and Measurements Report No. 80, "Induction of Thyroid Cancer by Ionizing Radiation," states that a significantly increased risk of thyroid cancer has not been detected in several studies on humans at the dose level misadministered to the patient. However, due to the likelihood of incomplete thyroid blockage, the patient will need to be monitored for signs of hypothyroidism.

Cause or Causes—This misadministration occurred due to personnel error during a time of heavy workload.

Actions Taken to Prevent Recurrence

Licensee—A new policy to color-code prepared dosages was implemented to more clearly and easily distinguish between therapeutic and diagnostic dosages.

State Agency—The licensee's corrective and preventative actions will be reviewed during the next inspection of the licensed activities by the North Carolina Division of Radiation Protection.

The patient has been contacted several times for follow-up observations; however, the patient lives out of town and has not been willing to cooperate. Therefore, no additional actions are expected.

This event is considered closed for the purpose of this report.

approximately 7000 licensees located in the remaining 21 States, the District of Columbia, and all U.S. territories. NRC has reviewed all incident and event reports received from NRC licensees through the second quarter of 1995. Using the criteria and guidelines in Appendix A of this report, the following occurrences were determined to be significant enough to be reported as AOs.

95-4 Medical Brachytherapy Misadministration at the University of Virginia, in Charlottesville, Virginia

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 3 in Table A-1) of this report notes that a therapeutic exposure to any part of the body not scheduled to receive radiation can be considered an AO.

Date and Place—March 14, 1995; University of Virginia Medical Center; Charlottesville, Virginia.

Nature and Probable Consequences—A patient was prescribed a manual brachytherapy procedure using cesium-137 (Cs-137) sources loaded in an applicator, for a total gynecological treatment dose of 3000 centigray (cGy) (3000 rad).

During insertion of the applicator into the patient, one of the sources fell onto the patient's bed and was unnoticed by the licensee staff involved in performing the procedure. A nurse found the source in the bed on March 15 and removed it. The source was reloaded into the applicator and the physician revised the prescribed dose to 2500 cGy (2500 rad). The licensee estimated that the source remained at approximately 10 centimeters (4 inches) from the patient's foot for 18 hours and delivered a dose of about 13 cGy (13 rad) to the foot.

The licensee notified the referring physician and the patient of the misadministration. An NRC medical consultant was obtained who concluded that the patient was receiving appropriate follow-up care. In addition, the licensee and the medical consultant concluded that the patient will not experience any adverse health effects as a result of the misadministration.

Cause or Causes—The licensee's staff involved in the brachytherapy procedure were not familiar with handling of the applicator that contained the Cs-137 sources. Also, because of anatomic characteristics of the patient, the physician had difficulty inserting the source carrier into the applicator. The design of the afterloading device allows the source to slide out of the carrier if any unusual manipulation of source carrier is required. The difficulty experienced by the physician in inserting the source in the applicator and the design of the source carrier resulted in the source falling out of the carrier during the insertion process.

Actions Taken to Prevent Recurrence

Licensee—The licensee provided training for its staff, involved in brachytherapy procedures, concerning the precautions which must be taken when handling an applicator such as the one used in the subject procedure. Also, emphasis was placed on the need to be more attentive during the source insertion process in order to account for all prescribed sources.

NRC—NRC conducted a special inspection on March 23-24, 1995, to review the circumstances surrounding the misadministration. The inspection report was issued on May 2, 1995. Enforcement action will be taken as appropriate.

This event is considered closed for the purpose of this report.

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95-5 Medical Therapeutic Radiopharmaceutical Misadministration of Iodine-131 at Massachusetts General Hospital in Boston, Massachusetts

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5 [a] in Table A-1) of this report notes that administering a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent and the actual dose is greater than 1.5 times the prescribed dose can be considered an AO.

Date and Place—May 9, 1995; Massachusetts General Hospital; Boston, Massachusetts.

Nature and Probable Consequences—A patient was prescribed a 296 megabecquerel (MBq) (8

millicurie [mCi]) dosage of iodine-131 (I-131) for hyperthyroidism; however, a dosage of 1106.3 MBq (29.9 mCi) was administered.

Representatives of the hospital informed the referring physician and the patient of the misadministration. An NRC medical consultant was obtained to evaluate the event and stated that the higher dosage given to the patient will result in a more likely achievement of the intended therapeutic goal to eliminate the patient's hyperthyroidism. Additionally, the consultant determined that it is unlikely that the patient is at significant risk of experiencing long-term consequences from receiving the higher dosage beyond the risk associated with the prescribed dosage. Therefore, the impact on the patient's health is expected to be negligible with no expected long-term disability. (The intent of the prescribed dose was to ablate the portion of the thyroid remaining after surgery and then support the patient with thyroid supplement the rest of her life. This did not change with the administered dose.)

Cause or Causes—The licensee stated that this event occurred because of a human error. The technologist involved in this procedure inadvertently switched the labeled lids on the vial shields containing the I-131 dosages prescribed for different patients. Additionally, the technician failed to check for the correct dosage on the vial label, and the wrong dose was administered to the intended patient.

Actions Taken to Prevent Recurrence

Licensee—The licensee instituted a procedure for checking the vial label before giving a dose. In addition, the licensee is obtaining a second dose calibrator which will be used in the out-patient dosing room of the Thyroid Clinic. Each dose will be re-assayed immediately before the I-131 is administered to the patient, rather than relying on the assay which was performed in the Thyroid Lab before the dose was transported to the outpatient dosing room.

NRC—NRC performed an inspection on May 12, 1995, to learn about the event and determined that it constituted a misadministration as defined in 10 CFR 35.2. NRC determined that this was an isolated violation of the licensee's Quality Management Program and issued a Notice of Violation at the Severity Level IV on June 26, 1995.

This event is considered closed for the purpose of this report.

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95-6 Multiple Medical Brachytherapy Misadministrations at Madigan Army Medical Center in Fort Lewis, Washington

The following information pertaining to this event is also being reported concurrently in the *Federal Register*. Appendix A (see Event Type 5[d] in Table A-1) of this report notes that administering a therapeutic dose from a sealed source such that the treatment dose differs from the prescribed dose by more than 10 percent and the event (regardless of health effects) affects two or more patients at the same facility can be considered an AO.

Date and Place—February 1994 through May 1995; Madigan Army Medical Center (MAMC); Fort Lewis, Washington.

Nature and Probable Consequences—Four patients were prescribed brachytherapy procedures, using iridium-192 seeds of different source strengths, and received doses other than those prescribed because of the same computer input error. (The same computer input error could cause either underdoses or overdoses because the algorithm used was dose dependent.) Details of the misadministrations are as follows:

Patient A: The patient was prescribed a dose of 2800 centigray (cGy) (2800 rad) for a gynecological brachytherapy treatment, but received a dose of about 1680 cGy (1680 rad) instead.

Patient B: Event 1 - The patient was prescribed a dose of 1600 cGy (1600 rad) for lung treatment, but received a dose of about 2128 cGy (2128 rad) instead.

Event 2 - On another day, the same patient was prescribed a dose of 1500 cGy (1500 rad) for lung treatment, but

SUPPORTING STATEMENT
FOR
10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL
(3150-0010)

EXTENSION WITH REVISIONS

DESCRIPTION OF THE INFORMATION COLLECTION

Part 35 of Title 10 of the Code of Federal Regulations contains requirements that apply to the Nuclear Regulatory Commission's licensees who are authorized to administer byproduct material or its radiation to humans for medical use.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

Part of the NRC's function is to license and regulate the use of byproduct material in order to assure protection of public health and safety. The NRC requires licensees to perform certain tasks to ensure fulfillment of their obligations. The records required in this part are the least burdensome way for licensees to demonstrate compliance. Occasionally, safety matters are of such significance that personnel need to be aware of the information in order to perform their jobs or work in a safe manner. In such cases, reports are required.

Sections 35.12(b) and (c) of 10 CFR Part 35 require that applicants submit a completed NRC Form 313, "Application for Materials License." The form elicits an orderly description of the applicant's complete radiation safety program. Requests for amendments and license renewals may be submitted in a letter format. This report is needed to assure the NRC that applicants' programs are adequate to protect health and minimize danger to life and property before the NRC can authorize receipt of radioactive material. NRC Form 313 has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

Section 35.13 requires that licensees apply for and receive a license amendment before using material not authorized by the license, before adding or changing key individuals, before receiving more material than authorized by the license, or before changing the area or addresses of authorized places of use. The triggering events are critical indicators of a potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection of the licensee's program. The information is required so that the staff can determine whether the licensee has individuals with adequate training and experience to safely use radioactive material, and the facilities and equipment necessary or required to assure protection of public health and safety.

Section 35.14 requires that licensees: 1) provide certain information for each individual no later than 30 days after the date the licensee permits the individual to work as an authorized user, or as an authorized nuclear pharmacist, 2) notify the NRC within 30 days if a key worker ends his

association with the licensee or has a name change, or 3) when the licensee's mailing address changes. The report for authorized user or authorized nuclear pharmacist is required in order to maintain the licensee's file with a current record of individuals authorized to use or prepare radioactive material. The report for changes in "key" workers is required because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure the safety of all licensed users. This report will trigger a check of the licensee's file to determine whether the licensee's remaining users are qualified to receive and use radioactive material safely. The NRC needs to be aware of mailing address changes to ensure that the licensee continues receiving correspondence such as information notices, bulletins, and other safety related documents.

Section 35.20 requires licensees to have a written program to keep radiation doses as low as reasonably achievable (ALARA). The program must be written to provide clear statements of authority, responsibility, and technical requirements. The written program is used by the licensee, the radiation safety officer, and authorized users. Its purpose is to ensure that licensees comply with the requirement to make a reasonable effort to maintain individual and collective occupational radiation doses ALARA.

Section 35.21(b)(2) requires that the licensee establish and implement the written policy and procedures that were submitted as part of the application. The written policy and procedures are needed so that NRC can review them and make a determination that the applicant can meet the requirements of the Atomic Energy Act and the Commission's regulations. The procedures must be implemented in order to provide for protection of public health and safety. The burden is included in the burden for the application, NRC Form 313, OMB Clearance No. 3150-0120.

Sections 35.22(a)(4) and (5) require that medical institution licensees retain a copy of radiation safety committee meeting minutes for the duration of the license, and prescribe the information required in the minutes. A copy of the minutes must be provided to each member. The record is required to document continuing management oversight of the radiation safety program.

Section 35.23(b) requires that licensees provide a written statement of authority, duties, responsibilities, and radiation safety activities for the radiation safety officer and radiation safety committee. The statement is needed so that managers and key users know their responsibilities. The statement must be retained for the duration of the license.

Section 35.29(b) requires that mobile nuclear medicine service licensees keep a letter of permission signed by the management of each client. This record is necessary to show that the client's management has permitted this work.

Section 35.31(b) requires that licensees make a record of minor radiation safety program changes. This record is needed to document what radiation safety factors were considered before implementing the minor change. This permits the NRC to evaluate the nature and appropriateness of the minor changes during inspections prior to renewal and will provide the licensee with

a complete record of the radiation safety program until the changes are incorporated into the license when renewed.

Section 35.32 contains requirements for a quality management program.

Section 35.32(a) requires that each applicant or licensee establish and maintain a written quality management program.
Section 35.32(b) requires that the licensee develop audit procedures, revise the quality management program when necessary, and retain records of each audit and management evaluation of the quality management program for 3 years.

Section 35.32(c) requires that the licensee retain records of the relevant facts of recordable events for 3 years.
Section 35.32(d) requires that the licensee retain records of written directives and administered radiation dose or radiopharmaceutical dosage for 3 years.

Section 35.32(e) allows the licensee to make modifications to the quality management program to increase the program's efficiency and requires that the modification be submitted to the NRC regional office within 30 days.

Section 35.32(f)(1) requires that an applicant for a new license submit a quality management program to the NRC regional office as part of the license application.

Sections 35.32(a), (b), (c), (d), (e), (f)(1) and (f)(2) are cleared separately under OMB Clearance No. 3150-0171. They are described here for information purposes only.

Section 35.33(a) requires:

(1) that the licensee notify by telephone the NRC Operations Center in case of a therapy misadministration within 24 hours after discovering the misadministration. This prompt notification is necessary because a therapy misadministration may present a clear and present radiation hazard to a member of the public that may be mitigated by NRC assistance.

(2) that a licensee file a written report to the NRC within 15 days after discovery of a misadministration. This report is required so that the NRC can determine whether there might be generic implications in the incident which indicate a need to notify all licensees. NRC allows the licensee 15 days to submit the report to give the licensee adequate time to review and analyze the event and to provide NRC with a complete history of the event. NRC requires submission of the report within 15 days so that NRC can promptly notify other licensees if it appears the precipitating event might be generic.

(3) that the licensee notify the referring physician and the patient, or human research subject, unless the referring physician informs the licensee that he will notify the patient, or unless contraindicated by factors known to the referring physician. These reports are needed so that the patient can ensure adequate follow-up care, if applicable.

Section 35.33(a) is cleared separately under OMB Clearance No. 3150-0171. It is described here for information purposes only.

Section 35.33(b) requires that the licensee retain a record of each misadministration for 5 years. The written records are required to determine what kinds of actions precipitate misadministrations, to provide input for enhancements and/or revisions to procedures, and provide an indicator of the licensee's management control of the radiation safety program. This section is cleared separately under OMB Clearance No. 3150-0171. It is described here for information purposes only.

Section 35.50(b)(4) requires that licensees make a record of a geometry dependence test for the dose calibrator. This record is required to demonstrate the relationship between volume configurations of the radiopharmaceutical and the accuracy of the reading given by the dose calibrator, so correction factors, if applicable, can be applied.

Section 35.50(e) requires that licensees retain a record of checks and tests of dose calibrator performance. The record is required to show that the dose calibrator is functioning correctly and is capable of accurately measuring radiopharmaceutical dosages, to establish trends in equipment performance, and to show compliance with regulatory requirements.

Section 35.51(a)(3) requires that the licensee note on a survey instrument the apparent exposure rate from a dedicated check source at the time of instrument calibration. This information is required so that the licensee can check the survey instrument for proper operation before making measurements. The burden is included in the burden estimate for Section 35.51(d).

Section 35.51(d) requires that licensees retain a record of survey instrument calibrations. This record is required to show that survey instruments were calibrated and operational.

Section 35.52(b) requires that licensees have procedures for use of instrumentation used to measure the radioactivity of alpha- or beta-emitting radionuclides for other than unit dosages. In particular, this section does not apply to unit dosages of alpha- or beta-emitting radionuclides from a manufacturer or a nuclear pharmacy licensed under 10 CFR Part 32. Part 35 licensees may use procedures provided by the manufacturer of the instrumentation. These procedures are necessary to ensure that licensees use the instrumentation correctly. Thus, an additional recordkeeping burden may be expected, although licensees who currently use alpha- or beta-emitting radionuclides already have procedures for using this instrumentation.

Section 35.53(c) requires that licensees retain a record of each radiopharmaceutical dosage measurement. This record is required for licensees to show that they are maintaining control of the use of radiopharmaceuticals.

Section 35.59(a) requires that licensees maintain the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources. These instructions are required so that individuals who handle sources can determine the specific safety measures appropriate for each kind of source used.

Section 35.59(d) requires that licensees retain a record of sealed source leak tests. This record is required to show that the leak test was done at the appropriate time, and that the source was not leaking.

Section 35.59(e)(2) requires that licensees file a report with the NRC within 5 days if leakage of a sealed source is detected. This report is needed so that NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.59(g) requires that licensees make a record of sealed source and brachytherapy source inventory. This inventory is required to show that possession of sealed sources did not exceed the amount authorized by the license. The 5 year recordkeeping requirement will help to assure continued control over sources that are only occasionally used.

Section 35.59(i) requires that licensees make a record of radiation surveys of areas where sealed sources and brachytherapy sources are stored. This record is necessary to document that adequate radiation shielding has been provided for such sources, and that dose rates in contiguous areas are within allowed levels.

Section 35.60(b) requires that licensees label each syringe or syringe radiation shield as to its contents. This label is needed because review of misadministration reports has indicated that in many cases misadministrations are caused by inadvertent transposition of syringes.

Section 35.61(b) requires that licensees label vial radiation shields with the identity of the radiopharmaceutical contained. NRC review of several misadministration reports indicates that many misadministrations occur when technicians draw a dosage from the wrong vial of radioactive material. Labels will help to reduce the chance of this happening.

Sections 35.70(d) and (g) require that the licensee establish action levels for radiation surveys. The action levels provide the individual who makes a radiation survey with information on what levels are expected and what levels require investigation. The sections also require that the licensee immediately notify the radiation safety officer if excessive levels are detected during a survey. This notification is needed so that the radiation

safety officer can take appropriate remedial action. The radiation safety officer is the primary individual onsite who is qualified to determine what action is needed to ensure worker and public health and safety, and whether that action is needed immediately or can be delayed.

Section 35.70(h) requires that licensees retain a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.80(f) requires that mobile nuclear medicine service licensees make a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.92(b) requires that licensees make a record of disposal of waste that was decayed in storage. The record is needed to show that the material was decayed for the required length of time, that its radioactivity cannot be distinguished from background radiation levels, and that a proper survey of each waste container was made prior to disposal.

Section 35.204(c) requires that licensees retain a record of molybdenum-99 concentration in radiopharmaceuticals. This record is needed to show that the concentration measurement was made and that the maximum molybdenum-99 concentration level was not exceeded.

Section 35.205(d) requires that the licensee post a time period of evacuation in areas where radioactive gases are used. In case of a spill, this provides notice to workers of how much time air handling equipment needs to reduce the air concentration to permissible limits. The licensee must retain a record of the calculations used to determine the evacuation time for the duration of use of the area.

Section 35.310(b) requires that licensees retain a record of radiation safety instruction given to personnel who care for radiopharmaceutical therapy patients. This record is needed to show that the training was given.

Sections 35.315(a)(2) requires that the licensee post radiopharmaceutical therapy patient room doors with a "Radioactive Materials" sign. This provides notice to hospital workers and the public that there is radioactivity in the room. The section also requires that the licensee note in the patient's chart how long visitors may stay in the patient's room. This is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules.

Section 35.315(a)(4) requires that licensees make a record of dose rates around radiopharmaceutical treatment rooms after administration of the dosage. This record is required to show that members of the public are not exposed to excessive levels of radiation.

Section 35.315(a)(8) requires that licensees make a record of the thyroid burden measurement of each individual who helped prepare or administer a therapeutic dosage of iodine-131. This record is required to show that the measurement was performed and that workers were not exposed to excessive levels of iodine-131.

Section 35.315(b) requires that the licensee promptly notify the radiation safety officer if the radiopharmaceutical therapy patient dies or has a medical emergency. This notification is required so that the radiation safety officer can take whatever actions are necessary to prevent a spread of radioactive contamination or loss of brachytherapy sources. The radiation safety officer is the primary individual onsite who is qualified to determine what action is required to ensure worker and public health and safety, and whether action is needed immediately or can be delayed.

Section 35.404(b) requires that licensees retain a record of the radiation survey of each patient who was treated with temporary implant sources. The record is required to show that the survey was performed.

Section 35.406(b) requires that licensees make a record of brachytherapy source use. This record is required so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

Section 35.406(c) requires that licensees make a record of radiation surveys of patients after implanting sources. This record is required to show that the survey was performed.

Section 35.406(d) requires that the licensee retain a record of the use of brachytherapy sources and special safety surveys. This record is needed to show that the licensee is providing adequate control for these sources. The record burden is included in the burden estimate for Sections 35.406(b) and (c).

Section 35.410(b) requires that licensees retain a record of training for personnel who care for implant patients. This record is required to show that the training was given.

Section 35.415(a)(2) requires that a licensee post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room. This posting is required to help protect against excessive radiation exposure to visitors.

Section 35.415(a)(4) requires that, after an implant of radioactive material, licensees record the results of a survey of the contiguous restricted and unrestricted areas and retain the record for 3 years. The record is used to demonstrate compliance with 10 CFR Part 20 requirements and to show that members of the public are not exposed to excessive levels of radiation.

Section 35.415(b) requires that the licensee notify the radiation safety officer immediately if the patient dies or has a medical emergency. This notification is required so that the radiation safety officer can take whatever action is necessary to prevent a spread of radioactive contamination or loss of sources. The radiation safety officer is the primary individual onsite who is qualified to determine what action is necessary to ensure worker public health and safety, and whether that action is required immediately or can be delayed.

Section 35.606 requires that licensees apply for and receive a license amendment before making certain changes in the teletherapy program. This license amendment process is necessary because the licensee may consider making changes that would cause radiation levels in restricted and unrestricted areas to exceed permissible levels. The burden is included in OMB Clearance No. 3150-0120.

Section 35.610(a) requires that licensees post written instructions for individuals who operate teletherapy units. These instructions are necessary to remind workers of proper operating procedures and to serve as a quick reference in case of emergencies or equipment malfunction.

Section 35.610(c) requires that licensees make a record of training for individuals who operate teletherapy units. This record is needed to show that the training was given.

Section 35.615(d)(4) requires that licensees retain a record of the teletherapy room radiation monitoring device function check. This record is needed to show that the check was made, and for trend analysis by the licensee.

Section 35.615(d)(5) requires that licensees retain a record of the functional check of the instrument or dosimeter used when the radiation monitor is inoperable. The burden is included in Section 35.615(d)(4) as this record is required only when the radiation monitor is inoperable.

Section 35.630(c) requires that licensees retain a record of each calibration, intercomparison, and comparison of teletherapy dosimetry equipment. These records are needed to show that measurements of radiation teletherapy doses were made with instruments capable of making accurate measurements.

Section 35.632(g) requires that licensees retain a record of teletherapy unit calibration. This record is needed to show that the calibrations were done and that licensees did not inadvertently administer incorrect radiation doses to patients.

Section 35.634(c) requires that the qualified teletherapy physicist report the results of teletherapy unit spot-checks promptly to the licensee. This assures the licensee that the results of each spot-check have been reviewed by an expert. The licensee must keep a copy of each report to assure that the review has been made.

Section 35.634(f) requires that licensees retain a record of spot-checks. This record is needed to show that the required checks were made.

Section 35.636(c) requires that licensees retain a record of safety checks for teletherapy facilities. This record is needed to show that the checks were made.

Section 35.641(c) requires that licensees retain a record of radiation measurements after installing a source in a teletherapy unit. These records provide assurance that the source is properly installed within the teletherapy

unit, and that dose rates outside the teletherapy room are within permissible limits.

Section 35.643(a)(3) requires that licensees include additional survey and facility description information if changes in an NRC approved installation were necessary for compliance with 10 CFR Part 20. The additional information in the report will facilitate a determination by the NRC that dose rates in restricted and unrestricted areas are within permissible limits. The 30 day submission requirement is contained in Section 35.645.

Section 35.643(b) requires that licensees request a license amendment if the licensee wants authorization for radiation levels in unrestricted areas which are above permitted levels. This report will trigger an in depth NRC review of safety considerations before it allows a licensee to operate the unit. The burden for the license amendment is included in OMB Clearance No. 3150-0120.

Section 35.645 requires that licensees mail a copy of teletherapy source installation records to the NRC. These records are needed to show that dose rates in restricted and unrestricted areas are within permissible levels. The submission must be made within 30 days after the completion of the action that initiated the record requirement. The 30-day requirement is imposed because of the especially high dose rates that can be found around teletherapy units.

Section 35.647(c) requires that licensees keep a record of teletherapy unit inspection and servicing. This record is needed to show that the required work was done.

Section 35.980(b)(2) requires an individual to obtain a written certification signed by a preceptor before the individual can be qualified as an authorized nuclear pharmacist. This is necessary to ensure that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Section 35.981 requires a licensee to receive an amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. Prior to January 1, 1995, there was no requirement to have an authorized nuclear pharmacist. This amendment is necessary to ensure that facilities have a qualified nuclear pharmacist on site.

2. Agency Use of the Information

The records that 10 CFR Part 35 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material.

The records of receipt, transfer, and disposal of byproduct material are reviewed by the NRC inspectors to determine that licensees have confined their possession and use of byproduct material to the locations, purposes, receipt, and quantities authorized in their licenses.

Reports are used by the agency in evaluating the protective actions required to avoid exposures to radiation or releases of radioactive materials that could impact public health and safety and the environment.

3. Reduction of Burden Through Information Technology

There are no current information technology applications that would reduce the burden of these information collection requirements. The NRC encourages applicants and licensees to use new automated information technology when it would be beneficial to them. However, because of the types of information and the infrequency of submission, the applications and reports may not lend themselves readily to the use of automated information technology for their submission. Consequently, the current percentage of electronic submission is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. In general, information required by the NRC in applications, reports, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees. Portions of the needed information might also be contained in other information submittals to the NRC or other Federal agencies. However, duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

5. Effort to Reduce Small Business Burden

While a number of licensees are considered small businesses, under the NRC's current definitions, the health and safety consequences of improper use of radioactive material are the same for large and small entities. It is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures while maintaining the required level of safety.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the possession, use, or transfer of byproduct material.

The required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments are submitted only once. Applications for renewal of licenses are submitted every 5 years. Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of public health and safety.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.5(d), Section 35.14 requires that licensees notify the NRC within 30 days if a key worker ends his association with the licensee. This prompt report is required because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure safety. This report will trigger a check of the licensee's file to determine whether the remaining key users are qualified to receive and use material safely.

Section 35.20 requires licensees to retain, for the duration of the license, a written program to keep radiation dose as low as reasonably achievable. The written program must be retained so that it can be used by the licensee, the radiation safety officer, and authorized users throughout the period of the license to ensure that a reasonable effort is made to maintain individual and collective occupational radiation doses as low as reasonably achievable.

Section 35.21(b)(2) requires that the licensee establish and implement the written policy and procedures that were submitted as part of the application. It is necessary that the policy and procedures be retained for the duration of the license so that they will be available to the licensee's staff for implementation and so that the NRC staff can review them to ensure that the applicant can meet the requirements of the Atomic Energy Act and the Commission's regulations for protection of public health and safety.

Sections 35.22(a)(4) and (5) require that medical institution licensees retain a copy of radiation safety committee meeting minutes for the duration of the license, and prescribe the information required in the minutes. Retention of the records for the duration of the license is required to show continuing management oversight of the radiation safety program.

Section 35.23(b) requires that licensees retain, for the duration of the license, a written statement of authority, duties, responsibilities, and radiation safety activities for the radiation safety officer and radiation safety committee. Retention of the statement for the period of the license is necessary so that managers and key users know their responsibilities.

Section 35.31(b) requires that licensees retain a record of minor radiation safety program changes until license renewal or termination. This record is needed to show what radiation safety factors were considered before implementing the minor change. This permits NRC to evaluate the nature and appropriateness of the minor changes during inspections prior to renewal and provides the licensee with a complete record of the radiation safety program until the changes are incorporated into the license at renewal.

Section 35.32(a) requires that each applicant or licensee establish and maintain a written quality management program for the duration of the licensed activity. Section 35.32(a) is cleared separately under OMB No. Clearance 3150-0171.

Section 35.33(a) requires:

(1) that the licensee notify by telephone the NRC Operations Center in case of a therapy misadministration within 24 hours after discovering the misadministration. This prompt notification is necessary because a therapy misadministration may present a clear and present radiation hazard to a member of the public that might be mitigated by NRC assistance.

(2) that a licensee file a written report to NRC within 15 days after discovery of a misadministration. This report is necessary so that the NRC can determine whether there might be generic implications in the incident which indicate a need to notify all licensees. NRC allows the licensee 15 days to submit the report so that it can review and analyze what has happened and provide NRC with a complete history of the event. NRC requires submission of the report within 15 days so that it can promptly notify other licensees if it appears the precipitating event might be generic.

Section 35.33(b) requires that the licensee retain a record of each misadministration for 5 years. These written records are needed to determine what kinds of actions precipitate misadministrations, and also provide an indicator of the licensee's management control of the radiation safety program.

Sections 35.33(a) and (b) are cleared separately under OMB Clearance No. 3150-0171.

Section 35.50(b)(4) requires that licensees retain a record of a geometry dependence test for the dose calibrator for the duration of use of the dose calibrator. This record is necessary throughout the duration of use of the equipment to demonstrate the relationship between volume configurations of the radiopharmaceutical and the accuracy of the reading given by the dose calibrator, and would be necessary for subsequent reconstruction in the event of an incident involving questions of dose calibration.

Section 35.50(e) requires that licensees retain a record of checks and tests of dose calibrator performance for the duration of use of the equipment. This record is needed throughout the duration of use of the equipment to show that the dose calibrator is functioning correctly and is capable of accurately measuring radiopharmaceutical dosages, and to establish trends in equipment performance.

Section 35.59(a) requires that licensees maintain, for the duration of source use, the manufacturer's written instructions for the safe use of sealed sources and brachytherapy sources. These instructions are needed so that, at any time during the duration of use, individuals who are handling sources can determine the specific safety measures appropriate for each kind of source used.

Section 35.59(e)(2) requires that licensees file a report with the NRC within 5 days if leakage of a sealed source is detected. This report is necessary so

that the NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that the licensee can review and analyze the source and the leak test result. NRC requires submission of the report within 5 days so that NRC can promptly notify other licensees if it appears there may be a generic problem.

Section 35.59(g) requires that licensees retain a record of sealed source and brachytherapy source inventory for 5 years. This inventory is needed to show that possession of sealed sources did not exceed the amount authorized by the license. The 5 year recordkeeping requirement is necessary to assure continued control over sources that are only occasionally used, and to ensure that the records will be available for periodic inspections, which may exceed a 3 year interval.

Section 35.205(d) requires that the licensee retain, for the duration of use of the area, a record of the calculations used to determine the evacuation time for areas where radioactive gases are used. In case of a spill, the record of the calculations, which is required to be posted, provides notice to workers of how much time air handling equipment needs to reduce the air concentration to permissible limits. This record is also needed to show that the calculations were performed. Retention beyond 3 years is necessary to provide notice of evacuation time to workers and to ensure that records of calculations are available to the NRC for periodic inspections, which may exceed 3 year intervals.

Section 35.315(a)(8) requires that licensees retain a record of the thyroid burden measurement of each individual who helped prepare or administer a therapeutic dosage of iodine-131 until the Commission authorizes their disposition. This record is needed to show that the measurement was performed and that workers were not exposed to excessive levels of iodine-131. Retention beyond 3 years is necessary to ensure that complete records of exposure of each individual are available to the individual and to the licensee so that the licensee can avoid accumulation of excessive exposures by individuals.

Section 35.415(b) requires that the licensee notify the radiation safety officer immediately if the patient dies or has a medical emergency. This immediate notification is necessary to permit the radiation safety officer to ensure that safety requirements are met for removal or disposal of the implanted radioactive material.

Section 35.630(c) requires that licensees retain a record of each calibration, intercomparison, and comparison of teletherapy dosimetry equipment for the duration of use of the teletherapy unit source. These records are necessary to show throughout the period of use of the equipment that measurements of radiation teletherapy doses were made with instruments capable of making accurate measurements, and for use in reconstruction in case of an incident.

Section 35.632(g) requires that licensees retain, for the duration of the license, a record of teletherapy unit calibration. This record is required to show that the calibrations were done and that licensees did not inadvertently

administer incorrect radiation doses to patients. It would also be necessary in the case of reconstruction of an incident.

Section 35.641(c) requires that licensees retain, for the duration of the license, a record of radiation measurements after installing a source in a teletherapy unit. These records are required throughout the period of the license to provide assurance that the source was properly installed within the teletherapy unit, and that dose rates outside the teletherapy room are within permissible limits. They would also be necessary in reconstruction following an incident involving the unit.

Section 35.645 requires that licensees mail a copy of the teletherapy source installation records to the NRC. This record is required to show that dose rates in restricted and unrestricted areas are within permissible levels. The submission must be made within 30 days after completion of the action that initiated the record requirement. The 30 day requirement is imposed because of the especially high dose rates that can be found around teletherapy units.

Section 35.647(c) requires that licensees keep a record of teletherapy unit inspection and servicing for the duration of the license. This record is required throughout the period of licensed activity to show that the required work was done and to establish a service history which may be used in incident investigations and evaluation of generic equipment problems.

8. Consultations Outside the NRC

During this clearance period, there have been consultations with the Advisory Committee on the Medical Use of Isotopes (ACMUI), a group which includes a number of representatives of the licensed medical community, which provides advice to the NRC staff. There have been consultations with staff members of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research and the FDA's Center for Biologics Evaluation and Research on amendments to the rule, and on supporting recordkeeping requirements. Additionally, the NRC has received public comments on amendments to the rule.

An invitation to comment on the current Part 35 information collection requirements was published in the Federal Register on March 27, 1996 (61 FR 13519-13520). There were no comments.

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of the Information

Reports submitted are generally subject to public disclosure in accordance with 10 CFR 2.790 and 10 CFR Part 9. Section 2.790 allows the NRC to withhold certain proprietary information (information of commercial value or "trade secrets") if, at the time of submittal of the report, the requirements for withholding the information are met (refer to 10 CFR 2.790(b)). Also, there are provisions in 10 CFR Part 9 for the NRC to withhold from public disclosure

documents such as reports of radiation exposure to individuals and other personal records.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:

These requirements will affect approximately 1982 licensees and applicants, of which 1348 of the licensees are hospitals, and 394 of the licensees are physicians in private practice.

The total annual burden is estimated to be about 376,407 hours per year (about 190 hours per licensee) for the 1,982 licensees covered by 10 CFR Part 35. The details are shown in Tables 1 and 2. The total cost for the NRC licensees is estimated at $45,168,840 (376,407 hours x $120.00). Cost is calculated at a rate of $120 per hour, which is based on NRC's fee recovery rate.

Agreement State Licensees:

10 CFR Part 35 is a Division III level of compatibility for Agreement States. The Agreement States are encouraged to adopt similar regulations, but are not required to have any degree of uniformity between the NRC regulations and the State regulations. The burden for Agreement State licensees is calculated on the basis of Agreement States having similar regulations for medical use programs.

The total annual burden is estimated to be about 942,820 hours per year (about 190 hours per licensee) for the estimated 4,955 licensees covered by equivalent regulations. The details are shown in Tables 3 and 4. The total cost for the Agreement State licensees is estimated at $113,138,400 (942,820 hours x $120.00).

13. Estimate of Other Additional Costs

None. For licensees under 10 CFR Part 35, it is most likely that purchases of equipment and services were made (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

14. Estimated Annualized Cost to the Federal Government

Application review activities are attributable to and reported under NRC Form 313, "Application for Material Licensee," OMB Clearance No. 3150-0120.

The "Quality Management Program and Misadministrations" information collection requirements are cleared under OMB Clearance No. 3150-0171.

Annual Cost of NRC staff review for activities other than application review (Professional effort is 239 hours @ $120.00 per hour) = $28,680. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden and Cost

NRC Licensees:

The revision is a net increase adjustment in burden as a result of an increase in the number of 10 CFR Part 35 licensees, and a reevaluation of the time required to perform individual activities and the number of times those activities are performed. Two new requirements were included as a result of rulemaking since the last burden was calculated. One requirement, which was inadvertently omitted during the last evaluation, was added. There is an increase in the number of NRC medical use licensees, from 1,900 to 1,982. The result is a net burden increase of 46,614 hours.

Agreement State Licensees: The burden for Agreement State licensees was not addressed in the previous OMB clearance package for 10 CFR Part 35. Its inclusion in this submittal will increase the overall burden to licensees reflected in this clearance submittal by 942,820.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There are no plans for publication of this information.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable

Table 1: Reporting Requirements - NRC Licensees

Section	No. of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.12(b)	See OMB Clearance No. 3150-0120		
35.12(c)	See OMB Clearance No. 3150-0120		
35.13	See OMB Clearance No. 3150-0120		
35.14	471	0.5	236
35.32(f)(1)	See OMB Clearance No. 3150-0171		
35.32(f)(2)	See OMB Clearance No. 3150-0171		
35.33(a)	See OMB Clearance No. 3150-0171		
35.59(e)(2)	2	2	4
35.60(b)	986,000	0.02	19,720
35.61(b)	876,200	0.02	17,524
35.70(d)	1,866	0.08	149
35.70(g)	1,866	0.08	149
35.315(a)(2)	3,200	0.2	640
35.315(a)(6)	3,200	0.25	800
35.315(b)	16	1	16
35.415(a)(2)	8,700	0.2	1,740
35.415(b)	73	1	73
35.606	See OMB Clearance No. 3150-0120		
35.610(a)	89	0.5	45
35.634(c)	534	0.5	267
35.643(a)(3)	1	4	4
35.643(b)	See OMB Clearance No. 3150-0120		

Table 1: Reporting Requirements - NRC Licensees continued

Section	No. of NRC Licensee Responses Annually	NRC Licensee Staff Hours per Submittal	Total Annual NRC Licensee Staff Burden Hours
35.645	45	0.5	23
35.980(b)(2)	20	1	20
35.981	See OMB Clearance No. 3150-0120		
TOTAL:	**1,882,283**	**12**	**41,410**

Table 2: Recordkeeping Requirements - NRC Licensees

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.20	See OMB Clearance No. 3150-0120*			license duration
35.21(b)(2)	See OMB Clearance No. 3150-0120*			license duration
35.22(a)(4) & (5)	1561	8	12,488	license duration
35.23(b)	See OMB Clearance No. 3150-0120*			license duration
35.29(b)	37	20	740	3 years after last service
35.31(b)	1,982	1	1,982	license renewal or termination
35.32(a)	See OMB Clearance No. 3150-0171			
35.32(b)	See OMB Clearance No. 3150-0171			
35.32(c)	See OMB Clearance No. 3150-0171			
35.32(d)	See OMB Clearance No. 3150-0171			
35.32(e)	See OMB Clearance No. 3150-0171			
35.33(b)	See OMB Clearance No. 3150-0171			
35.50(b)(4)	See 35.50(e)(4)			equipment duration
35.50(e)(1)	1,866	1	1,866	3 years
35.50(e)(2)	1,866	0.3	560	3 years
35.50(e)(3)	1,866	4	7,464	3 years
35.50(e)(4)	80	1	80	equipment duration
35.51(a)(3) & (d)	1,955	0.5	978	3 years
35.52(b)	55	0.2	11	equipment duration

*These documents are prepared as a written report and must be retained by the licensee for reference. The time spent making the record is included in the noted reporting section.

Table 2: Recordkeeping Requirements - NRC Licensees continued

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.53(c)	1,866	47	87,002	3 years
35.59(a)	1,982	0.5	991	source duration
35.59(d)	1,982	1	1,982	3 years
35.59(g)	1,982	0.6	1,189	5 years
35.59(i)	1,982	0.2	396	3 years
35.70(h)	1,866	86	160,476	3 years
35.80(f)	37	130	4,810	3 years
35.92(b)	1,866	14	26,124	3 years
35.204(c)	674	12	8,088	3 years
35.205(d)	1,866	0.5	933	duration of use of area
35.310(b)	973	4	3,892	3 years
35.315(a)(4)	973	1.5	1,460	3 years
35.315(a)(8)	973	1	973	until disposal authorized
35.404(b)	478	2	956	3 years
35.406(b)	478	4	1,912	3 years
35.406(c)	478	1	478	3 years
35.406(d)	Included in 35.406(b) and (c)			
35.410(b)	478	4	1,912	3 years
35.415(a)(4)	478	4	1,912	3 years
35.610(c)	89	1	89	3 years
35.615(d)(4)	89	8	712	3 years
35.615(d)(5)	Included in 35.615(d)(4)			

Table 2: Recordkeeping Requirements - NRC Licensees continued

Section	No. of NRC Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.630(c)	89	0.5	45	license duration
35.632(g)	89	4	356	duration of teletherapy source
35.634(c)	89	12	1,068	3 Years
35.634(f)	89	12	1,068	3 years
35.636(c)	Included in 35.634(f)			3 years
35.641(c)	Included in 35.634(f)			license duration
35.647(c)	89	0.05	4	license duration
TOTAL:			**334,997**	

Total NRC licensee burden hours: 376,407

Table 3: Reporting Requirements - Agreement State Licensees

Section	No. of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.12(b)	See OMB Clearance No. 3150-0120		
35.12(c)	See OMB Clearance No. 3150-0120		
35.13	See OMB Clearance No. 3150-0120		
35.14	1178	0.5	589
35.32(f)(1)	See OMB Clearance No. 3150-0171		
35.32(f)(2)	See OMB Clearance No. 3150-0171		
35.33(a)	See OMB Clearance No. 3150-0171		
35.59(e)(2)	4	2	8
35.60(b)	2,465,000	0.02	49,300
35.61(b)	2,190,500	0.02	43,810
35.70(d)	4,665	0.08	373
35.70(g)	4,665	0.08	373
35.315(a)(2)	8,000	0.2	1,600
35.315(a)(6)	8,000	0.25	2,000
35.315(b)	40	1	40
35.415(a)(2)	21,750	0.2	4,350
35.415(b)	183	1	183
35.606	See OMB Clearance No. 3150-0120		
35.610(a)	223	0.5	112
35.634(c)	1,335	0.5	668
35.643(a)(3)	3	4	12
35.643(b)	See OMB Clearance No. 3150-0120		

Table 3: Reporting Requirements - Agreement State Licensees continued

Section	No. of Agreement State Licensee Responses Annually	Agreement State Licensee Staff Hours per Submittal	Total Annual Agreement State Licensee Staff Burden Hours
35.645	113	0.5	57
35.980(b)(2)	No equivalent regulation required until 3 years after effective date of rule		
35.981	No equivalent regulation required until 3 years after effective date of rule		
TOTAL:	**4,705,652**	**11**	**103,475**

Table 4: Recordkeeping Requirements - Agreement State Licensees

Section	No. of Agreement State Recordkeepers (2.5 x No. NRC licensees)	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.20	See OMB Clearance No. 3150-0120*			license duration
35.21(b)(2)	See OMB Clearance No. 3150-0120*			license duration
35.22(a)(4) & (5)	3,903	8	31,224	license duration
35.23(b)	See OMB Clearance No. 3150-0120*			license duration
35.29(b)	93	20	1,860	3 years after last service
35.31(b)	4,955	1	4,955	license renewal or termination
35.32(a)	See OMB Clearance No. 3150-0171			
35.32(b)	See OMB Clearance No. 3150-0171			
35.32(c)	See OMB Clearance No. 3150-0171			
35.32(d)	See OMB Clearance No. 3150-0171			
35.32(e)	See OMB Clearance No. 3150-0171			
35.33(b)	See OMB Clearance No. 3150-0171			
35.50(b)(4)	See 35.50(e)(4)			equipment duration
35.50(e)(1)	4,665	1	4,665	3 years
35.50(e)(2)	4,665	0.3	1,400	3 years
35.50(e)(3)	4,665	4	18,660	3 years
35.50(e)(4)	200	1	200	equipment duration
35.51(a)(3) & (d)	4,888	0.5	2,444	3 years
35.52(b)	138	0.2	28	equipment duration

*These documents are prepared as a written report and must be retained by the licensee for reference. The time spent making the record is included in the noted reporting section.

Table 4: Recordkeeping Requirements - Agreement State Licensees continued

Section	No. of Agreement State Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.53(c)	4,665	47	219,255	3 years
35.59(a)	4,955	0.5	2,478	source duration
35.59(d)	4,955	1	4,955	3 years
35.59(g)	4,955	0.6	2,973	5 years
35.59(i)	4,955	0.2	991	3 years
35.70(h)	4,665	86	401,190	3 years
35.80(f)	93	130	12,090	3 years
35.92(b)	4,665	14	65,310	3 years
35.204(c)	1,685	12	20,220	3 years
35.205(d)	4,665	0.5	2,333	duration of use of area
35.310(b)	2,433	4	9,732	3 years
35.315(a)(4)	2,433	1.5	3,650	3 years
35.315(a)(8)	2,433	1	2,433	until disposal authorized
35.404(b)	1,195	2	2,390	3 years
35.406(b)	1,195	4	4,780	3 years
35.406(c)	1,195	1	1,195	3 years
35.406(d)	Included in 35.406(b) and (c)			
35.410(b)	1,195	4	4,780	3 years
35.415(a)(4)	1,195	4	4,780	3 years
35.610(c)	223	1	223	3 years
35.615(d)(4)	223	8	1,784	3 years
35.615(d)(5)	Included in 35.615(d)(4)			

Table 4: Recordkeeping Requirements - Agreement State Licensees continued

Section	No. of Agreement State Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Retention Period
35.630(c)	223	0.5	112	license duration
35.632(G)	223	4	892	duration of teletherapy source
35.634(c)	223	12	2,676	3 years
35.634(f)	223	12	2,676	3 years
35.636(c)	Included in 35.634(f)			3 years
35.641(c)	Included in 35.634(f)			license duration
35.647(c)	223	0.05	11	license duration
TOTAL:			839,345	

Total Agreement State licensee burden hours: 942,820

Total NRC and Agreement State licensee burden hours: 1,319,227

SUPPORTING STATEMENT
FOR
10 CFR 35.32 and 35.33
"QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS"
(3150-0171)

REVISED CLEARANCE EXTENSION

INTRODUCTION AND OVERVIEW

NRC regulations in 10 CFR Part 35 establish requirements for the medical use of byproduct material. The regulations are issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. This clearance extension addresses two provisions of 10 CFR Part 35: (1) a requirement that licensees establish and maintain a quality management program (QMP)(§ 35.32) and (2) requirements for notifications, records, and reports of misadministrations (§ 35.33).

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

In addition, the ACNP/SNM took the NRC to court, in American College of Nuclear Physicians and Society of Nuclear Medicine v. U.S. Nuclear Regulatory Commission. Only ten days after hearing arguments in the case, the court ruled in favor of the NRC, declaring that it saw "no need for a published opinion." 976 F.2d 45 (D.C. Cir. 1992)(Table). The court stated:

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

In 1993, the NRC contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM) to conduct an external review of the NRC's medical regulatory program. The goal of the external review was to develop an assessment of the adequacy and appropriateness of the current framework for the medical use of byproduct material. The quality management program (QMP) (§ 35.32) and requirements for notifications, records, and reports of misadministrations (§ 35.33) were included in that study.

In a letter to OMB, dated November 28, 1995, the ACNP/SNM again requested that OMB disapprove the ICR associated with 10 CFR 35.32 and 35.33 as they relate

to diagnostic and therapeutic applications of byproduct material.

In December 1995, the IOM submitted its report to the NRC. The majority report (there was a dissenting opinion as well) was highly critical of NRC regulation in the medical area, and of the QM rule in particular. The IOM findings have been and are being considered within the agency-wide Strategic Assessment and Re-baselining initiative. The staff is awaiting the Commission's direction on the medical use regulatory program.

In February 1996, the OMB approved a one-year extension of the information collection provisions of NRC's QM rule rather than the three-year approval that is customary. The one-year extension necessitated that NRC begin preparation of the 1997 OMB submittal within four-months of the previous approval. The elapsed time was not sufficient to resolve the issues associated with the prospective changes to NRC's medical use program.

The Commission is seeking OMB approval of a three-year clearance extension to allow sufficient time to consider what legislative and/or regulatory changes are appropriate for NRC's medical use program.

DESCRIPTION OF THE INFORMATION COLLECTION

In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or administered to a wrong individual which resulted in unnecessary exposures to radiation, or inadequate, or incorrect diagnostic or therapeutic procedures. The most frequent causes of these incidents were: insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. In an effort to reduce the frequency of such events, the NRC requires licensees to implement a QMP (§ 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. In response to comments, the final rulemaking that established these new requirements, which the agency believes are essential to adequately protect the health and safety of the public, also minimized the reporting burden. In the rulemaking, NRC also revised the definition for "misadministration" in § 35.2, "Definitions," and distinguished between the "misadministrations" and lesser "recordable events" for which reporting to NRC is not necessary. These revisions considerably reduced the number of incidents that must be reported to the NRC or the Agreement States. When compared to the previous definition, the number of incidents that meet the revised definition of misadministration has resulted in a greater than 10 fold reduction in the reporting burden. There has been a corresponding reduction in the regulatory effort.

The cost for this rule was "front loaded," in that, all affected licensees were required to submit a QMP to be reviewed by the applicable regulatory agency. This implementation burden has been completed by current NRC licensees and 19 of the 29 States who have agreements with the NRC that allow them to regulate the use of byproduct material as Agreement States. However, ten Agreement States have not completed their adoption of the rule. Therefore, this ICR cost estimate reflects the one-time cost for the development and submission of QMPs for approximately 2000 Agreement States

licensees in those ten Agreement States. It should be noted that the Commission is currently reviewing the issue of compatibility relative to the QM rule for the Agreement States. If relief is granted to the Agreement States from certain QM rule compatibility requirements, the staff will submit a modification of the burden estimate that reflects the changes.

A. JUSTIFICATION

1. Need for and Practical Utility of the Collection of Information

In order to obtain a license issued pursuant to 10 CFR Part 35, medical applicants, who plan to use byproduct material in certain diagnostic and therapeutic ranges, must submit a QMP to provide high confidence that byproduct material will be administered as directed by an authorized user physician (§ 35.32). The rulemaking and related regulatory guide were developed to include generally accepted good practices in the medical uses of byproduct material for therapy, and include specific measures intended to prevent many of the kinds of human errors observed and reported to the NRC over a number of years.

In comments provided during rulemeaking, members of the Society of Nuclear Medicine and NRC's Advisory Committee on the Medical Uses of Isotopes indicated a belief that NRC medical use licensees already had procedures in place to assure that the administration of byproduct material was as directed by an authorized user physician. However, when reviewed, 72 percent of the licensee-submitted QMPs did not contain such procedures. The unexpected number of licensees that did not submit (nor apparently have) procedures to assure that byproduct material is administered as directed by an authorized user is an indication of the need for a Quality Management Rule.

The recordkeeping and reporting requirements of the quality management rule serve a number of valuable functions. First, they provide assurance both to the licensees and to the NRC that sound safety practices are being followed, and that licensees are taking appropriate followup actions if and when mishaps occur. Second, they provide a basis for enforcement action by the NRC to correct safety deficiencies and take appropriate action against licensees and/or individuals if public health and safety is being endangered. Third, they furnish data that can be used to adjust NRC regulatory standards generically to ensure that they are sufficient to protect health and safety, but at the same time not more burdensome than necessary. Fourth, they can reveal generic problems of which the medical community can then be made aware by NRC.

For the calculations required in this justification, the staff estimates that 30 therapeutic misadministrations per year will be reported by NRC licensees over the next 3 years. The staff bases this on the number of such misadministrations reported by NRC licensees for years 1993, 1994, and 1995. Assuming that Agreement State licensees and NRC licensees

have similar medical use programs, and the Agreement States license 2.5 times as many licensees, the staff estimates that 105 (30+75) misadministrations per year will be reported nationwide. Information on the recordkeeping and reporting requirements is described by specific section below.

Section 35.32(a) requires that medical use licensees, who use byproduct material for limited diagnostic and therapy procedures, establish, implement, and maintain a QMP to provide high confidence that byproduct material will be administered as directed by an authorized user physician. The QMP must include written policies and procedures which require that prior to certain administrations, a written directive is prepared, that the individual's identity is verified by more than one method, that final treatment plans, doses, and administrations are in accordance with the written directive, and that any unintended deviation from the directive is identified, evaluated, and acted upon. At this time, all affected NRC licensees have submitted a QMP which has undergone an initial NRC review, or have provided a negative declaration that they will not utilize byproduct materials affected by the QMP requirements prior to the submission of a QMP. New licensees, subject to the requirements, must submit a written QMP with their application. Additionally, 2000 Agreement State licensees are expected to submit a QMP to the appropriate Agreement State within the next 3 years. Licensee implementation and maintenance of their QMP is reviewed during an NRC or Agreement State inspection.

Section 35.32(b)(1) requires licensees to develop procedures for and conduct a review of the QMP including, since the last review, an evaluation of a representative sample of administrations, all recordable events, and all misadministrations. Reviews must be conducted at intervals no greater than 12 months. This is necessary to evaluate the effectiveness of the QMP and identify issues that may lead to modifications of the QMP.

Section 35.32(b)(2) requires licensees to evaluate QMP reviews and make modifications, if required, to ensure their effectiveness.

Section 35.32(b)(3) requires licensees to retain records of each annual review of the QMP, including the evaluations and findings of the review, in an auditable form for 3 years. The existence of these reviews is confirmed during NRC inspection.

Section 35.32(c)(3) requires licensees to evaluate and respond to each "recordable event" by retaining a record of the relevant facts and corrective action, in an auditable form for 3 years. This enables the licensee to identify error trends. It enables the inspector to evaluate the licensee's response to such errors.

Section 35.32(d) requires licensees to retain each written directive and a record of each administration for 3 years after the date of the administration, to ensure that each administration was in accordance with the written directive. A sample of the licensee's written

directives is reviewed during an NRC inspection.

Section 35.32(e) requires the licensee to submit any voluntary modifications to the QMP to NRC within 30 days after the modification is made, to ensure that the modification does not decrease the effectiveness of the program.

Section 35.32(f)(1) requires each applicant for a new license to submit a QMP to NRC as part of a license application to ensure that the new licensee will implement a QMP that will provide high confidence that byproduct material will be administered as directed by the authorized user physician.

Section 35.32(f)(2) required licensees in existence on January 27, 1992, to submit certification that a QMP had been implemented as well as a copy of the QMP to assure NRC that a QMP had been implemented. This requirement has been satisfied.

Section 35.33(a)(1) requires licensees to notify NRC by telephone no later than the next calendar day after discovery of a misadministration. This will enable NRC to promptly take any necessary actions based on the circumstances.

Section 35.33(a)(2) requires licensees to submit a written report to NRC within 15 days of the discovery of a misadministration to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, and to assure that all notifications were made.

Section 35.33(a)(3) requires licensees to notify the referring physician and the individual subject to the misadministration no later than 24 hours after discovery, or as soon as possible, if the patient or the referring physician can not be reached within 24 hours. Patients and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Section 35.33(a)(4) requires the licensee to furnish a written report of the misadministration to the patient, if the patient has been notified orally of the misadministration, within 15 days of the discovery of the misadministration. To satisfy this requirement, the licensee may provide the patient with either a copy of the report that was submitted to NRC, or a description of both the event and any consequences that may affect him/her. The description of the event must include a statement that the report submitted to NRC can be obtained from the licensee.

Section 35.33(b) requires the licensee to retain a record of the misadministration for 5 years to ensure that the record is available for the next NRC inspection so that NRC can ascertain whether misadministrations have been investigated by the licensee and that corrective action has been taken.

2. Agency Use of Information

Quality Management Program (QMP) Requirements: The reporting and record keeping requirements related to the QMP allow license reviewers to determine if licensees have developed a systematic approach to providing high confidence that byproduct material or the radiation therefrom will be administered as requested by authorized users. In addition, it enables inspectors to determine compliance with the requirement to implement the QMP.

Notifications, Reports, and Records of Misadministrations: The notification, reporting and recordkeeping requirements ensure that the NRC is notified of significant events and that the patient and referring physician are notified of the event. In addition, it allows the NRC to determine whether to take any immediate actions, such as to conduct a special inspection of a licensee's facility or to alert other medical use licensees, to prevent similar events which may have generic implications. The recordkeeping requirements allow NRC inspectors to review misadministrations and other events that have occurred, including any corrective action taken by the licensee.

3. Reduction of Burden Through Information Technology

The NRC has not received any electronic submittals of QMPs. However, licensees have submitted parts of misadministration reports electronically. There is no legal obstacle to the use of information technology, and the NRC is developing processes that will soon assist licensees in doing so.

4. Effort to Identify Duplication and Use Similar Information

There is no source for the information other than from the medical use licensees. The Information Requirements Control Automated System has been searched. There is no duplication with other collections of information.

5. Effort to Reduce Small Business Burden

In 1990, prior to the rulemaking, the NRC conducted a pilot program (OMB Clearance No. 3150-0145) to determine the impact and efficacy of the proposed "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material." Several participants of the pilot program were licensees in private practices. Following the 60-day test, they indicated that, with certain modifications, they could incorporate the proposed rule into their procedures of medical practice and that the impact would be minimal. The NRC will re-address this issue in the planned revision of 10 CFR Part 35.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or is Conducted Less Frequently

If the collection is not conducted, there would be no assurance that circumstances resulting in misadministrations, that endanger the health and safety of the general public, would be corrected. Under the current requirements, less frequent reporting is not possible for the following reasons:

10 CFR 35.32: The requirement to develop and submit a QMP is a one-time effort which has been completed by all affected NRC licensees and approximately one-half of Agreement States licensees. Additionally, once a QMP that meets the rule is submitted, the frequency that licensees' QMPs are modified is determined by the licensee's need to modify the QMP to correct deficiencies in their own QMP program. Therefore, the stated frequencies are at the minimum level.

10 CFR 35.33: Licensees are required to report misadministrations, by telephone, within 24 hours after discovery, followed by a written report within 15 days after discovery. The requirement for one telephone call followed by a written report is the minimum frequency to inform the NRC about a misadministration so that any follow-up action can be taken.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines in 5 CFR 1320.6(b), Section 35.33 requires licensees to report misadministrations, by telephone, within 24 hours after discovery, followed by a written report within 15 days after discovery. Since a misadministration may have health and safety implications for patients or research subjects, the NRC believes that 24-hour notification is important to assure that appropriate follow-up action is immediately taken. The submittal of a report within 15 days assures that the licensee has adequately investigated the event, identified appropriate corrective actions to prevent recurrence, and met applicable notification, recordkeeping, and reporting requirements.

8. Consultations Outside NRC

The QM rule has been reviewed as part of the NRC-sponsored independent review of the NRC's medical use program by the National Academy of Sciences. Additionally, a Congressional appropriations committee recommended that NRC reconsider the ICR associated with this regulation. The NRC believes this concern will be satisfied through the ongoing review of the NRC medical use program which may include a revision of 10 CFR Part 35, including 10 CFR 35.32 and 33. This effort is expected to begin in 1997. Consultations and meetings with the medical community are planned as part of that rulemaking.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

None, except for proprietary information.

11 Justification for Sensitive Questions

There are no sensitive questions.

12. Estimated Burden and Burden Hour Cost

There are two primary considerations in the calculation of this burden: First, the current number of medical use licensees in the United States is approximately 2000 for the NRC and 5000 for the Agreement States. Of those licensees that require submission of a QMP (approximately 90 percent or 6300 licensees), all of the applicable NRC licensees (1800) and an estimated 2500 of the Agreement State licensees have submitted a QMP to the appropriate regulatory agency. Therefore, it is estimated that 2000 Agreement State licensees will submit a QMP within the next 3 years.

Second, based on findings from a pilot program and discussions with medical licensees in multiple public meetings during promulgation of the rule, it was assumed that 90 percent of licensees, who must implement a QMP, will have policies and procedures (e.g., prepared to meet professional audit programs or Joint Commission on Accreditation of Healthcare Organization requirements) that could be adjusted, prepared, and submitted to the NRC to comply with the requirements. However, based on the NRC's experience in reviewing the 1800 QMPs submitted by NRC licensees, 72 percent of the submittals did not meet the requirements, and modifications were required. The NRC has included this unexpected and additional burden in this estimate for the development of the 2000 QMPs to be submitted by the Agreement State licensees to the appropriate Agreement State.

These public burden estimates are based on NRC data, collected during the past 4 years and on staff projections of new applications and amendment requests expected to be received during the next 3 years. The estimates assume that the Agreement States will implement the rule exactly as has the NRC. Differences in Agreement State adoption or implementation would result in either greater or lesser burden. The average burden is calculated at the NRC labor cost rate of $120 per hour, which includes overhead. A burden breakout is included in Tables 1 through 3.

The following will be the estimated ICR burden and burden hour cost for the implemented rule:

BURDEN FOR NRC LICENSEES:

Each year, the NRC receives approximately 63 new license applications, and approximately 100 applications to amend existing licenses to add a modality, that require the establishment and submittal of a QMP. Since the modification of an existing QMP to add a modality may range from a minor change to a major effort, the average burden is estimated to be 10 hours. Therefore:

63 licensees X 40 hrs (new licensees-develop QMP) =	2,520 hrs/yr
100 licensees X 10 hrs (add modality-modify QMP) =	1,000 hrs/yr
63 licensees X 4 hrs (develop review procedures) =	252 hrs/yr
163 licensees X 72% (require modification) =	
117 X 3 hrs (modify) =	351 hrs/yr

Burden and cost for new applicants and new modalities added in NRC States = 4,123 hrs/yr X $120 = $494,760

An estimated 15 percent of the 1800 licensees who have previously submitted QMPs, will modify their existing QMP each year to increase the program's efficiency. This does not include the burden for modification of new applications and applications to add a modality to an existing license that does not meet the requirements.

1800 submitted QMPs X 15% = 270 modifications per yr
270 modifications X 3 hrs per licensee = 810 hrs/yr

Burden for NRC licensees to modify QMPs = 810 hrs/yr X $120 = $97,200

Burden Associated with Notifications, Reports, and Records of Misadministration:

NRC licensees reported an average of 30 misadministrations per year for years 1993 through 1995. The definitions for misadministrations focus on therapy events in which NRC frequently requests the services of a medical consultant to review the event, and conducts reactive inspections. In calculating the burden for 10 CFR 35.33, the time commitment for licensees to interact with these consultants and NRC inspectors has been considered. Therefore, this burden has been estimated to average 16 hours per licensee, per event. Additionally, NRC estimates 15 minutes for notification of event discovery, 30 minutes for notification of referring physician and individual who received the misadministration, and 15 minutes for furnishing the report.

30 misadministrations reported/yr X 17 hrs/event = 510 hrs/yr

Licensees must retain a record of a misadministration for 5 yrs:
30 misadministrations X 10 minutes (to file record) = 5 hrs/yr

Based upon inspections of implemented QMPs to date, 15 percent of NRC licensees were found to have records of "recordable events" (§ 35.32(c)(3)) during inspection. Therefore,

1800 X 15% = 270 "recordable events"/yr X 30 minutes (to record) = 135 hrs/yr

Each of the 1800 NRC licensees must retain the records of the annual QMP review for 3 years:

1800 X 1 hr/yr = 1,800 hrs/yr

Burden associated with notifications, reports, and records of misadministration = 2,450 hrs/yr X $120 = $294,000

TOTAL BURDEN FOR NRC LICENSEES = 7383 hrs/yr X $120 = $885,960/yr

BURDEN FOR AGREEMENT STATE LICENSEES:

In order to estimate the burden to the Agreement State licensees, the following assumptions were made:

1. Ninety percent of the 2000 Agreement State licensees will have existing policies and procedures that could be adjusted, prepared, and submitted to the Agreement State to comply with the requirements of the rule. An average burden of 5 hours is estimated for preparation and submittal of a modified QMP.

2. Ten percent of the 2000 licensees will have to develop and submit a QMP. This will be a one-time burden of approximately 40 hours for each of the 200 licensees.

3. Based on the NRC's experience, 72 percent of the 2000 QMPs initially submitted to the Agreement States will require modifications to meet the requirements of the rule. This will result in a burden of 3 hours each to modify the QMP for approximately 1440 licensees.

One time burden to Agreement State Licensees for Initial Development, Submittal (States who will adopt the rule within next 3 years):

Development of QMP by 10% of 2000 licensees = 200 licensees
X 40 hrs = 8000 hrs annualized over 3 yrs = 2667 hrs/yr

Preparation and submittal of existing procedures:
90% X 2000 licensees = 1800, annualized over 3 yrs =
600 submittals X 5 hrs each for preparation and submittal = 3,000 hrs/yr

Based on the NRC's experience, 72 percent of the QMP submittals will require modification:

2000 licensees X 72% (require modification)= 1440 annualized over 3 yrs = 480 QMPs/yr that require modification.
480 submittals/yr X 3 hrs/submittal to make modification = 1,440 hrs/yr

Each of the 2000 licensees must also develop procedures for an annual review of the QMP (4 hrs).

2000 licensees annualized over 3 yrs = 667 licensees/yr
667 licensees/yr X 4 hrs to develop procedures for QMP review = 2,668 hrs/yr

Agreement State licensees' burden = 9,775 hrs/yr X $120 = $1,173,000

Burden to New Applicants - Agreement State:

Each year, the NRC receives approximately 63 new license applications, and approximately 100 applications to amend existing licenses to add a modality, that require the establishment and submittal of a QMP. Because the Agreement States have 2.5 times the number of licensees as the NRC, it is estimated that an average of 158 applications for new licenses and 250 applications to add new modalities to existing licenses will be received each year. Since the modification of an existing QMP to add a modality may range from a minor change to a major effort, the average burden is estimated to be 10 hours. Therefore:

158 licensees X 40 hrs (new licensees-develop QMP) = 6,320 hrs/yr
250 licensees X 10 hrs (add modality - modify QMP) = 2,500 hrs/yr
158 licensees X 4 hrs
(new licensees-develop review procedures) = 632 hrs/yr
408 licensees X 72% require modification =
294 licensees X 3 hrs (modify) = 882 hrs/yr

Burden for new applicants and modalities added in Agreement States = 10,334 hrs/yr X $120 = $1,240,080

Burden for making modifications to previously submitted QMP:

An estimated 15 percent of the 2500 licensees who have previously submitted QMPs, will modify their existing QMP each year to increase the program's efficiency. This does not include the burden for modification of new applications and applications to add a modality to an existing

license that do not meet the requirements.

2500 submitted QMPs X 15% (mod./yr)= 375 modifications/yr
375 mod./yr X 3 hrs (to make modification) = 1,125 hrs/yr

Burden for Agreement State licensees to modify QMPs = 1,125 hrs/yr

Burden Associated with Notifications, Reports, and Records of Misadministration:

The Agreement States have approximately 2.5 times the number of licensees as the NRC. Additionally, the NRC has no information to demonstrate that the frequency of incidents at Agreement State licensees is different than that of the NRC licensees. Therefore, for purposes of estimating the burden, based on an average of 30 misadministrations per year for NRC licensees, the NRC estimates 75 misadministrations per year for Agreement State licensees.

The estimated burden to report a misadministration is 16 hours per event. Additionally, NRC estimates 15 minutes for notification of event discovery, 30 minutes for notification of referring physician and individual who received the misadministration, and 15 minutes for furnishing the report.

75 misadministrations reported/yr X 17 hrs/event = 1,275 hrs/yr

75 misadministrations X 10 minutes (to file record) = 13 hrs/yr

To date, based on inspection of NRC licensees, 15 percent of Agreement State licensees, per year, will have records of recordable events (§ 35.32(c)(3)) during inspection:

4500 X 15% = 675
675 records/yr X 30 minutes to make the record = 338 hrs/yr

Each of the 4500 Agreement State licensees must evaluate and retain records of an annual QMP review for 3 years:

4500 X 1 hr/yr = 4,500 hrs/yr

Burden associated with notifications, reports, and records of misadministration = 6,126 hrs/yr X $120 = $735,120

TOTAL BURDEN FOR AGREEMENT STATE LICENSEES =
27,360 hrs/yr X $120 = $3,283,200

Additional details on the reporting and recordkeeping burden are found in Tables 1 through 3 (attached)

The total compliance burden estimate, for NRC and Agreement State licensees is summarized below:

	Number of Licensees who will respond:	Total Annual Burden (hrs):	Cost: ($120/hr)
Reporting:	6300	24,400 hrs/yr	$2,928,000
Recordkeeping:		10,343 hrs/yr	1,241,160
Total Burden:		34,743 hrs/yr	$4,169,160

13. Estimate of Other Additional Costs

Not applicable.

14. Estimate of Annualized Cost to the Federal Government

Quality Management Program (QMP)

All initial QMPs for NRC licensees have been submitted and reviewed. Therefore, the continuing cost will be for the review of QMPs submitted as part of new license applications, when additional therapy modalities (e.g., brachytherapy, teletherapy) are added to an existing NRC license,

and within 30 days of modifying existing QMPs. The QMPs are reviewed as part of the license application for new and amended licenses, and modifications are reviewed at the time of inspection. The NRC receives approximately 63 new applications per year and approximately 100 requests to amend existing licenses to add a modality. Additionally, based on the number of QMP modifications submitted to the NRC in the past year, it is estimated that 15 percent of licensees will modify their QMPs each year.

Assuming 3 hours would be needed for the QMP review for 63 new licenses and 100 amendments to add therapy modalities per year:

3 hrs X 163 licensing actions/yr = 489 hrs/yr X $120 = $ 58,680/yr

Assuming 2 hours would be needed to review a modification made to a previously reviewed QMP and 270 (estimated 15 percent) modifications are submitted by NRC licensees per year:

2 hrs X 270 modifications/yr = 540 hrs/yr X $120 = $ 64,800/yr

The ongoing cost to the NRC for review of QMPs =
1029 hrs/yr X $120 = $123,480/yr

Notifications, Reports, and Records of Misadministrations

Based on statistical data, the staff estimates that 30 misadministrations per year will occur in NRC States over the next 3 years. Assuming that an average of 80 hours of NRC staff effort will be required to respond to each event, the cost to the NRC will be $288,000 per year.

80 hrs/misadministration X 30 misadministrations/yr = 2400 hrs/yr
2400 hrs/yr X $120/hr = $288,000/yr

The estimate includes time for the NRC Operations Center to respond to the original call, for the NRC staff to follow up with the action appropriate to the event (e.g., if needed, conduct an inspection, secure medical consultant services, etc.), and review the written report (submitted 15 days after the event was reported).

Total annualized cost to the NRC for all activities is estimated to be:
1029 hrs + 2400 hrs = 3429 hrs X $120 = $411,480/yr

These costs are fully recovered through fee assessments to NRC licensees, pursuant to 10 CFR Parts 170 and 171.

15. Reasons for Change in Burden or Cost

The following are the reasons for the most significant changes in the burden estimate:

1. The increase in the cost from $116/hr in the previous submission to $120/hr for the 1997 submission.

2. This estimate includes the one-time burden of the submission and review of the QMPs submitted by the approximately 2000 Agreement State licensees in the 10 States that have not yet adopted the rule. In the initial submission, it was assumed that the Agreement States would implement the QM rule by January 1995. However, at the time of the 1996 submittal, 13 of the 29 Agreement States had not as yet adopted the rule. Since the earlier submission, an additional three States, representing approximately 1000 licensees, have adopted the QM rule.

3. The estimated burden on the Agreement States' regulatory agencies, previously included in this ICR, is now included in OMB Clearance 3150-0183 "Office of State Programs Requests to Agreement States for Information."

4. At the time of the 1996 submittal, the best data the NRC possessed

estimated the number of licensee reported events that met the misadministration criteria as 25 misadministrations per year. Since that time, an improvement in data collection and analysis has increased that number to an average of 30 misadministrations per year. The Agreement States have approximately 2.5 times as many licensees. Therefore, we estimate approximately 105 misadministrations per year nationwide.

16. Publication for Statistical Use

The NRC tabulates and publishes an annual summary of misadministrations and other events.

17. Reason for Not Displaying the Expiration Date

The requirement will be contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

Statistical methods are not used in this collection of information.

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Table 1 (Annualized)

Reporting Requirements (§ 35.32): **(Assuming 6300 licensees)**

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.32(a)	Licensees:			
	Agreement State (one time): Develop and maintain a written QMP (includes submittal), Approximately 67 licensees (200 licensees/3 yrs)	40 hrs	*2,667	$320,040
	Submission of QMP (Submit existing procedures, 600 (90%) licensees (1800 licensees/3 years)	5 hrs	*3,000	$360,000
	NRC & Agreement State: 221 new application QMPs	40 hrs	8,840	$1,060,800
	350 amending license to add modality (submit QMP)	10 hrs	3,500	$420,000

Table 1

35.32(e)	Submit modification of QMP within 30 days after modification is made: (72% initial failure rate for first time submittals)			
	Agreement State Licensees (one time):			
	72% of initial submittals = 480 QMPs	3 hrs	*1,440	$172,800
	NRC Licensees:			
	Modify 72% of new and added modality applications =117	3 hrs	351	$42,120
	15% existing QMPS= 270	3 hrs	810	$97,200
	Agreement State Licensees:			
	Modify 72% of new and added modality applications = 294	3 hrs	882	$105,840
	15% of existing QMPs = 375	3 hrs	1125	$135,000
35.32(f)(1)	Submit a QMP to appropriate agency	Included in § 35.32(a)		
35.32(f)(2)	Submit written certification	Requirement complete		

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* One time burden for Agreement States that have yet to adopt the rule: 7,107 hrs/yr

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Reporting Burden (§ 35.32) per yr: 22,615 hrs/yr X $ 120 = $2,713,800

Table 2 (Annualized)

Reporting Requirements (§ 35.33): **(Assuming 105 misadministrations per yr)**

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.33(a)(1)	Notify NRC or Agreement State by phone no later than the next calendar day after discovery of misadministration.	15 min	26 hrs	$3,150
35.33(a)(2)	Licensee written report to regulatory agency within 15 days after discovery of misadministration.	16 hrs	1,680 hrs	$201,600
35.33(a)(3)	Licensee notification to referring physician and individual who received the misadministration no later than 24 hours after discovery.	30 min	53 hrs	$6,300
35.33(a)(4)	Licensee written report to patient within 15 days of misadministration.	15 min May be same report as 35.33(a)(2) above	26 hrs	$3,150

Reporting Burden (§ 35.33) per yr: 1,785 hrs/yr X $120 = $214,200

Table 3 (Annualized)

Recordkeeping burden (§ 35.32): (Assuming 6300 licensees)

Section	Item	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.32(b)(1)	Licensees: Develop procedures for review:			
	Agreement State (one-time): 667 initial development	4 hrs	*2,668	$320,160
	NRC and Agreement State: 221 New licensees/yr	4 hrs	884	$106,080
35.32(b)(2)	Licensees (6300 total): Evaluate QMP reviews and make modifications, if needed:	50 min.	5,250	$630,000
35.32(b)(3)	Retain records of each audit and management evaluation of the QMP for 3 years.	10 min.	1,050	$126,000
35.32(c)(3)	Retain record of relevant facts and corrective action relative to recordable event, for 3 years. (945 records/yr)	30 min.	473	$56,760
35.32(d)	Retain each written directive and a record of each administration for 3 years.	Historically, part of patient's medical record.		

Recordkeeping burden (§ 35.32) per yr: 10,325 hrs/yr X $120 = $1,239,000

*One-time burden for licenses of Agreement States that have yet to adopt the rule: 2,668 hrs/yr

Table 4 (Annualized)

Recordkeeping burden (§ 35.33): (Assuming 105 misadministrations per yr)

Section	Item	Assumed No. of Events/yr	Hours Per Event	Total Burden hrs/yr	Cost at $120/hr
35.33(b)	Licensee shall retain a record of the misadministration for 5 years.	105	10 min	18 hours	$2160

Recordkeeping burden (§ 35.33) per yr: 18 hrs/yr X $120 =$2160

PART 170

FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

GENERAL PROVISIONS

SCHEDULE OF FEES

ENFORCEMENT

[58 FR 38666]

Authority: 31 U.S.C. 9701; sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205, Pub. L. 101-576, 104 Stat. 2842, (31 U.S.C. 902).

GENERAL PROVISIONS

[48 FR 8194]

§ 170.1 Purpose.

The regulations in this part set out fees charged for licensing services rendered by the Nuclear Regulatory Commission as authorized under Title V of the Independent Offices Appropriation Act of 1952 (65 Stat. 290; 31 U.S.C. 483a) and provisions regarding their payment.

[52 FR 8225]

§ 170.2 Scope.

Except for persons who apply for or hold the permits, licenses, or approvals exempted in § 170.11, the regulations in this part apply to a person who is:

[58 FR 7715]

(a) An applicant for or holder of a specific byproduct material license issued pursuant to Parts 30 and 32 through 36 and 39 of this chapter.

[49 FR 21293]

(b) An applicant for or holder of a specific source material license issued pursuant to Part 40 of this chapter;

(c) An applicant for or holder of a specific special nuclear material license issued pursuant to Part 70 of this chapter;

(d) An applicant for or holder of specific approval of spent fuel casks and shipping containers issued pursuant to Part 71 of this chapter;

(e) An applicant for or holder of a specific license to possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation issued pursuant to Part 72 of this chapter;

(f) An applicant for or holder of a specific approval of sealed sources and devices containing byproduct material, source material, or special nuclear material;

54 FR 15372

(g) An applicant for or holder of a production or utilization facility construction permit, operating license, or manufacturing license issued pursuant to Part 50 of this chapter, or an early site permit, standard design certification, or combined license issued pursuant to Part 52 of this chapter;

49 FR 21293

(h) Required to have examinations and tests performed to qualify or requalify individuals as Part 55 reactor operators;

(i) Required to have routine and non-routine safety and safeguards inspections of activities licensed pursuant to the requirements of this chapter;

(j) Applying for or is holder of an approval of a standard reference design for a nuclear steam supply system of balance of plant;

54FR15372

(k) Applying for or already has applied for review, under 10 CFR Part 52, Appendix Q, of a facility site prior to the submission of an application for a construction permit;

49 FR 21293

(l) Applying for or already has applied for review of a standardized spent fuel facility design; or

(m) Applying for or has applied for since March 23, 1978, review of an item under the category of special projects in this chapter that the Commission completes or makes whether or not in conjunction with a license application on file—or that may be filed.

(n) An applicant for or holder of a license, approval, determination, or other authorization issued by the Commission pursuant to 10 CFR Part 61.

56 FR 31472

(o) Requesting preapplication/licensing review assistance by consulting with the NRC and/or by filing preliminary analyses, documents, or reports.

(p) An applicant for or a holder of a specific import or export license issued pursuant to 10 CFR part 110.

(q) An Agreement State licensee who files for or is holder of a general license under the reciprocity provisions of 10 CFR 150.20.

55 FR 21173

§ 170.3 Definitions.

As used in this part:

56 FR 31472

Act means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto.

55 FR 21173

"Advanced reactor" means any nuclear reactor concept other than light water reactors and high temperature gas cooled reactors.

56 FR 31472

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Act.

"Nonagreement State" means any other State.

55 FR 21173

"Application" means any request filed with the Commission for a permit, license, approval, exemption, certificate, other permission, or for any other service.

"Balance of plant" consists of the remaining systems, components, and structures that comprise a complete nuclear power plant and are not included in the nuclear steam supply system.

55 FR 21173

"Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

"Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

56 FR 31472

High Enriched Uranium means uranium enriched to 20 percent or greater in the isotope uranium-235.

55 FR 21173

"Human use" means the internal or external administration of byproduct, source, or special nuclear material, or the radiation therefrom, to human beings.

Indian organization means any commercial group, association, partnership, or corporation wholly owned or controlled by an Indian tribe.

Indian tribe means any Indian tribe, band, nation, or other organized group or community of Indians recognized as eligible for the services provided by the Secretary of the Interior because of their status as Indians.

"Inspections" means:

(1) Routine inspections designed to evaluate the licensee's activities within the context of the licensee having primary responsibility for protection of the public and environment.

(2) Non-routine inspections in response or reaction to an incident, allegation, followup to inspection deficiencies or inspections to determine implementation of safety issues. A non-routine or reactive inspection has the same purpose as the routine inspection.

56 FR 31472

Low Enriched Uranium means uranium enriched below 20 percent in the isotope uranium-235.

55 FR 21173

"Manufacturing license" means a license pursuant to Appendix M of Part 50 of this chapter to manufacture a nuclear power reactor(s) to be operated at sites not identified in the license application.

58 FR 38666

Materials License means a license, certificate, approval, registration, or other form of permission issued by the NRC pursuant to the regulations in 10 CFR parts 30, 32 through 36, 39, 40, 61, 70, 71 and 72.

57 FR 32691

Nonprofit educational institution means a public or nonprofit educational institution whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public.

55 FR 21173

"Nuclear reactor" means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission in a self-supporting chain reaction.

"Nuclear Steam Supply System" consists of the reactor core, reactor coolant system, and related auxiliary systems including the emergency core cooling system, decay heat removal system, and chemical volume and control system.

"Other production or utilization facility" means a facility other than a nuclear reactor licensed by the Commission under the authority of section 103 or 104 of the Atomic Energy Act of 1954, as amended (the Act), and pursuant to the provisions of Part 50 of this chapter.

"Part 55 Reviews" as used in this Part means those services provided by the Commission to administer requalification and replacement examinations and tests for reactor operators licensed pursuant to 10 CFR Part 55 of the Commission's regulations and employed by Part 50 licensees. These services also include related items such as the preparation, review, and grading of the examinations and tests.

"Person" as used in this part has the same meaning as found in Parts 30, 40, 50, and 70 of Title 10 of the Code of Federal Regulations.

"Power reactor" means a nuclear reactor designed to produce electrical or heat energy licensed by the Commission under the authority of section 103 or subsection 104b of the Act and pursuant to the provisions of § 50.21(b) or § 50.22 of this chapter.

"Production facility" means:

(1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233; or

57 FR 18388

(2) Any facility designed or used for the separation of the isotopes of plutonium, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

55 FR 21173

(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material except:

(i) Laboratory scale facilities designed or used for experimental or analytical purposes;

(ii) Facilities in which the only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U^{235} and plutonium produced by the irradiation, if the material processed contains not more than 10^{-4} grams of plutonium per gram of U^{235} and has fission product activity not in excess of 0.25 millicurie of fission products per gram of U^{235}; and

(iii) Facilities in which processing is conducted pursuant to a license issued under Parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special nuclear material.

"Reference systems concept" means a concept that involves the review of an entire facility design or major fraction of a facility design outside of the context of a license application. The standard design would be referenced in subsequent license applications.

"Research reactor" means a nuclear reactor licensed by the Commission under the authority of subsection 104c of the Act and pursuant to the provisions of § 50.21(c) of this chapter for operation at a thermal power level of 10 megawatts or less, and which is not a testing facility as defined by paragraph (m) of this section.

The phrase "review is completed" as used in this part means that the review has been brought to an end, whether by reason of issuance of a permit, license, approval, certificate, exemption, or other form of permission, or whether the application is denied, withdrawn, suspended, or action on the application is postponed by the applicant.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Source material" means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

"Special nuclear material" means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material but does not include source material; or

(2) Any material artificially enriched by any of the foregoing, but does not include source material.

55 FR 21173

Special projects means those requests submitted to the Commission for review for which fees are not otherwise specified in this chapter. Examples of special projects include, but are not limited to, topical and other report reviews, early site reviews, waste solidification facilities, route approvals for shipment of radioactive materials, and services provided to certify licensee, vendor, or other private industry personnel as instructors for Part 55 reactor operators. As used in this part, special projects does not include requests/reports submitted to the NRC:

(1) In response to a Generic Letter or NRC Bulletin which does not result in an amendment to the license, does not result in the review of an alternate method or reanalysis to meet the requirements of the Generic Letter, or does not involve an unreviewed safety issue;

(2) In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety, safeguards or environmental issue, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter, or bulletin; or

(3) As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts.

59 FR 36895

"Testing facility" means a nuclear reactor licensed by the Commission under the authority of subsection 104c of the Act and pursuant to the provisions of § 50.21(c) of this chapter for operation at:

(1) A thermal power level in excess of 10 megawatts; or

(2) A thermal power level in excess of 1 megawatt, if the reactor is to contain:

(i) A circulating loop through the core in which the applicant proposes to conduct fuel experiments; or

(ii) A liquid fuel loading; or

(iii) An experimental facility in the core in excess of 16 square inches in cross-section.

55 FR 21173

Uranium enrichment facility means:

(1) Any facility used for separating the isotopes of uranium or enriching uranium in the isotope 235, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(2) Any equipment or device, or important component part especially designed for this equipment or device, capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

57 FR 18388

"Utilization facility" means any nuclear reactor other than one designed or used primarily for the formation of plutonium or U^{233} and any other equipment or device determined by rule of the Commission to be a utilization facility within the purview of subsection 11cc of the Act.

55 FR 21173

§ 170.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

33 FR 11587

§ 170.5 Communications.

All communications concerning the regulations in this part should be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Communications may be delivered in person at the Commission's offices at 2120 L Street NW., Washington, DC, or at 11555 Rockville Pike, Rockville, Maryland.

53 FR 43419

§ 170.8 Information collection requirements: OMB approval.

This part contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

58 FR 38666

33 FR 11587

§ 170.11 Exemptions.

43 FR 7210

(a) No application fees, license fees, amendment fees, renewal fees, approval fees, or inspection fees shall be required for:

(1) [Deleted 56 FR 31472.]

(2) [Deleted 56 FR 31472.]

55 FR 21173

(3) [Reserved]

(4) A construction permit or license applied for by, or issued to, a non-profit educational institution for a production or utilization facility, other than a power reactor, or for the possession and use of byproduct material, source material, or special nuclear material. This exemption does not apply to those byproduct, source or special nuclear material licenses which authorize:

(i) Human use;

(ii) Remunerated services to other persons;

(iii) Distribution of byproduct material, source material, or special nuclear material or products containing byproduct material, source material, or special nuclear material; and

(iv) Activities performed under a Government agency contract.

60 FR 32218

(5) A construction permit, license, certificate of compliance, or other approval applied for by, or issued to, a Government agency, except where the Commission is authorized by statute to charge such fees.

(6) [Deleted 38 FR 18443.]

(7) [Deleted 38 FR 18443.]

(8) [Deleted 56 FR 31472.]

59 FR 36895

(9) State-owned research reactors used primarily for educational training and academic research purposes. For purposes of this exemption, the term *research reactor* means a nuclear reactor that—

(i) Is licensed by the Nuclear Regulatory Commission under section 104c. of the Atomic Energy Act of 1954 (42 U.S.C. 2134(c)) for operation at a thermal power level of 10 megawatts or less; and

(ii) If so licensed for operation at a thermal power level or more than 1 megawatt, does not contain—

(A) A circulating loop through the core in which the licensee conducts fuel experiments;

(B) A liquid fuel loading; or

(C) An experimental facility in the core in excess of 16 square inches in cross-section.

45 FR 50705

(10) Activities of the Commission undertaken, pursuant to Part 75 of this chapter, solely for the purpose of implementation of the US/IAEA Safeguards Agreement.

(11) [Deleted 56 FR 31472.]

36 FR 16173

(b) (1) The Commission may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of this part as it determines are authorized by law and are otherwise in the public interest.

(2) Applications for exemption under this paragraph may include activities such as, but not limited to, the use of licensed materials for educational or noncommercial public displays or scientific collections.

(3) [Deleted 43 FR 7210.]

§ 170.12 Payment of fees.

(a) *Application fees.* Each application for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. The NRC will not issue a new license or amendment prior to the receipt of the prescribed fee. All application fees will be charged irrespective of the Commission's disposition of the application or a withdrawal of the application.

(b) *License fees.*

(1) Fees for applications for materials licenses not subject to full cost reviews must accompany the application when it is filed.

(2) Fees for applications for permits and licenses that are subject to fees based on the full cost of the reviews are payable upon notification by the Commission. The NRC intends to bill each applicant at quarterly intervals for all accumulated costs for each application the applicant has on file for Commission review until the review is completed. Each bill will identify the applications and costs related to each.

(c) *Amendment fees and other required approvals.* (1) Amendment fees for materials licenses and approvals not subject to full cost reviews must accompany the application when it is filed.

(2) Fees for applications for license amendments, other required approvals and requests for dismantling, decommissioning, and termination of licensed activities that are subject to the full cost of the review are payable upon notification by the Commission. The NRC intends to bill each applicant at quarterly intervals for all accumulated costs for each application the applicant has on file for Commission review until the review is completed except for those costs relating to amendment and other approvals for early site permits that were deferred before August 9, 1991. These costs will be billed in a deferred manner consistent with that addressed in paragraph (d)(4) of this section. Each bill will identify the applications and costs related to each.

(d) *Renewal fees.*

(1) [Reserved 61 FR 16203.]

(2) Fees for applications for renewals that are subject to the full cost of the review are payable upon notification by the Commission. Except for those costs deferred before August 9, 1991, as noted in paragraphs (d)(3) and (d)(4) of this section, the NRC intends to bill each applicant at quarterly intervals for all accumulated costs for each application that the applicant has on file for Commission review until the review is completed. Each bill will identify the applications and the costs related to each.

(3) Costs for review of an application for renewal of a standard design certification which have been deferred prior to the effective date of this final rule shall be paid as follows: The full cost of review for a renewed standard design certification must be paid by the applicant for renewal or other entity supplying the design to an applicant for a construction permit, combined license issued under 10 CFR part 52, or operating license, as appropriate, in five (5) equal installments. An installment is payable each of the first five times the renewed certification is referenced in an application for a construction permit, combined license, or operating license. The applicant for renewal shall pay the installment, unless another entity is supplying the design to the applicant for the construction permit, combined license, or operating license, in which case the entity shall pay the installment. If the design is not referenced, or if all costs are not recovered, within fifteen years after the date of renewal of the certification, the applicant for renewal shall pay the costs for the application for renewal, or remainder of those costs, at that time.

(4) Costs for the review of an application for renewal of an early site permit which have been deferred prior to the effective date of this rule will continue to be deferred as follows: The holder of the renewed permit shall pay the applicable fees for the renewed permit at the time an application for a construction permit or combined license referencing the permit is filed. If, at the end of the renewal period of the permit, no facility application referencing the early site permit has been docketed, the permit holder shall pay any outstanding fees for the permit.

(e) *Approval fees.* (1) Fees for applications for materials approvals that are not subject to full cost recovery of the review must accompany the application when it is filed. Fees for applications or preapplication consultations and reviews subject to the full cost of the review are payable upon notification by the Commission. The NRC intends to bill each applicant at quarterly intervals until the review is completed. Each bill will identify the applications and the costs related to each.

(2)(i) The full cost of review for a standardized design approval or certification that has been deferred prior to the effective date of this final rule must be paid by the holder of the design approval, the applicant for certification, or other entity supplying the design to an applicant for a construction permit, combined license issued under 10 CFR part 52, or operating license, as appropriate, in five (5) equal installments. An installment is payable each of the first five times the approved/certified design is referenced in an application for a construction permit, combined license issued under 10 CFR part 52, or operating license. In the case of a standard design certification, the applicant for certification shall pay the installment, unless another entity is supplying the design to the applicant for the construction permit, combined license, or operating license, in which case the other entity shall pay the installment.

(ii)(A) In the case of a design which has been approved but not certified and for which no application for certification is pending, if the design is not referenced, or if all costs are not recovered, within five years after the date of the preliminary design approval (PDA) or the final design approval (FDA), the applicant shall pay the costs, or remainder of those costs, at that time.

(B) In the case of a design which has been approved and for which an application for certification is pending, no fees are due until after the certification is granted. If the design is not referenced, or if all costs are not recovered, within fifteen years after the date of certification, the applicant shall pay the costs, or remainder of those costs, at that time.

(C) In the case of a design for which a certification has been granted, if the design is not referenced, or if all costs are not recovered, within fifteen years after the date of the certification, the applicant shall pay the costs for the review of the application, or remainder of those costs, at that time.

57 FR 13625

(f) *Special Project Fees.* Fees for applications for special projects such as topical reports are based on the full cost of the review and are payable upon notification by the Commission. The NRC intends to bill each applicant at quarterly intervals until the review is completed. Each bill will identify the applications and the costs related to each.

61 FR 16203

≫ (g) *Inspection fees.* Fees for all inspections subject to full cost recovery will be assessed on a per inspection basis for completed inspections and are payable, on a quarterly basis, upon notification by the Commission. Inspection costs include preparation time, time on site, and documentation time and any associated contractual service costs, but exclude the time involved in the processing and issuance of a notice of violation or civil penalty.

55 FR 21173

(h) *Method of payment.* Fee payments shall be made by check, draft, money order or electronic fund transfer made payable to the U.S. Nuclear Regulatory Commission. Where specific payment instructions are provided on the bills to applicants or licensees, payment should be made accordingly, e.g., bills of $5,000 or more will normally indicate payment by electronic fund transfer.

57 FR 13625

(i) *Part 55 review fees.* The costs for Part 55 review services will be subject to fees based on NRC time spent in administering the examinations and tests that are generally given at the reactor site and any related contractual costs. The costs also include related items such as preparing, reviewing, and grading of the examinations and tests. The NRC intends to bill the costs at quarterly intervals to the licensee employing the operators.

61 FR 16203

§ 170.20 Average cost per professional staff-hour.

≫ Fees for permits, licenses, amendments, renewals, special projects, Part 55 requalification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 that are based upon the full costs for the review or inspection will be calculated using the following applicable professional staff-hour rates:

Reactor Program (§ 170.21 Activities)	$128 per hour.
Nuclear Materials and Nuclear Waste Program (§ 170.31 Activities).	$120 per hour.

SCHEDULE OF FEES

61 FR 16203

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

≫ Applicants for construction permits, manufacturing licenses, operating licenses, import and export licenses, approvals of facility standard reference designs, requalification and replacement examinations for reactor operators, and special projects and holders of construction permits, licenses, and other approvals shall pay fees for the following categories of services.

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

54 FR 25658

Facility categories and type of fees	Fees [1,2]
A. Nuclear Power Reactors	
Application for Construction Permit	$125,000
Early Site Permit, Construction Permit, Combined License, Operating License.	Full Cost.
Amendment, Renewal, Dismantling-Decommissioning and Termination, Other Approvals.	Full Cost.
Inspections [3]	Full Cost.

54 FR 15372

B. Standard Reference Design Review	
Preliminary Design Approvals, Final Design Aporovals, Certification	Full cost.
Amendment, Renewal, Other Approvals	Full cost.
C. Test Facility/Research Reactor/ Critical Facility	
Application for Construction Permit	$5,000
Construction Permit, Operating Licenses	Full cost
Amendment, Renewal, Dismantling-Decommissioning and Termination, Other Approvals.	Full cost.
Inspections [3]	Full cost.
D. Manufacturing License	
Application	$125,000.
Preliminary Design Approval, Final Design Approval.	Full cost.
Amendment, Renewal, Other Approvals.	Full cost.
Inspections [3]	Full cost.

Facility categories and type of fees	Fees [1] [2]
E. Uranium Enrichment Plant	
[Reserved]	
F. Advanced Reactors	
Application for Construction Permit	$125,000
Early Site Permit, Construction Permit, Combined License, Operating License.	Full Cost.
Amendment, Renewal, Other Approvals.	Full cost.
Inspections [3]	Full cost.
G. Other Production and Utilization Facility	
Application for Construction Permit	$125,000.
Construction Permit, Operating License.	Full cost.
Amendment, Renewal, Other Approvals.	Full cost.
Inspections [3]	Full cost.
H. Production or Utilization Facility Permanently Closed Down	
Inspections [3]	Full cost.
I. Part 55 Reviews	
Requalification and Replacement Examinations for Reactor Operators.	Full cost.

[57 FR 18368]

54 FR 15372

SCHEDULE OF FACILITY FEES—Continued

[See footnotes at end of table]

Facility categories and type of fees	Fees[1,2]
J. Special Projects:[4]	
Approvals and preapplication/licensing activities	Full Cost.
Inspections[3]	Full Cost.
K. Import and export licenses:	
Licenses for the import and export only of production and utilization facilities or the export only of components for production and utilization facilities issued pursuant to 10 CFR Part 110:	
1. Application for import or export of reactors and other facilities and exports of components which must be reviewed by the Commissioners and the Executive Branch, for example, actions under 10 CFR 110.40(b):	
Application-new license	$7,800
Amendment	$7,800
2. Application for export of reactor and other components requiring Executive Branch review only, for example, those actions under 10 CFR 110.41(a)(1)–(8):	
Application-new license	$4,800
Amendment	$4,800
3. Application for export of components requiring foreign government assurances only:	
Application-new license	$3,000
Amendment	$3,000
4. Application for export of facility components and equipment not requiring Commissioner review, Executive Branch review, or foreign government assurances:	
Application-new license	$1,200
Amendment	$1,200
5. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require in-depth analysis or review:	
Amendment	$120

59 FR 36895

61 FR 16203

[1] Fees will not be charged for orders issued by the Commission pursuant to § 2.202 of this chapter or for amendments resulting specifically from the requirements of these types of Commission orders. Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., §§ 50.12, 73.5) and any other sections now or hereafter in effect regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. Fees for licenses in this schedule that are initially issued for less than full power are based on review through the issuance of a full power license (generally full power is considered 100 percent of the facility's full rated power). Thus, if a licensee received a low power license or a temporary license for less than full power and subsequently receives full power authority (by way of license amendment or otherwise), the total costs for the license will be determined through that period when authority is granted for full power operation. If a situation arises in which the Commission determines that full operating power for a particular facility should be less than 100 percent of full rated power, the total costs for the license will be at that determined lower operating power level and not at the 100 percent capacity.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect at the time the service was provided. For those applications currently on file or which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for any topical report, amendment, revision or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20. In no event will the total review costs be less than twice the hourly rate shown in § 170.20.

[3] Inspections covered by this schedule are both routine and non-routine safety and safeguards inspections performed by NRC for the purpose of review or follow-up of a licensed program. Inspections are performed throughout the full term of the license to ensure that the authorized activities are being conducted in accordance with the Atomic Energy Act of 1954, as amended, other legislation, Commission regulations or orders, and the term and conditions of the license. Non-routine inspections that result from third-party allegations will not be subject to fees.

[4] Fees will not be assessed for requests/reports submitted to the NRC:

1. In response to a Generic Letter or NRC Bulletin that does not result in an amendment to the license, does not result in the review of an alternate method or reanalysis to meet the requirements of the Generic Letter, or does not involve an unreviewed safety issue;
2. In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety, safeguards, or environmental issue, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter, or bulletin; or
3. As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts.

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

≫ Applicants for materials licenses, import and export licenses, and other regulatory services and holders of materials licenses, or import and export licenses shall pay fees for the following categories of services. This schedule includes fees for health and safety and safeguards inspections where applicable.

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2,3]
1. Special nuclear material:	
A. Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U–235 in unsealed form or 200 grams or more of U–233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only:	
License, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI):	
License, Renewal, Amendment	Full Cost.
Inspections	Full Cost.

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2] [3]
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers: [4]	
Application—New license	$550.
Amendment	$300.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1A: [4]	
Application—New license	$600.
Amendment	$290.
E. Licenses for construction and operation of a uranium enrichment facility:	
Application	$125,000.
License, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
2. Source material:	
A. (1) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode:	
License, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
(2) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal except those licenses subject to fees in Category 2.A. (1):	
License, renewal, amendment	Full Cost.
Inspections	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A. (1):	
License, renewal, amendment	Full Cost.
Inspections	Full Cost.
B. Licenses which authorize the possession, use and/or installation of source material for shielding:	
Application—New license	$160.
Amendment	$240.
C. All other source material licenses:	
Application—New license	$2,800.
Amendment	$420.
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—New license	$3,000.
Amendment	$550.
B. Other licenses for possession and use of byproduct material issued pursuant to Part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—New license	$1,200.
Amendment	$580.
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material:	
Application—New license	$4,100.
Amendment	$520.
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material:	
Application—New license	$1,500.
Amendment	$430.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units):	
Application—New license	$1,200.
Amendment	$360.
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes:	
Application—New license	$1,500.
Amendment	$370.
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes:	
Application—New license	$6,000.
Amendment	$780.

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SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2,3]
H. Licenses issued pursuant to Subpart A of Part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of Part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part 30 of this chapter:	
Application—New license	$2,400.
Amendment	$1,000.
I. Licenses issued pursuant to Subpart A of Part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of Part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part 30 of this chapter:	
Application—New license	$4,400.
Amendment	$860.
J. Licenses issued pursuant to Subpart B of Part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter:	
Application—New license	$1,600.
Amendment	$290.
K. Licenses issued pursuant to Subpart B of Part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter:	
Application—New license	$1,300.
Amendment	$310.
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution:	
Application—New license	$4,300.
Amendment	$660.
M. Other licenses for possession and use of byproduct material issued pursuant to Part 30 of this chapter for research and development that do not authorize commercial distribution:	
Application—New license	$1,500.
Amendment	$810.
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C:	
Application—New license	$1,900.
Amendment	$590.
O. Licenses for possession and use of byproduct material issued pursuant to Part 34 of this chapter for industrial radiography operations:	
Application—New license	$3,900.
Amendment	$720.
P. All other specific byproduct material licenses, except those in Categories 4A through 9D:	
Application—New license	$550.
Amendment	$300.
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material:	
License, renewal, amendment	Full Cost.
Inspections	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—New license	$3,400.
Amendment	$410.
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—New license	$1,700.
Amendment	$290.
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies:	
Application—New license	$3,200.
Amendment	$640.
B. Licenses for possession and use of byproduct material for field flooding tracer studies:	
License, renewal, amendment	Full Cost.
6. Nuclear laundries:	

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2]
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material:	
Application—New license	$5,100.
Amendment	$790.
7. Human use of byproduct, source, or special nuclear material:	
A. Licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	$2,800.
Amendment	$470.
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to Parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	$3,000.
Amendment	$580.
C. Other licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—New license	$1,400.
Amendment	$440.
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities:	
Application—New license	$760.
Amendment	$350.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution:	
Application—each device	$3,400.
Amendment—each device	$1,200.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices.	
Application—each device	$1,700.
Amendment—each device	$600.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution:	
Application—each source	$720.
Amendment—each source	$240.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel:	
Application—each source	$360.
Amendment—each source	$120.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers:	
Approval, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
B. Evaluation of 10 CFR Part 71 quality assurance programs:	
Application—Approval	$340.
Amendment	$250.
Inspections	Full Cost.
11. Review of standardized spent fuel facilities:	
Approval, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
12. Special projects: [5]	
Approvals and preapplication/licensing activities	Full Cost.
Inspections	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance:	
Approvals	Full Cost.
Amendments, revisions, and supplements	Full Cost.
Reapproval	Full Cost.
B. Inspections related to spent fuel storage cask:	
Certificate of Compliance	Full Cost.
C. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities pursuant to 10 CFR Parts 30, 40, 70, and 72 of this chapter:	
Approval, Renewal, Amendment	Full Cost.
Inspections	Full Cost.
15. Import and Export licenses:	

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SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2,3]
Licenses issued pursuant to 10 CFR Part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite:	
A. Application for export or import of high enriched uranium and other materials, including radioactive waste, which must be reviewed by the Commissioners and the Executive Branch, for example, those actions under 10 CFR 110.40(b). This category includes application for export or import of radioactive wastes in multiple forms from multiple generators or brokers in the exporting country and/or going to multiple treatment, storage or disposal facilities in one or more receiving countries:	
Application—new license	$7,800.
Amendment	$7,800.
B. Application for export or import of special nuclear material, source material, tritium and other byproduct material, heavy water, or nuclear grade graphite, including radioactive waste, requiring Executive Branch review but not Commissioner review. This category includes application for the export or import of radioactive waste involving a single form of waste from a single class of generator in the exporting country to a single treatment, storage and/or disposal facility in the receiving country:	
Application—new license	$4,800.
Amendment	$4,800.
C. Application for export of routine reloads of low enriched uranium reactor fuel and exports of source material requiring only foreign government assurances under the Atomic Energy Act:	
Application—new license	$3,000.
Amendment	$3,000.
D. Application for export or import of other materials, including radioactive waste, not requiring Commissioner review, Executive Branch review, or foreign government assurances under the Atomic Energy Act. This category includes application for export or import of radioactive waste where the NRC has previously authorized the export or import of the same form of waste to or from the same or similar parties, requiring only confirmation from the receiving facility and licensing authorities that the shipments may proceed according to previously agreed understandings and procedures:	
Application—new license	$1,200.
Amendment	$1,200.
E. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require in-depth analysis, review, or consultations with other agencies or foreign governments:	
Amendment	$120.
16. Reciprocity:	
Agreement State licensees who conduct activities in a non-Agreement State under the reciprocity provisions of 10 CFR 150.20:	
Application (initial filing of Form 241)	$1,100.
Revisions	$200.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for preapplication consultations and reviews and applications for new licenses and approvals, issuance of new licenses and approvals, amendments and certain renewals to existing licenses and approvals, safety evaluations of sealed sources and devices, and certain inspections. The following guidelines apply to these charges:

(a) *Application fees.* Applications for new materials licenses and approvals; applications to reinstate expired, terminated or inactive licenses and approvals except those subject to fees assessed at full costs, and applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20, must be accompanied by the prescribed application fee for each category, except that:

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category; and

(2) Applications for licenses under Category 1E must be accompanied by the prescribed application fee of $125,000.

(b) *License/approval/review fees.* Fees for applications for new licenses and approvals and for preapplication consultations and reviews subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(b), (e), and (f).

(c) *Renewal/reapproval fees.* Applications subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(d).

(d) *Amendment/Revision Fees.*

(1) Applications for amendments to licenses and approvals and revisions to reciprocity initial applications, except those subject to fees assessed at full costs, must be accompanied by the prescribed amendment/revision fee for each license/revision affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories in which case the amendment fee for the highest fee category would apply. For those licenses and approvals subject to full costs (fee Categories 1A, 1B, 1E, 2A, 4A, 5B, 10A, 11, 12, 13A, and 14), amendment fees are due upon notification by the Commission in accordance with § 170.12(c).

(2) An application for amendment to a materials license or approval that would place the license or approval in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for the new category.

(3) An application for amendment to a license or approval that would reduce the scope of a licensee's program to a lower fee category must be accompanied by the prescribed amendment fee for the lower fee category.

(4) Applications to terminate licenses authorizing small materials programs, when no dismantling or decontamination procedure is required, are not subject to fees.

(e) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. The fees assessed at full cost will be determined based on the professional staff time required to conduct the inspection multiplied by the rate established under § 170.20 plus any applicable contractual support services costs incurred. Inspection fees are due upon notification by the Commission in accordance with § 170.12(g).

[2] Fees will not be charged for orders issued by the Commission pursuant to 10 CFR 2.202 or for amendments resulting specifically from the requirements of these types of Commission orders. However, fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections now or hereafter in effect) regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For those applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect at the time the service was provided. For applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by §170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in §170.20. The minimum total review cost is twice the hourly rate shown in §170.20.

[4] Licensees paying fees under Categories 1A, 1B, and 1E are not subject to fees under Categories 1C and 1D for sealed sources authorized in the same license except in those instances in which an application deals only with the sealed sources authorized by the license. Applicants for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee Category 1C only.

[5] Fees will not be assessed for requests/reports submitted to the NRC:

(a) In response to a Generic Letter or NRC Bulletin that does not result in an amendment to the license, does not result in the review of an alternate method or reanalysis to meet the requirements of the Generic Letter, or does not involve an unreviewed safety issue;

(b) In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety or environmental issue, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter, or bulletin; or

(c) As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts.

53FR26332

§ 170.32 Schedule of fees for health and safety, and safeguards inspections for materials licenses.

Materials licensees shall pay inspection fees as set forth in § 170.31

ENFORCEMENT

49 FR 21293

§ 170.41 Failure by applicant or licensee to pay prescribed fees.

In any case where the Commission finds that an applicant or a licensee has failed to pay a prescribed fee required in this part, the Commission will not process any application and may suspend or revoke any license or approval issued to the applicant or licensee or may issue an order with respect to licensed activities as the Commission determines to be appropriate or necessary in order to carry out the provisions of this part, Parts 30, 32 through 35, 40, 50, 61, 70, 71, 72, and 73 of this Chapter, and of the Act.

49 FR 24113

§ 170.51 Right to Review and Appeal of Prescribed Fees.

All debtors' requests for review of the fees assessed and appeal or disagreement with the prescribed fee (staff hours and contractual) must be submitted in accordance with the provisions of 10 CFR 15.31, "Disputed Debts," of this title.

PART 171

ANNUAL FEES FOR REACTOR OPERATING LICENSES, AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY NRC

Sec.

59 FR 12539

Authority: Sec. 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330, as amended by sec. 3201, Pub. L. 101–239, 103 Stat. 2106 as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388 (42 U.S.C. 2213); sec. 301, Pub. L. 92–314, 86 Stat. 222 (42 U.S.C. 2201(w)); sec. 201, 88 Stat. 1242 as amended (42 U.S.C. 5841); sec. 2903, Pub. L. 102–486, 106 Stat. 3125 (42 U.S.C. 2214 note).

56 FR 31472

§ 171.1 Purpose.

The regulations in this part set out the annual fees charged to persons who hold licenses, Certificates of Compliance, sealed source and device registrations, and quality assurance program approvals issued by the United States Nuclear Regulatory Commission, including licenses, registrations, approvals, and certificates issued to a Government agency.

56 FR 31472

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a power reactor, test reactor or research reactor issued under part 50 of this chapter. These regulations also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program approval, and to a Government agency as defined in this part.

51 FR 33224

§ 171.5 Definitions.

"Budget" means the funds appropriated by Congress for the NRC for each fiscal year, and if that appropriation is not passed on or before September 1 for that fiscal year, the funds most recently appropriated by Congress for the most recent fiscal year.

56 FR 31472

Budget Authority means the authority, in the form of appropriations, provided by law and becoming available during the year, to enter into obligations that will result in immediate or future outlays involving Federal government funds. The appropriation is an authorization by an Act of Congress that permits the NRC to incur obligations and to make payments out of the Treasury for specified purposes. Fees assessed pursuant to Public Law 101–508 are based on NRC budget authority.

Byproduct Material means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

Certificate Holder means a person who holds a certificate of compliance, or other package approval issued by the Commission.

51 FR 33224

"Commission" means the United States Nuclear Regulatory Commission or its duly authorized representatives.

"Federal fiscal year" means a year that begins on October 1 of each calendar year and ends on September 30 of the following calendar year. Federal fiscal years are identified by the year in which they end (e.g., fiscal year 1987 begins in 1986 and ends in 1987).

56 FR 31472

Government Agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the government.

High Enriched Uranium Fuel means uranium enriched to 20 percent or greater in the isotope uranium–235.

Low Enriched Uranium Fuel means uranium enriched below 20 percent in the isotope uranium–235.

58 FR 38666

Materials License means a license, certificate, approval, registration, or other form of permission issued by the NRC pursuant to the regulations in 10 CFR parts 30, 32 through 36, 39, 40, 61, 70, 71 and 72.

57 FR 32691

Nonprofit educational institution means a public or nonprofit educational institution whose primary function is education, whose programs are accredited by a nationally recognized accrediting agency or association, who is legally authorized to provide a program of organized instruction or study, who provides an educational program for which it awards academic degrees, and whose educational programs are available to the public.

51 FR 33224

"Nuclear reactor" means an apparatus, other than an atomic weapon, used to sustain fission in a self-supporting chain reaction.

"Operating license" means having a license issued pursuant to § 50.57 of this chapter. It does not include licenses that only authorize possession of special nuclear material after the Commission has received a request from the licensee to amend its licensee to permanently withdraw its authority to operate or the Commission has permanently revoked such authority.

56 FR 31472

Overhead and General and Administrative costs means:

(1) The Government benefits for each employee such as leave and holidays, retirement and disability benefits, health and life insurance costs, and social security costs;

(2) Travel costs;

(3) Direct overhead, e.g., supervision and support staff that directly support the NRC safety mission areas (administrative support costs, e.g., rental of space, equipment, telecommunications and supplies); and

(4) Indirect costs that would include, but not be limited to, NRC central policy direction, legal and executive management services for the Commission and special and independent reviews, investigations, and enforcement and appraisal of NRC programs and operations.

Some of the organizations included are the Commissioners, Secretary, Executive Director for Operations, General Counsel, Government and Public Affairs (except for international safety and safeguards programs), Inspector General, Investigations, Enforcement, Small and Disadvantaged Business Utilization and Civil Rights, the Technical Training Center, Advisory Committees on Nuclear Waste and Reactor Safeguards, and the Atomic Safety and Licensing Board Panel and Appeal Panel. The Commission views these budgeted costs as support for all its regulatory services provided to applicants, licensees, and certificate holders, and these costs must be recovered pursuant to Public Law 101–508.

51 FR 33224

"Person" means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission; any state or any political subdivision of, or any political entity within, a state; any foreign Government or nation or any political subdivision of any such government or nation; or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

"Power reactor" means a nuclear reactor designed to produce electrical or heat energy and licensed by the Commission under the authority of section 103 or subsection 104b of the Atomic Energy Act of 1954, as amended, and pursuant to the provisions of § 50.21(b) or § 50.22 of this chapter.

56 FR 31472

Quality Assurance Program Approval is the document issued by the NRC to approve the quality assurance program submitted to the NRC as meeting the requirements of § 71.101 of this chapter. Activities covered by the quality assurance program may be divided into two major groups: those activities including design, fabrication and use of packaging and those activities for use only of packaging.

Registration Holder as used in this part means any manufacturer or initial distributor of a sealed source or device containing a sealed source that holds a certificate of registration issued by the NRC or a holder of a registration for a sealed source or device manufactured in accordance with the unique specifications of, and for use by, a single applicant.

Research Reactor means a nuclear reactor licensed by the Commission under the authority of subsection 104c of the Act and pursuant to the provisions of § 50.21(c) of this chapter for operation at a thermal power level of 10 megawatts or less, and which is not a testing facility as defined in this section.

Source Material means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores which contain by weight one-twentieth of one percent (0.05%) or more of

(i) Uranium,

(ii) Thorium, or

(iii) Any combination thereof.

Source material does not include special nuclear material.

Special Nuclear Material means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing, but does not include source material.

Testing Facility means a nuclear reactor licensed by the Commission under the authority of subsection 104c of the Act and pursuant to the provisions of § 50.21(c) of this chapter for operation at:

(1) A thermal power level in excess of 10 megawatts; or

(2) A thermal power level in excess of 1 megawatt, if the reactor is to contain:

(i) A circulating loop through the core in which the applicant proposes to conduct fuel experiments; or

(ii) A liquid fuel loading; or

(iii) An experimental facility in the core in excess of 16 square inches in cross-section.

51 FR 33224

§ 171.7 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the regulations in this part by an officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized as binding on the Commission.

58 FR 38666

§ 171.8 Information collection requirements: OMB approval

This part contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3401 *et seq.*).

53 FR 43419

§ 171.9 Communications.

All communications regarding the regulations in this part should be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Communications may be delivered in person to the Commission's Offices at 11555 Rockville Pike, Rockville, Maryland, or at 2120 L Street NW., Washington, DC.

59 FR 12539

§ 171.11 Exemptions.

(a) An annual fee is not required for:

(1) A construction permit or license applied for by, or issued to, a nonprofit educational institution for a production or utilization facility, other than a power reactor, or for the possession and use of byproduct material, source material, or special nuclear material. This exemption does not apply to those byproduct, source, or special nuclear material licenses which authorize:

(i) Human use;

(ii) Remunerated services to other persons;

(iii) Distribution of byproduct material, source material, or special nuclear material or products containing byproduct material, source material, or special nuclear material; or

(iv) Activities performed under a Government contract.

59 FR 36895

(2) Federally-owned and State-owned research reactors used primarily for educational training and academic research purposes. For purposes of this exemption, the term research reactor means a nuclear reactor that—

(i) Is licensed by the Nuclear Regulatory Commission under section 104c. of the Atomic Energy Act of 1954 (42 U.S.C. 2134(c)) for operation at a thermal power level of 10 megawatts or less; and

(ii) If so licensed for operation at a thermal power level of more than 1 megawatt, does not contain—

(A) A circulating loop through the core in which the licensee conducts fuel experiments;

(B) A liquid fuel loading; or

(C) An experimental facility in the core in excess of 16 square inches in cross-section.

58 FR 38666

(b) The Commission may, upon application by an interested person or on its own initiative, grant an exemption from the requirements of this part that it determines is authorized by law or otherwise in the public interest. Requests for exemption must be filed with the NRC within 90 days from the effective date of the final rule establishing the annual fees for which the exemption is sought in order to be considered. Absent extraordinary circumstances, any exemption requests filed beyond that date will not be considered. The filing of an exemption request does not extend the date on which the bill is payable. Only timely payment in full ensures avoidance of interest and penalty charges. If a partial or full exemption is granted, any overpayment will be refunded. Requests for clarification of or questions relating to an annual fee bill must also be filed within 90 days from the date of the initial invoice to be considered.

56 FR 31472

(c) An exemption for reactors under this provision may be granted by the Commission taking into consideration each of the following factors:

(1) Age of the reactor;

(2) Size of the reactor;

(3) Number of customers in rate base;

(4) Net increase in KWh cost for each customer directly related to the annual fee assessed under this part; and

(5) Any other relevant matter which the licensee believes justifies the reduction of the annual fee.

58 FR 38666

(d) The Commission may grant a materials licensee an exemption from the annual fee if it determines that the annual fee is not based on a fair and equitable allocation of the NRC costs. The following factors must be fulfilled as determined by the Commission for an exemption to be granted:

(1) There are data specifically indicating that the assessment of the annual fee will result in a significantly disproportionate allocation of costs to the licensee, or class of licensees; or

(2) There is clear and convincing evidence that the budgeted generic costs attributable to the class of licensees are neither directly or indirectly related to the specific class of licensee nor explicitly allocated to the licensee by Commission policy decisions; or

(3) Any other relevant matter that the licensee believes shows that the annual fee was not based on a fair and equitable allocation of NRC costs.

§ 171.13 Notice.

The annual fees applicable to an operating reactor and to a materials licensee, including a Government agency licensed by the NRC, subject to this part and calculated in accordance with §§ 171.15 and 171.16, will be published as a notice in the **Federal Register** as soon as is practicable but no later than the third quarter of FY 1996 through 1998. The annual fees will become due and payable to the NRC in accordance with § 171.19 except as provided in § 171.17. Quarterly payments of the annual fees of $100,000 or more will continue during the fiscal year and be based on the applicable annual fees as shown in §§ 171.15 and 171.16 of the regulations until a notice concerning the revised amount of the fees for the fiscal year is published by Commission.

§ 171.15 Annual Fees: Reactor operating licenses.

≫ (a) Each person licensed to operate a power, test, or research reactor shall pay the annual fee for each unit for which the person holds an operating license at any time during the Federal FY in which the fee is due, except for those test and research reactors exempted in § 171.11 (a)(1) and (a)(2).

(b) The FY 1996 uniform annual fee for each operating power reactor which must be collected by September 30, 1996, is $2,748,000. This fee has been determined by adjusting the FY 1995 annual fee downward by approximately 6 percent. The FY 1995 annual fee was comprised of a base annual fee and an additional charge (surcharge). The activities comprising the base FY 1995 annual fee are as follows:

(1) Power reactor safety and safeguards regulation except licensing and inspection activities recovered under 10 CFR Part 170 of this chapter.

(2) Research activities directly related to the regulation of power reactors.

(3) Generic activities required largely for NRC to regulate power reactors, e.g., updating Part 50 of this chapter, or operating the Incident Response Center.

(c) The activities comprising the FY 1995 surcharge are as follows:

(1) Activities not attributable to an existing NRC licensee or class of licensees; e.g., reviews submitted by other government agencies (e.g., DOE) that do not result in a license or are not associated with a license; international cooperative safety program and international safeguards activities; low-level waste disposal generic activities; uranium enrichment generic activities; and

(2) Activities not currently assessed under 10 CFR Part 170 licensing and inspection fees based on existing Commission policy, e.g., reviews and inspections conducted of nonprofit educational institutions, and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act.

61 FR 16203

(3) The FY 1991 surcharge to be added to each operating power reactor is $266,000. This amount is calculated by dividing the total cost for these activities ($29.0 million) by the number of operating power reactors (109).

(4) The FY 1992 surcharge to be added to each operating power reactor is $281,000. This amount is calculated by dividing the total cost for these activities ($30.6 million) by the number of operating power reactors (109).

59 FR 26097

(d) [Reserved 61 FR 16203.]

61 FR 16203

(e) The FY 1996 annual fees for licensees authorized to operate a nonpower (test and research) reactor licensed under Part 50 of this chapter, except for those reactors exempted from fees under § 171.11(a), are as follows:

Research reactor	$52,800
Test reactor	$52,800

56 FR 31472

(f) For FY 1992 through 1995 annual fees for operating reactors will be calculated and assessed in accordance with § 171.13 of this section.

§ 171.16 Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

(a) Person(s) who conduct activities authorized under

(1) 10 CFR part 30 for byproduct material;

(2) 10 CFR part 40 for source material, and

(3) 10 CFR part 70 for special nuclear material,

(4) 10 CFR part 71 for packaging and transportation of radioactive material, and

(5) 10 CFR part 72 for independent storage of spent nuclear fuel and high level waste;

shall pay an annual fee for each license, certificate, approval or registration the person(s) holds on the date the annual fee is due. If a person holds more than one license, certificate, registration or approval, the annual fee will be the cumulative total of the annual fees applicable to the licenses, certificates, registrations or approvals held by that person. For those licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

(b) The basis for the annual fee is the sum of NRC budgeted costs for each FY for those

(1) Generic and other research activities directly related to the regulation of materials licenses as defined in this part; and

(2) Other safety, environmental, and safeguards activities for materials licenses (except costs for licensing and inspection activities directly associated with plant-specific licensing and inspections that are recovered under part 170 of this chapter).

61 FR 16203

(c) A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification, the licensee may pay reduced annual fees for FY 1996 as follows:

	Maximum annual fee per licensed category
Small businesses not engaged in manufacturing and small not-for-profit organizations (gross annual receipts):	
$350,000 to $5 million	$1,800
Less than $350,000	400
Manufacturing entities that have an average of 500 employees or less:	
35 to 500 employees	1,800
Less than 35 employees	400
Small Governmental jurisdictions (including publicly supported educational institutions) (population):	
20,000 to 50,000	1,800
Less than 20,000	400
Educational institutions that are not State or publicly supported, and have 500 employees or less.	
35 to 500 employees	1,800
Less than 35 employees	400

(1) A licensee qualifies as a small entity if it meets the size standards established by the NRC (See 10 CFR 2.810).

56 FR 31472

(2) A licensee who seeks to establish status as a small entity for purposes of paying the annual fees required under this section shall file a certification statement with the Commission. The licensee shall file the required certification on NRC Form 526 for each license under which it is billed. The NRC shall include a copy of Form NRC 526 with each annual fee invoice sent to a licensee for purposes of billing under this section. A licensee who seeks to qualify as a small entity shall submit the completed NRC Form 526 with the reduced annual fee payment.

(3) For purposes of this section, the licensee shall submit a new certification with its annual fee payment each year.

➤ (4) For FY 1996, the maximum annual fee a small entity is required to pay is $1,800 for each category applicable to the license(s).

(d) The FY 1996 annual fees for materials licensees and holders of certificates, registrations or approvals subject to fees under this section are shown below. The FY 1996 annual fees, which must be collected by September 30, 1996, have been determined by adjusting downward the FY 1995 annual fees by approximately 6 percent. The FY 1995 annual fee was comprised of a base annual fee and an additional charge (surcharge). The activities comprising the FY 1995 surcharge are shown in paragraph (e) of this section.

61 FR 16203

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
1. Special nuclear material:	
A.(1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material:	
Babcock & Wilcox (SNM–42)	$2,403,000
Nuclear Fuel Services (SNM–124)	2,403,000
(b) Low Enriched Uranium in Dispersable Form Used for Fabrication of Power Reactor Fuel:	
Combustion Engineering (Hematite) (SNM–33)	1,179,000
General Electric Company (SNM–1097)	1,179,000
Siemens Nuclear Power (SNM–1227)	1,179,000
Westinghouse Electric Company (SNM–1107)	1,179,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations:	
B&W Fuel Company (SNM–1168)	469,200
(b) All Others:	
General Electric (SNM–960)	318,600
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI)	260,900
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers	1,200
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1.A.(2)	2,800
E. Licenses for the operation of a uranium enrichment facility	[11] N/A
2. Source material:	
A.(1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride	597,800
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
Class I facilities [4]	57,000
Class II facilities [4]	32,200
Other facilities [4]	20,600
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4)	41,800
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2)	7,400
B. Licenses which authorize only the possession, use and/or installation of source material for shielding	450
C. All other source material licenses	8,100
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	15,400
B. Other licenses for possession and use of byproduct material issued pursuant to Part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	5,200
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to Part 40 of this chapter when included on the same license	10,400
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to Part 40 of this chapter when included on the same license	4,100
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units)	2,900
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	3,500
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	18,100

61 FR 16203

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
H. Licenses issued pursuant to Subpart A of Part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of Part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part 30 of this chapter	4,600
I. Licenses issued pursuant to Subpart A of Part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of Part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part 30 of this chapter	8,200
J. Licenses issued pursuant to Subpart B of Part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter	3,500
K. Licenses issued pursuant to Subpart B of Part 31 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter	3,000
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution	11,400
M. Other licenses for possession and use of byproduct material issued pursuant to Part 30 of this chapter for research and development that do not authorize commercial distribution	5,100
N. Licenses that authorize services for other licenses, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, and 4C.	5,600
O. Licenses for possession and use of byproduct material issued pursuant to Part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized pursuant to Part 40 of this chapter when authorized on the same license	13,000
P. All other specific byproduct material licenses, except those in Categories 4A through 9D	1,600
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material	[4] 94,300
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	13,300
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	7,100
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	7,500
B. Licenses for possession and use of byproduct material for field flooding tracer studies	12,200
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material	13,600
7. Human use of byproduct, source, or special nuclear material:	
A. Licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license	9,500
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to Parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license	21,700
C. Other licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license	4,300
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities	1,600
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	6,700
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	3,400

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SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees[1, 2, 3]
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	1,400
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	720
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
Other Casks	[6] N/A
B. Approvals issued of 10 CFR Part 71 quality assurance programs.	72,700
Users and Fabricators	950
Users	[6] N/A
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	260,900
B. General licenses for storage of spent fuel under 10 CFR 72.210	[7] N/A
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities pursuant to 10 CFR Parts 30, 40, 70, and 72	[8] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	388,400
17. Master materials licenses of broad scope issued to Government agencies	[10] 1,077,000
18. Department of Energy:	1,812,000
A. Certificates of Compliance	
B. Uranium Mill Tailing Radiation Control Act (UMTRCA) activities	

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the fiscal year. However, the annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses prior to October 1, 1995, and permanently ceased licensed activities entirely by September 30, 1995. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a POL during the fiscal year and for new licenses issued during the fiscal year will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1.A.(1) are not subject to the annual fees of Category 1.C and 1.D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of Parts 30, 40, 70, 71, or 72 of this chapter.

[3] For FYs 1997 and 1998, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the **Federal Register** for notice and comment.

[4] A Class I license includes mill licenses issued for the extraction of uranium from uranium ore. A Class II license includes solution mining licenses (in-situ and heap leach) issued for the extraction of uranium from uranium ores including research and development licenses. An "other" license includes licenses for extraction of metals, heavy metals, and rare earths.

[5] Two licenses have been issued by NRC for land disposal of special nuclear material. Once NRC issues a LLW disposal license for byproduct and source material, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, Parts 71 and 72 Certificates of Compliance, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to the users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Categories 7B or 7C.

[10] This includes Certificates of Compliance issued to DOE that are not under the Nuclear Waste Fund.

[11] No annual fee has been established because there are currently no licensees in this particular fee category.

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≫ (e) The activities comprising the FY 1995 surcharge are as follows:

(1) LLW disposal generic activities;

(2) Activities not attributable to an existing NRC licensee or classes of licensees; e.g., international cooperative safety program and international safeguards activities; support for the Agreement State program; site decommissioning management plan (SDMP) activities; and

(3) Activities not currently assessed under 10 CFR part 170 licensing and inspection fees based on existing law or Commission policy, e.g., reviews and inspections conducted of nonprofit educational institutions and Federal agencies; activities related to decommissioning and reclamation and costs that would not be collected from small entities based on Commission policy in accordance with the Regulatory Flexibility Act.

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59 FR 26097

(f) To recover FY 1991 costs relating to LLW disposal generic activities, an additional charge of $62,300 has been added to fee Categories 1.A.(1), 1.A.(2) and 2.A.(1); an additional charge of $1,400 has been added to fee Categories 1.D., 1.D., 2.C., 3.A., 3.B., 3.C., 3.L., 3.M., 3.N., 4.A., 4.B., 4.C., 5.B., 6.A., and 7.B., and an additional charge of $21,000 has been added to fee Category 17. For comparative purposes the table following shows, for each materials fee category, the total surcharge assessed in FY 1991, the FY 1991 amended surcharges and the amount of overpayment resulting in a refund due or a credit given certain categories of materials licensees.

SCHEDULE OF MATERIALS ANNUAL FEE SURCHARGES

Fee category [1]	FY 1991 surcharge assessed [2]	FY 1991 amended surcharge [2]	Amount of overpayment
Special nuclear material:			
1.A.(1)	$143,500	$62,400	$81,100
1.A.(2)	35,900	62,400	
1.B	1,500	1,500	
1.C	100	100	
1.D	1,500	1,500	
Source material:			
2.A.(1)	$143,500	$62,400	$81,100
2.A.(2)	100	100	
2.B	100	100	
2.C	1,500	1,500	
Byproduct material:			
3.A	$1,500	$1,500	
3.B	1,500	1,500	
3.C	1,500	1,500	
3.D	100	100	
3.E	100	100	
3.F	100	100	
3.G	100	100	
3.H	100	100	
3.I	100	100	
3.J	100	100	
3.K	100	100	
3.L	1,500	1,500	
3.M	1,500	1,500	
3.N	1,500	1,500	
3.O	100	100	
3.P	100	100	
Waste disposal and processing:			
4.A	$35,900	1,500	$34,400
4.B	1,500	1,500	
4.C	1,500	1,500	
Well logging:			
5.A	$100	$100	
5.B	1,500	1,500	
Nuclear laundries:			
6.A	$1,500	$1,500	
Medical—human use:			
7.A	$100	$100	
7.B	1,500	1,500	
7.C	100	100	
Civil defense:			
8.A	$100	$100	
Device/sealed source evaluation:			
9.A	$100	$100	
9.B	100	100	
9.C	100	100	
9.D	100	100	
Transportation:			
10.B	$100	$100	
Spent fuel storage:			
13.B	$100	$100	
Master licenses:			
17	$22,500	$21,000	$1,500

[1] A full description of the various fee categories is found in § 171.16(d).

[2] Includes $100 surcharge to recover costs not paid by small entities.

59 FR 26097

(g) To recover FY 1992 costs relating to LLW disposal generic activities, an additional charge of $61,700 has been added to fee categories 1.A.(1), 1.A.(2), and 2.A.(1); an additional charge of $1,500 has been added to fee Categories 1.B., 1.D., 2.C., 3.A., 3.B., 3.C., 3.L., 3.M., 3.N., 4.N., 4.A., 4.B., 4.C., 5.B., 6.A., and 7.B., and an additional charge of $23,100 has been added to fee Category 17. For comparative purposes the following table shows, for each materials fee category, the total surcharge assessed in FY 1992, the FY 1992 amendment surcharges and the amount of overpayment resulting in a refund due or a credit given for certain categories of materials licensees.

59 FR 26097

Fee category [1]	FY 1992 surcharge assessed [2]	FY 1992 amended surcharge [2]	Amount of overpayment
Special nuclear material:			
1.A.(1)	$155,250	$61,850	$93,400
1.A.(2)	38,950	61,850	
1.B	1,750	1,650	100
1.C	150	150	
1.D	1,750	1,650	100
Source material:			
2.A.(1)	155,250	61,850	93,400
2.A.(2)	150	150	
2.B	150	150	
2.C	1,750	1,650	100
Byproduct material:			
3.A	1,750	1,650	100
3.B	1,750	1,650	100
3.C	1,750	1,650	100
3.D	150	150	
3.E	150	150	
3.F	150	150	
3.G	150	150	
3.H	150	150	
3.I	150	150	
3.J	150	150	
3.K	150	150	
3.L	1,750	1,650	100
3.M	1,750	1,650	100
3.N	1,750	1,650	100
3.O	150	150	
3.P	150	150	
Waste disposal and processing:			
4.A	38,950	1,650	37,300
4.B	1,750	1,650	100
4.C	1,750	1,650	100
Well logging:			
5.A	150	150	
5.B	1,750	1,650	100
Nuclear laundries:			
6.A	1,750	1,650	100
Medical—human use:			
7.A	150	150	
7.B	1,750	1,650	100
7.C	150	150	
Civil defense:			
8.A	150	150	
Device/sealed source evaluation:			
9.A	150	150	
9.B	150	150	
9.C	150	150	
9.D	150	150	
Transportation:			
10.B	150	150	
Spent fuel storage:			
13.B	150	150	
Master licenses:			
17	36,150	23,250	12,900

[1] A full description of the various fee categories is found in § 171.16(d).
[2] Includes $150 surcharge to recover costs not paid by small entities.

59 FR 36895

§ 171.17 Proration.

Annual fees will be prorated for NRC licensees as follows:

(a) Reactors. The annual fee for reactors (power or nonpower) that are subject to fees under this part and are granted a license to operate on or after October 1 of a FY is prorated on the basis of the number of days remaining in the FY. Thereafter, the full fee is due and payable each subsequent FY. Licensees who have requested amendment to withdraw operating authority permanently during the FY will be prorated based on the number of days during the FY the license was in effect before the possession only license was issued or the license was terminated.

60 FR 32218

(b) Materials licenses (including fuel cycle licenses). (1) *New licenses and terminations.* The annual fee for a materials license that is subject to fees under this part and issued on or after October 1 of the FY is prorated on the basis of when the NRC issues the new license. New licenses issued during the period October 1 through March 31 of the FY will be assessed one-half the annual fee for that FY. New licenses issued on or after April 1 of the FY will not be assessed an annual fee for that FY. Thereafter, the full fee is due and payable each subsequent FY. The annual fee will be prorated for licenses for which a termination request or a request for a POL has been received on or after October 1 of a FY on the basis of when the application for termination or POL is received by the NRC provided the licensee permanently ceased licensed activities during the specified period. Licenses for which applications for termination or POL are filed during the period October 1 through March 31 of the FY are assessed one-half the annual fee for the applicable category(ies) for that FY. Licenses for which applications for termination or POL are filed on or after April 1 of the FY are assessed the full annual fee for that FY.

60 FR 32218

(2) *Downgraded licenses.* (i) The annual fee for a materials license that is subject to fees under this part and downgraded on or after October 1 of a FY is prorated upon request by the licensee on the basis of when the application for downgrade is received by the NRC provided the licensee permanently ceased the stated activities during the specified period. Requests for proration must be filed with the NRC within 90 days from the effective date of the final rule establishing the annual fees for which a proration is sought. Absent extraordinary circumstances, any request for proration of the annual fee for a downgraded license filed beyond that date will not be considered.

(ii) Annual fees for licenses for which applications to downgrade are filed during the period October 1 through March 31 of the FY will be prorated as follows:

(A) Licenses for which applications have been filed to reduce the scope of the license from a higher fee category(ies) to a lower fee category(ies) will be assessed one-half the annual fee for the higher fee category(ies) and one-half the annual fee for the lower fee category(ies), and, if applicable, the full annual fee for fee categories not affected by the downgrade; and

(B) Licenses with multiple fee categories for which applications have been filed to downgrade by deleting a fee category will be assessed one-half the annual fee for the fee category being deleted and the full annual fee for the remaining categories.

(iii) Licenses for which applications for downgrade are filed on or after April 1 of the FY are assessed the full fee for that FY.

56 FR 31472

§ 171.19 Payment.

(a) Method of payment. Fee payments shall be made by check, draft, money order or electronic fund transfer made payable to the U.S. Nuclear Regulatory Commission. Federal agencies may also make payment by either Standard Form SF-1081 (Voucher and Schedule of Withdrawals and Credits) or by the On-line Payment and Collection System (OPAC's). Where specific payment instructions are provided on the bills to applicants or licensees, payment should be made accordingly, e.g., bills of $5,000 or more will normally indicate payment by electronic fund transfer.

61 FR 16203

(b) For FY 1996 through FY 1998, the Commission will adjust the fourth quarterly bill for operating power reactors and certain materials licensees to recover the full amount of the revised annual fee. If the amounts collected in the first three quarters exceed the amount of the revised annual fee, the overpayment will be refunded. The NRC will refund any "flat" materials renewal fees payments received for renewal applications filed in FY 1996, as appropriate. All other licensees, or holders of a certificate, registration, or approval of a QA program will be sent a bill for the full amount of the annual fee upon publication of the final rule or on the anniversary date of the license. Payment is due on the invoice date and interest accrues from the date of the invoice. However, interest will be waived if payment is received within 30 days from the invoice date.

(c) For FYs 1996 through 1998, annual fees in the amount of $100,000 or more and described in the **Federal Register** notice pursuant to § 171.13 must be paid in quarterly installments of 25 percent as billed by the NRC. The quarters begin on October 1, January 1, April 1, and July 1 of each fiscal year.

(d) For FYs 1996 through 1998, annual fees of less than $100,000 must be paid as billed by the NRC. Beginning in FY 1996, materials license annual fees that are less than $100,000 will be billed on the anniversary of the license. The materials licensees that will be billed on the anniversary date of the license are those covered by fee categories 1.C. and 1.D.; 2.A.(2) through 2.C.; 3.A. through 3.P.; 4.B. through 9.D.; and 10.B. For annual fee purposes, the anniversary date of the license is considered to be the first day of the month in which the original license was issued by the NRC. During the transition year of FY 1996, licensees with license anniversary dates falling between October 1, 1995, and the effective date of the FY 1996 final rule will receive an annual fee bill payable on the effective date of the final rule, and licensees with license anniversary dates that fall on or after the effective date of the final rule will be billed on the anniversary of their license. Starting with the effective date of the FY 1996 final rule, licensees that are billed on the license anniversary date will be assessed the annual fee in effect on the anniversary date of the license.

171.21 [Removed] 53 FR 52632

56 FR 31472

§ 171.23 Enforcement.

If any person required to pay the annual fee fails to pay when the fee is due, or files a false certification with respect to qualifying as a small entity under the Regulatory Flexibility Criteria, the Commission may refuse to process any application submitted by or on behalf of the person with respect to any license issued to the person and may suspend or revoke any licenses held by the person. The filing of a false certification to qualify as a small entity under § 171.16(c) of this part may also result in punitive action pursuant to 18 U.S.C. 1001.

§ 171.25 Collection, interest, penalties, and administrative costs.

All annual fees in §§ 171.15 and 171.16 will be collected pursuant to the procedures of 10 CFR part 15. Interest, penalties and administrative costs for late payments will be assessed in accordance with 10 CFR part 15, of this chapter, 4 CFR part 102, and other relevant regulations of the United States Government, as appropriate. In the event a quarterly installment is not made by the appropriate due date specified in § 171.19, the full fee becomes due and payable, with interest, penalties, and administrative costs of collection calculated from the date that quarterly installment was due.

Attachment D

DSI No. 7, "Materials/Medical Oversight"

STRATEGIC ASSESSMENT ISSUE PAPER

DSI 7: MATERIALS/MEDICAL OVERSIGHT

INTRODUCTION

In August 1995, the Nuclear Regulatory Commission (NRC) staff initiated a Strategic Assessment and Rebaselining Project. This project was intended to take a new look at the NRC by conducting a reassessment of NRC activities in order to redefine the basic nature of the work of the agency and the means by which that work is accomplished, and to apply to these redefined activities a rigorous screening process to produce (or rebaseline) a new set of assumptions, goals, and strategies for the NRC. The results of this project are intended to provide an agency-wide Strategic Plan which can be developed and implemented to allow the NRC to meet the current and future challenges.

A key aspect of this project was the identification and classification of issues that affect the basic nature of NRC activities and the means by which this work is accomplished. These issues fall into three categories. The first category includes broad issues defined as Direction-Setting Issues (DSIs). DSIs are issues that affect NRC management philosophy and principles. The second category includes subsumed issues. Subsumed issues are those that should be considered along with the DSIs. The third category includes related issues. These are issues that should be considered after the Commission makes a decision on the option(s) for a DSI. Also, as part of the project, other issues of an operational nature were identified. These are not strategic issues and are appropriately resolved by the staff, and are not discussed in the issue papers.

Following the reassessment of NRC activities, issue papers were prepared to provide a discussion of DSIs and subsumed issues, and to obtain a review of these broad, high-level issues. These papers are intended to provide a brief discussion of the options as well as summaries of the consequences of the options related to the DSIs. Final decisions related to the DSIs will influence the related issues which are listed, but not discussed, in each issue paper. As part of the Strategic Assessment and Rebaselining Project, the issue papers are being provided to interested parties and to the public. Following distribution of the issue papers, a series of meetings are planned to provide a forum to discuss and receive comment on the issue papers. After receiving public comment on the issue papers, the Commission will make final decisions concerning the DSIs and options. These decisions will then be used to develop a Strategic Plan for the NRC. In summary, the Strategic Assessment and Rebaselining Project will analyze where the NRC is today, including internal and external factors, and outline a path to provide direction to move forward in a changing environment.

I. SUMMARY

A. Direction-Setting Issue

The Nuclear Regulatory Commission (NRC) Byproduct Materials Program currently regulates approximately 6,400 specific and 35,000 general licenses for the possession and use of nuclear materials in medical, academic, and industrial applications. The Materials Program includes licensing and inspection activities, primarily administered by the NRC regional offices, and exempt distribution licenses and sealed source and device (SS&D) reviews, which are handled by NRC Headquarters. The various regulated products and uses range from large quantities of radioactive materials in complex devices or in the manufacture of radiopharmaceuticals to small quantities in radioactive tracer studies or in simple devices. The NRC is evaluating the level of control and regulation needed to oversee its diverse Nuclear Materials Program. Many of the applications pose similar risks and could be regulated by other Federal and State agencies. Specifically, the NRC has been considering whether to continue to regulate or to revise its oversight of the medical uses of nuclear byproduct materials. To obtain input on the medical regulation issue, the NRC contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM), to perform an external review and to assess the adequacy and appropriateness of the current regulatory framework. The IOM final report, "Radiation in Medicine: A Need for Regulatory Reform," provides recommendations to give regulatory authority over medical uses to the States, with a Federal agency other than the NRC providing leadership and guidance[1]. A decision on the Medical Use Program may effect a rethinking of the NRC's fundamental philosophy on the extent to which it should regulate other nuclear materials. This issue paper provides options associated with the Direction-Setting Issue (DSI) of what should be the future role and scope of the NRC's Nuclear Materials Program, and in particular, NRC's regulation of the medical use of nuclear material. The options include expanding, retaining and revising, retaining in part, or eliminating the Nuclear Byproduct Materials Program with particular emphasis on medical use.

B. Options

Option 1: Increase Regulatory Responsibility With Addition of X-Ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

This option would transfer the regulatory responsibility for non-Atomic Energy Act of 1954, as amended (AEA), sources of ionizing radiation, such as x-ray, linear accelerators, and naturally occurring and accelerator-produced

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[1] See Attachment, "Regulation of Radiation in Medicine - IOM Issues"

radioactive materials (NARM), from other Federal agencies and the States to the NRC. An Agreement States Program would continue. Legislation would be required to implement this option.

Option 2: Continue Ongoing Program (With Improvements)

This option would maintain the current regulatory responsibility of the NRC and the States, while making continual improvements to increase efficiency and revising regulations to be more risk-informed and performance-based rather than prescriptive. Some of these improvements are currently ongoing (business process reengineering [BPR]) or are on temporary hold (revision of Part 35 of Title 10 of the Code of Federal Regulations [10 CFR Part 35]). Legislation would not be required.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High-Risk Activities

This option would decrease regulatory responsibility for all materials that pose a low risk to the workers and the public. Examples of these materials include diagnostic nuclear medicine, gas chromatographs, some portable gauges, and so on. The NRC would retain oversight of SS&D reviews, manufacturers and distributors, and high-risk applications, such as medical therapy, radiography, and large irradiators. Specific regulations and guidance in the high-risk area would be revised to make them more risk-informed and performance-based.

Option 4: Discontinue Regulation of All Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Recommendation)

In this option, the regulatory authority over all medical uses of byproduct material would be given to the States, with a Federal agency (not NRC) in a guidance leadership role. The NRC would retain authority for SS&D reviews, manufacturers and distributors, and all nonmedical applications. Findings under Section 81 of the AEA for exemption or legislation would be required to discontinue NRC responsibilities over medical uses. Legislation would be required to give authority to the States and to name a lead Federal agency.

Option 5: Discontinue Materials Program

In this option, the regulatory authority for byproduct material applications would be given to another Federal agency or the States, with the assumption that an acceptable level of safety would be maintained. The NRC would have no remaining authority for any byproduct materials oversight. Legislation would be required.

II. DESCRIPTION OF ISSUES

A. Background/Bases

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

Section 81 of the AEA directs the NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material. Among other things, Section 81 authorizes the NRC "to issue general or specific licenses to applicants seeking to use byproduct material." Byproduct material is defined in Section 11e(1) of the AEA as nuclear materials created or made radioactive by exposure to the radiation during the fissioning process in a reactor. As provided under the AEA, the NRC also regulates Federal licensees in all States. The NRC has only limited responsibility, however, for regulating uses of nuclear material by the Department of Energy or the Department of Defense.

The nuclear materials licensees can be categorized into several major groups covering various products and uses regulated by the NRC and the Agreement States, under either a specific license or a general license.[2]

1. Specific Licensed Nuclear Materials

These groups include (1) broad-scope materials licenses; (2) manufacturers and distributors; (3) hospitals, clinics, nuclear pharmacies, and private physicians; (4) limited research and development operations; (5) measuring systems; (6) irradiators; (7) industrial radiography; (8) well logging; and (9) other material licenses. All of these licensees are regulated under applicable provisions in 10 CFR Parts 19, 20, and 30 for byproduct materials. In addition, individual sections of Title 10 provide specific requirements for some activities, such as medical, radiography, and irradiators.

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[2] In addition, the Commission has exempted certain nuclear material uses, activities, and products from regulation. The most widely exempted products are residential smoke detectors that contain small quantities of americium-241.

Presented below are descriptions of the major groups of nuclear materials licensees regulated by NRC and the Agreement States that require a specific license.

a. Broad-Scope Materials Licenses

The broad-scope licensees include universities, medical schools, large medical centers, large manufacturers, and research and development facilities that cannot operate under a more limited specific license without seriously disrupting their programs. These licensees use nuclear materials for a wide variety of activities, including research and development, laboratory testing, and medical diagnosis and therapy. Broad-scope licenses authorize the use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the radiation safety committee. Under the broad-scope license, the NRC places significant reliance on the organization's radiation safety committee and radiation safety officer to ensure that NRC's regulations are met. At present, the NRC regulates about 300 broad-scope licensees.

b. Manufacturers and Distributors

Manufacturers and distributors of nuclear materials include those that fabricate SS&Ds (e.g., brachytherapy sources, portable gauges, radiography cameras), as well as those that make radiopharmaceuticals. The manufacturers usually use unsealed nuclear materials that must be controlled to a greater extent than sealed materials. Currently, NRC licenses 129 manufacturers and distributors under 10 CFR Part 32. Twenty of these manufacturers also have received broad-scope licenses from the NRC.

c. Hospitals, Medical Clinics, Nuclear Pharmacies, and Private Physicians

The Medical Use Program represents approximately one-third of NRC's nuclear materials licensees and includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 2,000 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35.

d. Limited Research and Development Operations

Research and development licenses are issued for possession and use of specifically designated radionuclides in academic institutions, industrial facilities, and medical institutions for nonmedical use. The NRC regulates approximately 500 limited research and development licensees under applicable sections of 10 CFR Parts 20 and 30.

e. Measuring Systems

Measuring system licenses are issued for the possession and use of measuring devices and are regulated under applicable sections of 10 CFR Parts 20, 30, and 70. Measuring systems include fixed gauges for measuring or controlling parameters, such as material density, flow, thickness, or weight; portable gauges, such as moisture-density gauges used at fixed locations; x-ray fluorescence analyzers; gas chromatographs; and others. The NRC regulates approximately 2,200 measuring system licensees.

f. Irradiators

Irradiator licensees use radiation for purposes such as sterilizing blood products, disposable medical supplies, and food and polymerizing compounds in wood finishes. Irradiators are also used for some research applications. Approximately 40 irradiator licensees are authorized, pursuant to 10 CFR Part 36, to possess radioactive material in excess of 10,000 curies each for use in irradiation activities. Several commercial NRC-licensed irradiator licensees use more than 6 million curies to process materials in their facilities. The NRC regulates 204 irradiator licensees.

g. Industrial Radiography

In industrial radiography, radiographers use sealed radiation sources to make x-ray-like pictures of metal objects such as pipes and valves. Radiography is a form of nondestructive testing that uses radiation from sealed sources (principally iridium-192 and cobalt-60) to examine the internal structure of objects. The portable radiography devices may contain radioactive sources with as much as 200 curies of iridium-192 or 100 curies of cobalt-60. The NRC has issued about 160 industrial radiography licenses pursuant to 10 CFR Part 34.

h. Well Logging

In well logging, sealed nuclear sources, unsealed radioactive trace material, and radioactive markers are used for subsurface surveying to obtain geological information. The testing procedures are primarily used in oil, gas, and mineral exploration to identify subsurface geologic formations. NRC licenses about 60 firms for well logging under the provisions of 10 CFR Part 39.

i. Other Material Licenses

The other types of materials uses that require a specific license include such diverse activities as nuclear laundries, which clean protective clothing contaminated with radioactive material; leak test and other service companies that provide services to other licensees to leak test sealed sources or

devices containing sealed sources, to analyze leak test samples, to calibrate radiation survey or monitoring equipment, or to repair devices containing sealed sources; waste disposal services; and others. The NRC has about 900 licensees performing these remaining diverse activities.

2. General Licensed Devices

Although specific licensees must submit a license application to the NRC and receive a written specific license, this is not the case for most general licensees. An NRC general license becomes effective on the basis of the general license provisions in NRC's regulations. In most cases, a general license is effective without the filing of an application with the Commission or the issuance of a licensing document to the license holder. An example would be the acceptance of a nuclear materials product at the point of sale, which would make the buyer a general licensee.

General license provisions authorize a variety of activities, such as holding title to licensed material, as well as use of licensed material contained in a device. The generally licensed devices must meet regulatory standards for design and manufacture so that they may be used by persons with minimal instruction in their proper use. (As previously discussed, manufacturers and distributors of devices intended for use under a general license must be specifically licensed for this purpose.)

Examples of these devices include static eliminators, nuclear gauges, and self-luminous signs. An NRC database indicates that there are approximately 35,000 general licensees that use about 600,000 regulated devices.

3. Exempt Distribution Licenses

In addition to specific and general license products and uses, the Commission has exempted certain nuclear material products, quantities, or concentrations from the requirements for a license and from the regulations. These exemptions have been made with prior findings that such exemptions will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. Exemptions have been authorized for products such as gemstones, watches with tritium paint, and smoke detectors, once there has been an initial transfer or distribution of the product.

4. Sealed Source and Device Reviews

The NRC further exercises its statutory responsibilities by the certification or registration of SS&Ds. SS&D manufacturers submit specific information on manufacturing techniques, prototype test results, and other data related to engineering and radiation safety to the NRC or the appropriate Agreement State. These data are evaluated and an SS&D certificate is issued after a

determination is made that the product is safe for the proposed uses. The NRC maintains a registry of SS&Ds approved by the NRC and the Agreement States. Applicants for specific licenses can reference these approved products in their applications.

B. External Factors

Notwithstanding the aforementioned oversight process, the operational history and knowledge base inherent in the current nuclear materials industry allows opportunities for streamlining NRC's Regulatory Program. The nuclear materials industry, with an operational history exceeding 40 years, has a firm foundation in the knowledge and understanding of the properties of nuclear materials and the applicable handling and radiation safety procedures, as well as the metallurgical and engineering requirements for fabricating SS&Ds. However, even with such an operational history, some factors, such as technological advances and aging equipment, may affect streamlining considerations.

1. Technological Advances

The nuclear materials industry has been and will continue to be affected by technological advances in other fields. For example, advanced computer technology has been combined with the use of sealed sources for new products and devices. This has been the case especially in radiation medicine with the advent of the gamma knife (used for brain radiosurgery) and remote afterloading brachytherapy devices. Technological enhancements are not limited to radiation medicine. As the SS&Ds are affected by more sophisticated nonnuclear technology, the regulations, review process, and qualifications of NRC technical staff required to review these applications may change. In the case of the gamma knife, for example, there are no specific medical use requirements in 10 CFR Part 35, although the regulations do address procedures for conventional cobalt-60 teletherapy devices.

2. Aging Equipment

Additionally, with a mature industry, some licensed nuclear material devices are becoming old and/or obsolete. One result may be increased mechanical and metallurgical problems. Aging devices may warrant special consideration when and if the NRC undertakes to streamline its Regulatory Program, especially in the areas of routine inspections and guidance to licensees.

3. External Interest

Unlike the organized opposition to nuclear reactors or nuclear waste disposal, the public (in most cases) has been supportive (at times, by remaining silent) on the use of nuclear materials in medicine, industry, and commerce. There

have been times, however, when the public has expressed concern about new uses of nuclear radiation (e.g., opposition to irradiation of fresh foods). For the most part, the external interests in the Materials Program have involved a few concerned citizens, licensees and their associations and professional societies, and the news media. The print media have published in-depth articles on issues such as radiation medicine misadministrations that have resulted in deaths; radioactively contaminated sites whose licenses have been terminated; and reconcentrated radioactive sewage sludges found at sewer treatment facilities. Additionally, Congress has shown and continues to show interest in the Nuclear Materials Programs of both NRC and the Agreement States.

An example of this external interest is found in the medical use of byproduct materials. During the past several years, the medical community, regulated by NRC and Agreement States, has been very vocal on specific requirements of Part 35. In general, this medical community, including physicians, physicists, pharmacists, hospitals, professional associations, and others, regards the detailed prescriptive requirements of Part 35 as unnecessarily burdensome. A specific target has been the regulation on "Quality Management Program and Misadministrations" (the QM rule), which became effective on January 27, 1992. The medical community has asserted that the requirements are an intrusion into medical practice, are cost-ineffective, and have no utility. The QM rule was strongly opposed by several professional societies, which made their views known to the Office of Management and Budget (OMB). In June 1992, OMB disapproved the record collection requirements of the QM rule on the basis that the NRC had not demonstrated that the rule would yield significant benefits. The NRC Commissioners overrode the OMB determination, citing the necessity of the information collection requirements for public health and safety. In addition, the American College of Nuclear Physicians and the Society of Nuclear Medicine took the NRC to court to overturn the QM rule. The court ruled in favor of the NRC. Shortly after, in November 1992, a patient in Indiana, Pennsylvania, died as a result of a therapy misadministration. A month later, the Cleveland Plain Dealer ran a week-long series entitled "Lethal Doses: Radiation That Kills." These events resulted in congressional hearings on NRC's Medical Radiation Program and its Agreement States Program that raised questions about the adequacy of control of the medical use of byproduct material by the NRC and the Agreement States. As a result of the two opposing, strongly held views of the regulated medical community, and Congress and the media, the Commission directed the staff to reevaluate the Medical Use Program with the assistance and advice of the NAS. To that end, the staff contracted with the Institute of Medicine of the NAS to perform the external review mentioned earlier in this issue paper. The report of that review, "Radiation in Medicine: A Need for Regulatory Reform," is discussed in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

4. Full Cost Recovery

Another significant external factor is the Omnibus Budget Reconciliation Act of 1990, which requires that the NRC recover almost 100 percent of its budget authority. The number of NRC licensees has declined since about 1990 due primarily to the requirement for full fee recovery. This declining trend will continue, with the number of licensees decreasing by about one third if States that are currently negotiating agreements (Massachusetts, Pennsylvania, Ohio, and Oklahoma) become Agreement States and additional States continue to pursue this status. The reduced number of NRC licensees will further compound the full-fee-recovery cost issue, even though the BPR efforts will likely reduce licensing fees for some categories of NRC licensees. Also, State interest in becoming an Agreement State may be reduced by NRC changes in funding for Agreement State training and technical assistance.

C. Internal Factor

In addition to the described external factors, an ongoing internal initiative could affect any decision on the role and scope of the Nuclear Materials Program.

Business Process Reengineering

In 1994, the staff began a major reevaluation of the regulatory process in NRC's oversight of licensed materials. This reevaluation is being carried out as part of a BPR effort. Phase I was completed in the spring of 1995. This phase was directed toward proposing a fundamentally new approach to materials licensing designed to (1) perform at least an order of magnitude faster than the current system; (2) be supported by clear, consistent, and timely regulatory guidance; and (3) ensure that no adverse effect on public health and safety results from its implementation. The new process will use modern information technology to streamline operations. The new approach focuses on including performance requirements in NRC's regulations, discontinuing the current practice of incorporating licensee practices and procedures in license conditions, and considering changes to the duration of materials licenses. As part of these efforts, a rulemaking has been promulgated to extend qualified materials licenses for an additional 5 years.

It is envisioned that the BPR will have a significant impact on the entire Nuclear Materials Program during the next several years. The number of licensing actions should significantly decrease, as should the amount of required review time. Inspections for certain materials licensees will be streamlined or eliminated. Overall, as a result of the reengineering efforts, the NRC's Materials Program should be significantly more efficient and responsive to both the public and licensees. During the past several years, the NRC's Materials Program has remained at about the same level in the use of

staff and resources. However, in fiscal year 1997 the program will begin to decrease in both staff and technical assistance contractual support. This decrease is due, partially, to the increased efficiencies in licensing and inspection anticipated from BPR, and partially from additional Agreement States.

III. DISCUSSIONS

A. Discussion of Direction-Setting Issue

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility.

Also to be considered is the interpretation that the Commission has adopted and implemented that medical patients are included in the "public."

The options on the role and scope of the Nuclear Materials Program are the result of management and staff review and subsequent initiatives such as the Medical Management Plan, BPR, and planned revisions to 10 CFR Parts 34 and 35. Other factors influencing the development of options included resource limitations, growth in the number of Agreement States, a desire for increased efficiency and effectiveness, and the recommendations of the IOM.

Although the primary focus of the Byproduct Materials Program is on protecting public health and safety, it must also ensure that the extent of control is tempered by the risk to the public. The focus should be on the safety-significant issues and on providing timely and consistent guidance and licensing that will allow licensees to meet the regulations and standards in the most efficient and economic way. In turn, these considerations need to be viewed in terms of a broader, changing environment. For example, it is anticipated that the number of Agreement States will increase over the next 5 years, significantly reducing the number of NRC licensees. The NRC will need to consider what steps to take to account for the anticipated reduction in resources. Although the BPR process is a step in the right direction, additional steps need to be initiated. The NRC may also have to consider changes in how it regulates areas of low public risk. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

B. Discussion of Subsumed Issue

As a part of selecting an option on the future role and scope of the NRC's Byproduct Materials Program, the following strategic issues should be considered and resolved as a result of this issue paper.

Issue: What should be the role of NRC in regulating the medical use of nuclear material?

Under the AEA, NRC has responsibility for two categories of radiation medicine use. Regulation of these two broad categories represents approximately one-third of NRC's Nuclear Materials Program. One category of radiation medicine is nuclear medicine, which employs radioactive drugs (radiopharmaceuticals). These drugs usually contain only very small quantities of radioactive material, which is used primarily for the diagnosis and followup of disease. Nuclear medicine occasionally includes the use of larger quantities of unsealed radioactive material for therapy, especially for diseases of the thyroid gland. The other category of radiation medicine is radiation therapy (radiation oncology). In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed quantities of radioactive material are used both external to and within a patient. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by electronic devices not regulated under the AEA, such as x-ray equipment and linear accelerators, is used in the other 75 percent of treatments. Therapeutic radiation devices, such as a gamma knife, may contain more than 6,000 curies, while diagnostic nuclear medicine procedures may be limited to microcurie or millicurie quantities.

By authority of the AEA and Commission policy, the NRC regulates the medical use of nuclear materials as necessary to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients.

Over the years, the Commission has made a concerted effort to improve and strengthen the Medical Use Program. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. Also, in February 1979, NRC issued a policy statement to guide its Regulatory Program in the medical area. A fundamental tenet in the policy statement is

the commitment to protect patient safety without intrusion into the practice of medicine. However, there has been frequent tension with the regulated medical community on a number of medical use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. This tension and opposition to NRC's regulation of the medical uses of byproduct material have been a continuing problem.

Additional problems arise from the jurisdictional responsibilities for the different sources of radiation. Jurisdiction over various aspects of the regulation and use of ionizing radiation in medicine is exercised by both the Federal Government, primarily through the Department of Health and Human Services, the Food and Drug Administration (FDA) and the NRC, and the States. Within this regulatory framework, the NRC has jurisdiction over the medical use of byproduct and special nuclear material and regulates radiation safety associated with the actual use of these products. The FDA regulates the manufacture and distribution of radiopharmaceuticals, biologics, and medical devices for safety and efficacy. For the most part, FDA does not regulate at the user level. The States have broad regulatory authority over the general public health and safety of their residents. This includes authority over the use of all sources of ionizing radiation, except AEA material, which is regulated by the NRC. The States control most of radiation medicine, but the degree to which they exercise control varies from State to State.

In 1992, the staff began to develop a Medical Management Plan to guide the conduct of the Medical Use Regulatory Program. Although delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings, the plan was subsequently completed and initiated. In parallel, the staff was directed by the Commission to initiate an external review of the Medical Use Regulatory Program.

As a result, NRC contracted with the NAS in 1994 for the IOM to conduct that external review, addressing not only the role of the NRC but also the roles of the FDA and the States in this area. The IOM has completed its review and recommended that regulatory authority over medical uses of byproduct material be given to the States. The IOM also recommended that only licensed users have access to byproduct material and identifies the Department of Health and Human Services (DHHS) as the agency that should exercise a leadership role in the radiation safety community. Further, the report suggests that DHHS assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research.

The NRC has reviewed the IOM recommendations at length and has held several public meetings on them. As of August, 1996, the NRC had received 41 comments on the subject. Although some commentors supported the recommendations, the CRCPD expressed concern about the elimination of the entire medical use

program and the absence of Federal authority in the medical use area. DHHS stated that it could not support the recommendation that it provide the leadership role suggested by IOM. A more extensive summary of the recommendations and comments appears in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

IV. OPTIONS

In this section, the five options described earlier are detailed, including, if applicable, required regulatory or legislative changes, impacts, resource implications, and the reaction of stakeholders.

Option 1: Increase Regulatory Responsibility With Addition of X-ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

Option

Under this option, the NRC would continue with its ongoing program and improvements and seek legislation for regulatory oversight of other sources of ionizing radiation, including x-ray, accelerators, and discrete NARM. Discrete sources of NARM include radium sources used in medicine and industry and the wastes resulting from cyclotrons and linear accelerators. They do not include wastes from the mining and processing of radium or other radionuclides. An Agreement States Program would continue. This option would significantly increase NRC's jurisdiction in the control of ionizing radiation; it would result in responsibility being taken away from other Federal agencies and the States. Variations of this option could include consideration of limiting oversight to specific applications, such as industrial and commercial uses, or to only those applications that pose a high risk (Option 3).

Regulatory Changes

Legislation would be needed to remove the responsibility for the regulation of these sources of radiation from other Federal agencies and the States and to transfer it to NRC. Coupled with this action would be new and revised policy statements, such as the 1979 Medical Policy Statement, memoranda of understanding with other Federal agencies, and agreements with the Agreement States. Rulemaking to expand and modify existing regulations and generation or revision of the companion guidance documents for the NRC staff and licensees would be necessary.

Impacts

This option would ensure increased uniformity and consistency in the regulation of all sources and uses of ionizing radiation. It would avoid substantive differences in regulations and oversight between AEA and non-AEA sources of radiation. Also, it could eliminate regulatory advantage of one radiation modality over another for a given application (e.g., x-ray radiography versus gamma radiography). This option would require an expansion of NRC's technological base to include specialists in x-ray and accelerator equipment, and the medical and commercial uses of this equipment. It would result in a significant increase in the number of NRC licensees (which would multiply 5 to 10 times), especially in the medical area. This increase would require additional personnel and physical resources, including the possibility of additional regional offices. Such wide-sweeping legislation may be difficult to support in the absence of a compelling safety problem.

The resources required to develop the necessary legislation would include resources from the other Federal agencies currently providing some radiation protection or source and device oversight (e.g., FDA, the Environmental Protection Agency [EPA]), as well as NRC. A comprehensive program that would implement such legislation, that is to regulate all discrete NARM, including promulgation of regulations, guidance development, and inspection at frequencies comparable to those of similar NRC licensees, could require several hundred full-time equivalent (FTE) positions.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) would need to be expanded to include other areas of expertise such as diagnostic and interventional radiology.

Reaction of Stakeholders

As described in more detail in Option 4, the Agreement States that now have authority for non-AEA sources support the approach for a single Federal agency to be responsible for all radiation use.

Option 2: Continue Ongoing Program (With Improvements)

Option

Under this option, the current regulatory responsibility of NRC and the States would be maintained. However, there would be continual improvements to increase efficiency and revision of regulations to make them more risk-informed and performance-based rather than prescriptive. Some of these improvements are ongoing or are on temporary hold (e.g., BPR and Part 35 revisions).

The ongoing BPR of the licensing process will result in the use of modern information technology to streamline operations. The envisioned new licensing process is composed of three major concepts: (1) a Regulatory Product Design Center in which technical members of the materials licensing and inspection community can interact face to face or by way of the computer, to design and prepare the regulatory products necessary to support, maintain, and enhance the new licensing process; (2) improved processing of licenses through reviewer-performed and computer-assisted licensing, using a graded approach commensurate with the safety hazards the application poses; and (3) a new way of working in agency-wide teams. The agency-wide team concept, based on BPR philosophy, will include such attributes as collaborative team-based decisions and parallel concurrences.

In addition, NRC is identifying regulations that are obsolete, unnecessarily burdensome, too prescriptive, or that overlap or duplicate the regulations of other agencies. As part of this effort, NRC is reviewing Part 35 to evaluate whether it can be revised to reflect a more risk-informed, performance-based regulation. To this end, the staff has requested input from the ACMUI and the Agreement States on what revisions should be made to Part 35 if NRC were to retain its current statutory authority and also if NRC were to ramp down in the regulation of patient safety. Examples of staff-identified and staff-suggested requirements needing revision or possible rescission include the As Low As it Reasonably Achievable (ALARA) Program, the Quality Management Program, the misadministration definitions and reporting, dose calibrator checks, surveys, calibration of devices (using industry standards where possible), and training and experience requirements. Other sections of the regulations pertaining to materials are also being reviewed for appropriate revisions.

Regulatory Changes

No legislative changes are needed to implement this option. However, rulemaking would have to be initiated to revise the byproduct materials regulations, such as Part 35. In addition, internal guidance documents (e.g., inspection procedures, standard review plans, etc.) as well as several regulatory guides, including Regulatory Guide 10.8, would have to be revised to reflect the proposed changes.

Impacts

This option would result in the development of more risk-informed, performance-based regulations and increased agency efficiencies obtained by implementation of BPR initiatives.

Amending the regulations and modifying guidance documents and associated regulatory guides has already been budgeted as part of the Medical Management Plan. No additional resources would be necessary for the medical use area. Also, an overall reduction in needed materials resources is anticipated over the next 5 years. This reduction is predominantly due to the increased efficiencies anticipated with the implementation of planned BPR initiatives, as well as anticipation that there will be an increase in the number of Agreement States within the next 5 years. This possibility could result in a reduction of approximately 20 FTEs by the year 2000.

Reaction of Stakeholders

Based on IOM interviews and comments on the IOM report, many medical licensees would continue to support NRC's divesting itself of responsibilities in the medical area.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High Risk-Activities

Option

This option places priority on the tenet that the regulation of byproduct materials should be consistent with the risk involved. Although the NRC has effectively regulated areas of high risk (e.g., manufacturers, large irradiators, etc.), it may be overregulating areas that involve low-risk activities or sources. Low-risk activities could include the use of devices such as gas chromatographs and certain gauges, and diagnostic nuclear medicine. The oversight of these low-risk activities may be an unnecessary expenditure of resources because of the limited additional protection it provides.

Under this option, the NRC would modify its existing regulatory responsibility of low-risk activities and maintain its current responsibility (with some program modifications) for high-risk activities. This could be accomplished through policy decisions on decreasing or discontinuing oversight in certain areas, rulemaking, or an agreed-upon definition of low risk established and coordinated with other Federal agencies, the States, and the conduct of a public comment process. This option would encompass the overall Materials Program and would affect medical as well as nonmedical programs. The low-risk applications could be placed in a category of licenses (such as general licenses) that warrants minimal regulatory oversight with no formalized inspection frequency and minimal licensing requirements. However, some audit activity might have to be established to periodically assess the general licensee's byproduct material possession and performance.

Once low risk has been defined, this option would necessitate reevaluation of those licensees currently licensed by the general license provisions, as well as those activities previously determined to be exempt from regulation. A reassessment of these licensing categories may result in moving activities and uses from one category to another.

In this option, the NRC would probably maintain its current level of regulatory oversight for the manufacturers of radiopharmaceuticals and sealed sources because these activities would most likely be considered higher risk activities.. The NRC would also maintain its current level of regulatory oversight for other high-risk applications, such as therapeutic uses of byproduct material, large irradiators, and industrial radiography. For the high-risk applications, the existing specific regulations would be revised to be more risk-informed and performance-based, or consideration may be given to limiting oversight to Part 20 compliance only.

Regulatory Changes

The transfer of some of the current specific licenses to general licenses or to some other category that warrants minimal regulatory oversight would not require legislative changes. The transfer of low-risk activities to general licenses would require modifications to current general license regulations in Part 31, as well as modifications to current licensing regulatory guides, internal standard review plans, and inspection procedures.

Impacts

This option would result in increased efficiency and effectiveness within the agency by focusing NRC's limited resources on higher risk activities and those licensees that warrant enhanced oversight because of poor performance. This option might result in the elimination of approximately 50 percent of the NRC's current specific licensee base. For the remaining high-risk licensees, the NRC would revise the applicable regulations and guidance documents using a risk-informed, performance-based approach.

It is anticipated that a few FTEs over about a year would be required to complete an analysis and recategorize licensees. If NRC completely discontinues its oversight of the low-risk activities, associated legislative efforts may also require several FTEs over several years.

With NRC either completely discontinuing its regulatory oversight of lower risk activities or reducing its oversight, the current specific licensee base could be decreased by about half. Allowing for some resources to track and audit general licensees, a reduction of approximately 50 FTEs from current licensing, inspection, and other materials activities might be realized. This reduction includes those FTEs eliminated by the BPR.

Option 4: Discontinue Regulation of all Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Institute of Medicine Recommendation)

Option

Under this option, the NRC would request that Congress (1) discontinue NRC's regulatory authority over all medical uses of byproduct material (including biomedical research), (2) give this regulatory authority to the States, and (3) name another Federal agency (not NRC) to a guidance leadership role. The IOM report has recommended that this Federal agency be the DHHS. The leadership role would be nonregulatory and would assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research. In this option, the NRC would retain responsibility for oversight of the manufacture and distribution of byproduct material (including SS&Ds) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State. Also, the Conference of Radiation Control Program Directors (CRCPD) would continue to develop its model regulations for adoption by the States. The CRCPD would be expected to continually reevaluate its regulations to maintain congruence with any scientific advances in knowledge on radiation bioeffects, and benefits and risks of the medical uses of ionizing radiation. The NRC's ongoing program for nonmedical licensees would remain as in Option 2.

Regulatory Changes

Legislation would be needed to remove responsibility for the regulation of the medical uses of byproduct material from the AEA. In lieu of legislation, if NRC made the requisite findings under Section 81 of the AEA, the NRC could by "exemption" eliminate this aspect of the Materials Program. Rulemaking to rescind or modify regulations in Parts 30, 33, and 35, among others, would follow. This route would require public notice and comment rulemaking. Coupled with these actions would be a revision or rescission (in whole or in part) of the 1979 Medical Policy Statement, the enforcement policy, agreements with the 29 Agreement States, and the memorandum of understanding with the FDA, as well as NRC regulatory guides, manuals, and directives.

Impacts

This option would result in the elimination of approximately one-third of the NRC's current specific licensee base. The States would be responsible for all radiation medicine applications, which would result in the potential for increased uniformity of the regulation of all radiation medicine within a given State. However, the level of oversight may vary considerably from State to State because currently some States provide oversight (licensing and

inspection) through State radiologic health personnel, and others by a simple registration process. Additionally, inconsistencies could develop between regulation of basic radiation safety in medical and nonmedical applications. Finally, DHHS does not support the IOM's recommendation that DHHS be given a leadership role.

Some of the non-Agreement States may lack the resources, including qualified personnel, to set up their own safety programs and decide not to regulate in this area and both the Agreement States and the non-Agreement States may view the action as an unfunded mandate. Also, revision of the agreements with each of the 29 Agreement States would be necessary. Additionally, the event database would no longer include misadministrations or events involving overexposures to workers or members of the public (non-patients) as a result of the medical use of byproduct material. Federal facilities would be responsible for self-regulation of the medical uses of byproduct material. Proposed legislation would need to address State regulation of Federal authorities or facilities.

For those facilities conducting both biomedical and nonmedical research, there would continue to be a dual system of regulation.

Resources associated with efforts for legislation and rulemaking would entail a few FTEs for a period of about 5 years.

The Medical Use Program includes approximately 50 FTEs, which would be eliminated. The majority of these FTEs, approximately 70 percent, come from the regional materials licensing, inspection, and event evaluation activities. Also, the number of medical consultants under contract to NRC could be reduced from approximately 12 (current) to less than half that number. These consultants are used on an as-needed basis in response to medical misadministrations resulting in an overexposure, as well as nonmedical events that might require the services of a physician or a scientist consultant to assess radioactive dose estimates and possible consequences. Currently, the majority of provided services is in response to medical misadministrations.

Reaction of Stakeholders

As of the end of August 1996, the staff had received 50 written comments on the IOM report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized in Appendix 3 to the Attachment to this Issue Paper.

Option 5: Discontinue Materials Program

Option

Under this option, the NRC would request that Congress discontinue NRC's regulatory authority over all byproduct material uses, give this regulatory authority to the States, and name a Federal agency (not NRC) to a guidance role for all sources of radiation, as discussed in Option 4. This option presumes that an acceptable level of safety would be maintained by the States. The NRC would have no remaining authority for any byproduct materials oversight. This option is an extension of the previous option to all materials uses.

Also, there would be no change in the proper disposal of byproduct materials at low-level waste disposal sites.

Regulatory Changes

This might be viewed as subject to the procedures of the Unfunded Mandate legislation. Legislation would be needed to remove responsibility for the regulation of all uses of byproduct material from the AEA. Rulemaking would be needed to rescind the regulations in 10 CFR Parts 30 through 39, and certain policy statements and memoranda of understanding would have to be rescinded or drastically revised. Also, all agreements with the 29 Agreement States would have to be rescinded.

Impacts

In addition to the impacts described in Option 4, this option would result in elimination of NRC's oversight of all specific and general byproduct materials licenses, thereby dramatically decreasing the resources of the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs. The States would be responsible for all medical, academic, and commercial applications of byproduct materials.

The lead Federal agency could possibly serve as a safety backup if a State requested assistance. The lead Federal agency role could be filled by an existing Federal agency such as the EPA, DHHS, or the Occupational Safety and Health Administration, with legislation modifying its authorities and responsibilities. Alternatively, a new agency or office within an existing agency could be created, thereby consolidating activities currently vested among several agencies. Greater uniformity might be achieved by consolidating a guidance role in one federal agency. However, because each State would be responsible for implementing its regulatory program as it deems appropriate, there could potentially be quite diverse programs among the 50 States.

Resources associated with efforts for legislation and rulemaking would entail several FTEs over a period of 5 to 7 years.

The number of budgeted FTEs for the Byproduct Materials Program is approximately 140 FTEs in Headquarters and the regions. These FTEs include all managers and technical, administrative, and support staff. Nearly all of these FTEs could be eliminated or redirected, in part, to other activities, recognizing that a few FTEs would be needed to handle residual activities. In addition, staff from other NRC offices who support the NMSS Byproduct Materials Program could be reduced by the current number of FTEs that handle byproduct materials issues or provide support to this NMSS Program.

Reaction of Stakeholders

Reaction from the regulated community could depend on whether consensus develops among the States to follow the guidance established by the federal agency. Manufacturers of some sources and devices could be particularly concerned about the possibility of having to comply with a multiplicity of State requirements.

The Agreement States might support this option to the extent they find it consistent with their consensus view described in Option 4.

Federal agencies would self-regulate. Some indicated in their comments on the IOM report that they did not have the resources necessary to develop and implement an oversight program, as indicated in the Department of Defense's comments on that report.

V. RELATED ISSUES

After the Commission has made decisions concerning the Direction-Setting and Subsumed Issues discussed above, additional issue(s) such as those related to implementation details will be addressed as the Strategic Plan is implemented. The Related Issues are listed in this section to provide a more complete understanding of the higher level Direction-Setting and Subsumed Issues.

A. Is escalated enforcement effective in preventing future violations by materials licensees? Would it be more effective to augment the inspection process than to impose civil penalties?

This is a Commission issue because it involves the Commission's reconsideration of its policy on its Enforcement Program for materials licensees and may lead to rulemaking. It is related to the DSI because NRC's enforcement policy for materials must reflect the philosophy established by the DSI. It is a related issue rather than a subsumed issue because it will

reflect the extent to which the materials licensee community follows NRC's enforcement activities and will be addressed in more detail than is appropriate for the DSI.

B. What should be the NRC's policy relative to the need for and the frequency of renewals for materials licensees?

This is a Commission issue because a change to the current frequency of renewals will involve policy and perhaps rulemaking. This issue is related to the DSI because the DSI will establish how important materials license renewals will be in the future. It is a related issue rather than a subsumed issue because different classes of materials licensees may require different renewal policies. Such differentiation will lead to more detail than is appropriate for the DSI. The staff is actively engaged in addressing this issue.

C. What should be NRC's policy relative to frequency of renewals for fuel fabrication facility licenses?

This is a Commission issue because a change in the current frequency of renewing fuel fabrication facility licenses will involve policy and perhaps rulemaking. The issue is related to the DSI because the philosophy for renewing fuel fabrication facility licenses should be consistent with the philosophy for renewing materials licenses to be developed here. It is a related issue rather than a subsumed issue because it will reflect such aspects of fuel fabrication facility regulation as criticality concerns, which are beyond the scope of this DSI.

D. Does NRC have an acceptable program, given that history and operating experience have required revocation of very few licenses? Is there a set of licensees that NRC should be regulating differently?

Rather than revoke licenses or reject applications, NRC generally helps bring weak licensees and applicants up to acceptable standards. Such activities are often very staff-intensive and include multiple deficiency letters, pre-licensing meetings, and site visits; confirmatory action letters; increased inspection frequencies; enforcement conferences; and imposition and monitoring of "Get Well Programs." Although such activities generally bring weak licensees up to acceptable standards, this may not be the most cost-effective use of NRC's limited materials resources.

This issue, originally a subsumed issue, goes beyond the question of whether NRC should regulate a certain materials area and concentrates on the "how" or the methodology of regulation. As such, this issue will be directed by the decisions made on the Byproduct Materials Program and will require an in-depth

evaluation that is beyond the scope of the current issue paper. For these reasons, and depending on decisions by the Commission, this subsumed issue will be addressed as a related issue.

E. Should a single Federal agency regulate radiation safety?

This issue is directly linked to the Agreement States' comments on the IOM recommendations in which the Agreement States technical staffs said that "All radiation use (medical and nonmedical uses) should be consolidated under one Federal agency to include NARM, AEA material, and machine-produced radiation. Consensus was not reached as to which Federal agency should have the authority, or whether it should be an existing agency."[3]

It appears most appropriate to consider the issue of single agency jurisdiction from several perspectives. As stated above, a single agency could be responsible for radiation regardless of source, to include AEA material, NARM, and machine-produced radiation. Alternatively, a single agency could hold all authorities, to include such authorities as standard-setting (now vested in EPA), approval of medical devices and radiopharmaceuticals (now in DHHS),and applications (now in NRC).

This is a Commission issue because it involves policy concerns that are fundamental to NRC's mission, that in fact go beyond NRC's regulation of materials to include its regulation of nuclear reactors as well. It is clearly a related, rather than a subsumed, issue, because it is well beyond the scope of this DSI.

V. COMMISSION'S PRELIMINARY VIEWS

Staff actions regarding the various options should be held in abeyance pending the Commission's final decision on this issue paper.

The Commission preliminarily favors a combination of Option 2 (Continue the Ongoing Program with Improvements) and Option 3 (Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities). In implementing Option 3, the NRC would utilize the risk-informed performance based approach, as discussed in DSI 12, to determine which activities in the materials area, and specifically in the medical area, are low-risk activities. The general approach described in Option 3 of this DSI appears to be a reasonable starting point for identifying the types of activities that can be affected by this process.

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[3] Report of Joint NRC/Agreement State technical workshop, March 5-6, 1966

In implementing these options with regard to the NRC's medical program, the NRC would consult with its Advisory Committee on the Medical Uses of Radioisotopes (ACMUI) for guidance on low-risk medical activities, revisions to 10 CFR 35, and possible implementation methods. The NRC would also evaluate the feasibility of using professional medical organizations and societies as a potential source for developing professional standards and guidance that would be adhered to by NRC medical licensees and could be adopted by the NRC as regulatory requirements.

In the public comments on this issue, the NRC particularly solicits the views of other affected organizations such as the Organization of Agreement States and the CRCPD on applying a risk-informed performance based approach to NRC's oversight of medical activities. The NRC also solicits the public's views on the feasibility and desirability of NRC's striving to have the remaining non-Agreement States acquire Agreement State authority for medical-use only. In addition, the Commission solicits the public's views on whether a single agency should regulate radiation safety. Finally, the NRC specifically seeks comments on the Attachment to this issue paper titled "Regulation of Radiation in Medicine - IOM Issues."

ACRONYMS

ACMUI	Advisory Committee on Medical Uses of Isotopes
AEA	Atomic Energy Act
ALARA	As Low as is Reasonably Achievable
BPR	Business Process Redesign
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors
DHHS	Department of Health and Human Services
DSI	Direction-Setting Issue
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FTE	Full-Time Equivalent
IOM	Institute of Medicine
NARM	Naturally Occurring and Accelerator-Produced Radioactive Materials
NAS	National Academy of Sciences
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
OMB	Office of Management and Budget
QM RULE	Quality Management Program and Misadministrations
SS&D	Sealed Source and Device

REGULATION OF RADIATION IN MEDICINE - IOM ISSUES[1]

I INTRODUCTION

Under the Atomic Energy Act (AEA), the Nuclear Regulatory Commission (NRC) regulates the medical use of reactor - generated radioactive materials to provide for the radiation safety of workers and the general public. It also regulates the radiation safety of patients when justified by the risk. NRC's responsibilities include the regulation of radiopharmaceuticals and sealed sources, but not machine-produced x-rays nor naturally occurring or accelerator produced radioisotopes.

Over the years, NRC has had a concerted effort to improve and strengthen its Medical Use Program. In these efforts, it has repeatedly addressed two difficult issues; how can it best protect patient safety without intruding into the practice of medicine; and how can it best deal with the numerous jurisdictional responsibilities for different sources of radiation? To obtain external advice on these and other issues, in 1994 the NRC contracted with the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) to review NRC's Medical Use Program and to address the roles of the regulatory agencies in this area. In December, 1995, the IOM provided NRC with a prepublication copy of its report, "Radiation in Medicine - A Need for Regulatory Reform." The final report was issued in March 1996.

The report documents the committee's consideration of seven alternative regulatory systems, ranging from no regulation (laissez-faire) to Federal control of all aspects of medical care. Between these extremes, the committee considered a variety of Federal and State regulatory systems. The committee concluded that the Federal government should relinquish regulation of radiation in medicine to the States, with the Department of Health and Human Services (DHHS) providing support, coordination, and guidance to them. To bring about this change, the committee made eight recommendations; two to Congress, three to the NRC, and three to the Conference of Radiation Control Program Directors and the States.

This document provides an overview of the committee's report, including issues identified by the NRC staff about each of the recommendations, and a summary of the public comments received to date.

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[1] Some of the text in this paper closely parallels text in the Institute of Medicine report which is the subject of this paper.

The second section of this report, "Background," briefly discusses the use of radiation in medicine, the regulatory authorities of the Federal and State agencies, NRC's particular responsibilities, regulations, and activities, and a summary of the history of the NRC program which led the agency to seek a review of its Medical Use Program.

The third section of this report summarizes the IOM committee's view of the present situation, and describes the seven alternative regulatory systems considered by the committee. It describes each alternative and presents the committee's views of the positive and negative aspects of that alternative. It concludes with the committee's basis for selecting its preferred alternative, State Regulation with Federal Guidance.

The fourth section of this report addresses the committee's recommendations associated with the preferred alternative. It contains a brief description of each recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal issues, and some pertinent public comments.

The fifth section documents NRC actions on the report to date and provides a general summary of the 47 comments received so far. Lists of specific commentors and brief summaries of their comments appear in appendices.

II BACKGROUND

This section contains a brief description of the ways ionizing radiation is used in medicine, followed by a discussion of the Federal and State regulatory authorities over that radiation. It then summarizes NRC's medical use program including its applicable regulations, its licensee community, and its activities. It then sketches the history of NRC's efforts to improve the program, including the events and issues that led NRC to seek a review by the NAS. Finally, the section documents NRC's goals for the study and the recommendations NRC requested from NAS.

Ionizing radiation is used for both diagnosis and treatment. Diagnostic uses are classified under two basic headings; radiology and nuclear medicine. In radiology, (such as the use of x-rays) the radiation administered is external to the patient; in nuclear medicine, it is internal. Nuclear medicine employs radioactive drugs (radiopharmaceuticals). When used for diagnosis or followup, these drugs usually contain only very small quantities of radioactive material.

Ionizing radiation used for treatment is also typically classified into categories depending on whether the source of radiation is external or internal to the patient. These areas are called teletherapy (external

sources), brachytherapy (internal) and therapeutic nuclear medicine (internal). Brachytherapy and teletherapy use sealed sources; therapeutic nuclear medicine uses radiopharmaceuticals. In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by devices not regulated under the AEA, such as linear accelerators, is used in the other 75 percent of therapy.

Regulatory authority over ionizing radiation in medicine is widely dispersed among several government agencies at the Federal, State, and local levels. At the Federal level, by authority of the Atomic Energy Act (AEA) and Commission policy, the NRC regulates the medical use of byproduct material[2] to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients. NRC's regulatory authority is limited to byproduct material (such as cobalt^{60} or iodine^{131}), so it does not regulate naturally occurring or accelerator produced materials (NARM), or accelerator produced radiation. For example, NRC does not regulate the use of radium or x-ray equipment in medicine.

The Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) oversees the approval of radiation-producing devices (including x-ray equipment) and radiopharmaceuticals (including NARM). In addition to these approvals, FDA's regulatory program includes review of problem reports, enforcement actions including product removal and recall, and civil prosecution of manufacturers. The Department of Transportation (DOT) regulates the transportation of radionuclides. The Environmental Protection Agency (EPA) sets generally applicable environmental standards to protect the public from radiation, and the Occupational Health and Safety Administration (OSHA) is responsible for worker safety.

States have broad regulatory authority over the general public health and safety of their residents, including authority over all sources of ionizing radiation except the authority preempted by the Federal Government as discussed above[3]. The AEA does permit States to obtain authority to regulate byproduct material by becoming one of NRC's Agreement States. In that case,

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[2] Byproduct material is defined as nuclear material created or made radioactive by exposure to radiation during the fissioning process in a reactor.

[3] Although Federal pre-emption applies to source and special nuclear material as well as byproduct material, regulation of those materials is beyond the scope of this document

the NRC formally relinquishes its regulatory authority to a State based on the NRC's determination that the State's program is adequate and compatible with NRC's. (As provided under the AEA, the NRC retains regulatory authority over Federal licensees in all States.) Presently there are 29 Agreement States.

The degree to which States exercise control over all medical uses of radiation varies from State to State. The Agreement States normally apply the standards which they have developed for NRC materials to other sources of radiation within their State, although there is no requirement that they do so. Likewise, there is no requirement for non-Agreement States to regulate the sources of radiation for which they are responsible. This situation has led to inconsistencies in the regulation of other sources of radiation in those States.

NRC's (and its Agreement States') regulation of radiation in medicine is based principally on two parts of the Code of Federal Regulations(CFR); 10 CFR Part 20, Standards for Protection Against Radiation, and 10 CFR Part 35, Medical Use of Byproduct Material. These regulations limit the amount of radiation that a worker or member of the public may receive, establish the controls that a licensee must exercise over radioactive materials, establish training and experience requirements for users of the materials, set quality management and reporting requirements, and provide a number of technical and administrative requirements for the possession and use of the materials.

NRC's medical program constitutes about one-third of its Nuclear Materials Program. Currently there are about 2,000 NRC licensees authorized for the medical use of byproduct material under 10 CFR Part 35. In addition, the 29 Agreement States have issued about 4,500 licenses authorizing the medical use of nuclear material. These medical-use licensees include hospitals, clinics, and physicians in private practice.

NRC's regulatory program consists of developing regulations and guidance, issuing new licenses, and ensuring compliance. NRC promulgates new regulations and modifies existing ones through staff-initiatives or in response to petitions. NRC provides guidance to its staff and licensees by issuing regulatory guides for licensing and procedures for inspection. NRC's medical licensing activities include issuing about 85 new licenses a year, and approving about 1,400 amendments. NRC ensures compliance with its regulations by communicating safety issues to licensees, inspecting them to observe their performance, and exercising its enforcement authority over licensees who are in violation.

Over the years, and especially since the mid 1980s, the Commission has made a concerted effort to improve and strengthen the medical use program. In 1967 the Atomic Energy Commission codified its medical regulations into 10 CFR Part

35. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. In February 1979, NRC issued a policy statement to guide its regulatory program in the medical area. A key issue in the policy statement is NRC's commitment to protect patient safety without intrusion into the practice of medicine. NRC regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients. Since then, the tension inherent in NRC's commitment has arisen in a number of key medical-use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. The doctor/patient relationship and NRC's regulation of medical use of nuclear material has been a continuing problem, up to the present.

A second set of problems arises from the jurisdictional responsibilities for the different sources of radiation. As discussed above, jurisdiction over various aspects of the use of ionizing radiation in medicine is exercised by a number of agencies in the Federal Government and by the States. Because of the diversity of, and occasionally overlapping, responsibilities, dual regulation or gaps in regulation may occur.

In 1992, the staff began to develop a medical management plan to guide the conduct of the medical use regulatory program. The plan was delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings on administrations in both the Senate and the House. The staff subsequently completed the medical management plan, and, in parallel, was directed by the Commission to initiate an external review of the NRC's and the Agreement States' medical use regulatory program.

As a result, in January 1994, NRC contracted with the IOM to conduct that external review, including a review of NRC's regulations, policies, practices, and procedures. NRC set three goals for the study; 1) examination of the overall risk associated with the use of ionizing radiation in medicine; 2) examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical use of byproduct material. The NRC sought specific recommendations on two major issues. First, it requested recommendations on a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate

commerce for application to human beings should be allocated among Federal Government agencies and between the Federal and State governments. Second, the NRC requested recommendations on appropriate criteria to measure the effectiveness of regulatory programs needed to protect public health and safety.

III IOM REPORT - ALTERNATIVES

This section presents IOM alternatives and recommendations. It begins with the IOM broad view of the regulation of radiation in medicine to provide insight into the basis for IOM decisions on the regulatory alternatives it considered and the recommendations it made.

1) IOM committee's View of the Current Situation

The IOM committee noted that NRC regulates only 10% of all ionizing radiation found in medicine, and that public health and safety would be better served by uniform regulation of all such use. It therefore concluded that NRC's current system of regulation and enforcement should be revised and that regulation of all radiation uses in medicine should be conducted by the States.

The committee examined the existing regulatory system and identified several problems that it concluded needed to be addressed. In particular, it judged the NRC's present set of regulations and its approach to regulation to be burdensome, costly, and unduly prescriptive. In addition, it found that actions taken by the NRC against user institutions, in its public announcements and its unrealistic paperwork demands, tended to be disproportionate to the violations.

The committee determined that the benefits resulting from the NRC's efforts to reduce adverse events may not be commensurate with the constraints imposed. It stated that the NRC's regulatory policy, although seemingly effective, might have gone beyond the point where "an additional dollar spent on regulation achieves an equivalent dollar benefit to patients or the public."

The committee judged that, given the strength and leadership of the Conference of Radiation Control Program Directors (CRCPD) and the *Suggested State Regulations for the Control of Radiation (SSRCR)* which the CRCPD promulgates, that State programs would remain intact and expand to cover byproduct use if Federal regulation were to be relaxed. The committee believed that all sources of ionizing radiation would be treated more uniformly, in that they would *all* be subject to State regulation.

The committee's recommendation would eliminate NRC's medical use program, but retain the basic structure of federal regulation and responsibility. In particular, the committee would have Federal agencies retain responsibility for the generation, transport, non-medical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and of equipment that generates ionizing radiation. A Federal agency would assume a guidance role for the States.

2) Alternative Regulatory Systems

The committee considered NRC's request for recommendations on a uniform national approach to regulation broadly. It examined a wide spectrum of alternative structures through which all ionizing radiation in medicine might be regulated. The committee report discusses seven alternatives, which are

A Continue the Existing Situation
B Laissez-Faire (No Regulation)
C State Regulation Only
D State Regulation with Federal Guidance
E State Regulation with Reserve Federal Authority
F Centralized Federal Regulation
G Health Finance Agency

After considering the alternatives, the committee found Alternative D, State Regulation with Federal Guidance, to be its preferred choice. Brief descriptions of the seven alternatives, and the basis for the committee's choice follow.

A Continue the Existing Situation

The committee considered two ways to continue the existing situation, which it describes as A1, Status Quo, and A2, Status Quo Modified. Alternative A1, Status Quo, would be for the NRC to continue to operate exactly as it does today. Alternative A2, Status Quo Modified, would have the NRC eliminate, or announce that it will not enforce, its requirements for quality management programs (10 CFR Part 35.32) and for notifications and records of misadministrations (10 CFR Part 35.33). The committee's considered this modification because NRC has received considerable criticism from the medical community for promulgating these requirements.

The committee found no positive aspects to the Status Quo. It found a positive aspect of the Modified Status Quo in that this Alternative would not require legislative change and thus would be the easiest way to change the existing system to address the medical community's concern. Further, in the committee's view, the NRC could make useful changes to its work culture. The committee found the negative aspects of the Status Quo to be that this

alternative did not address two of the committee's concerns; first, that ionizing radiation in medicine is not treated consistently - sources used regularly in the practice of medicine are treated unevenly. The committee raised the issue of whether NRC regulation is necessary, given that NARM and machine-produced regulation has been left to the States and the FDA. Second, this alternative does not address the committee's concern that safety can be maintained at lower cost.

B Laissez-Faire (No Regulation)

In this Alternative, all forms of regulation, Federal and State, would be eliminated and responsibilities for radiation safety would be left to medical practice, medical societies, and the marketplace.

The committee found that a positive aspect of Laissez-Faire would be the cost savings resulting from an absence of regulation. The committee found negative aspects of this Alternative to be that not everybody is conscientious about radiation protection, and the committee had little expectation that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. Further the committee noted that most States now regulate ionizing radiation to some degree and it seemed unlikely that they could all be convinced to follow this alternative. This approach would be unwieldy, as the existing federal regulatory structure for radiation control of non-medical applications would continue unchanged.

C State Regulation Only

This Alternative would eliminate NRC control of medical uses of byproduct material and would give regulatory authority to the States. Under this alternative, byproduct materials would be regulated the same way x-ray machines, linear accelerators, pharmaceuticals and other medical devices and materials are currently regulated. Under this alternative, Federal agencies would still have a number of responsibilities; FDA would continue to regulate safety and efficacy of radiopharmaceuticals and radiation devices, DOT would continue to regulate the transportation of byproduct material, and NRC would license the manufacture of byproduct material. The committee noted that this alternative would permit States to choose the laissez-faire approach. However, the committee expected that under this Alternative, the CRCPD would encourage States to adopt its Suggested State Regulations for Control of Radiation (SSRCR).

The committee found the positive aspect of this Alternative to be the assumption that all States with existing programs would continue and expand them based on the SSRCR and thus reinforce the movement toward greater uniformity. The committee found negative aspects to be that it had no

assurance that States want this responsibility, that not all States currently have strong regulatory programs in place for NARM and machine-produced radiation, and that some State legislatures might be responsive to strong antiregulatory interest groups. The committee also felt that the lack of Federal leadership under this Alternative would make it difficult to encourage States to adopt CRCPD guidelines and that States might abandon the radiation safety programs now in place without the incentive from a Federal agency to continue operating them.

D State Regulation with Federal Guidance

This Alternative modifies Alternative C by identifying a Federal Agency, other than the NRC, to exercise a leadership role in the radiation safety community, with DHHS as a suggested agency. This is the committee's preferred Alternative.

As the committee has developed this Alternative, the Federal agency would assist in developing recommended State laws and regulations for all ionizing radiation in medicine. It could work with CRCPD to enhance the existing SSRCR and promote their adoption. The committee felt that development of guidelines through a collaborative process with the Federal agency, the States, the CRCPD, and professional organizations would result in successful implementation by all participants. Additional functions of the Federal Agency could include assisting States, investigating crises, educating the public, collecting risk data, conducting research, and monitoring the effects of shifting responsibility for regulating radiation in medicine to the States.

Under this Alternative, States would have to establish a regulatory program that includes byproduct material. Since, under this Alternative, the NRC and Agreement States would continue to regulate the manufacture of byproduct material, manufacturers would not be able to distribute byproduct material to their users unless the users were licensed by their States. Consequently this requirement would provide an inducement to States to expand or revise their existing radiation control programs to include byproduct material. Federal facilities would be encouraged to either expand their existing procedures for NARM to include byproducts or adopt the SSRCR for byproduct material.

The committee found several positive aspects of this Alternative. It includes the advantages of Alternative C, State Regulation Only, with the additional advantage of a Federal agency to provide non-regulatory oversight and leadership. The committee would expect the Federal agency to assume a leadership role for the Federal government as a whole. In addition, this Alternative would ensure that a State would be required to have a regulatory program for byproduct material for that material to be used in the State. The

committee found negative aspects of this Alternative to be the costs of the Federal agency, and that the agency could not guarantee either the quality of any State program or the safety of ionizing radiation in,medicine.

E State Regulation with Reserve Federal Authority

This Alternative would go beyond Alternative D, State Regulation with Federal Guidance, and empower the Federal agency identified in that Alternative to exercise regulatory authority over any State unwilling or unable to enact a regulatory structure that encompasses ionizing radiation in medicine.

This Alternative would be identical to Alternative D, with the exception that if a State did not have a radiation control program it would become subject to the regulations for byproduct material devised for Federal medical centers. The Federal agency would enforce its authority only if the State did not assume any responsibility to adequately protect public health and safety. This authority would be analogous to the NRC's present authority to resume regulatory control over an Agreement State.

The committee found this alternative to have all of the positive aspects of Alternatives C and D, with the advantage that placing DHHS in the leadership role would, in the committee's view, yield more reasonable regulations if they are needed. The committee found negative aspects to be the need to set minimum standards for State programs and the need to assess those programs. This would have the effect that all States would become similar to NRC's present Agreement States. The committee was also concerned about funding, and Federal authority over what it expected to be a minority of States.

F Centralized Federal Regulation

This Alternative would make a Federal agency responsible for regulating medical uses, not only of byproduct material, but of NARM and machine-produced radiation as well. The Alternative would federalize regulation of all ionizing radiation in medicine, including standard-setting, licensing, and inspection. If this Alternative were to be adopted, the committee would recommend centralization within DHHS rather than NRC because the committee considered it best suited to administer public health programs and because it already has various levels of authority over ionizing radiation in medicine. If NRC were to be the lead federal agency, its legislative authority would need to be expanded beyond byproduct materials.

The committee found positive aspects of this alternative to include promotion of uniformity in regulation of radiation in medicine, provision for States who do not want responsibility for radiation control programs, and the development of national standards. The committee noted that the positive aspects of the Federal role described in Alternative D, State Regulation with Federal

Guidance, also apply to this Alternative. The committee found negative aspects to include the increased Federal costs of such a role, and the difficulty in achieving uniformity due to the regulatory involvement of a number of Federal agencies (DOT, EPA, OSHA) in addition to the committee's proposed DHHS. Finally, the committee noted that since NRC would continue to be responsible for the non-medical uses of byproduct material, it would be necessary for NRC and DHHS to work very closely together to avoid inconsistencies.

G Health Finance Agency

This Alternative would place regulatory authority for all health care into a single, centralized agency to counter inconsistency and inefficiency. The new agency would acquire the regulatory power now held by the medical components of the NRC and by parts of DHHS. The agency would have the power to regulate health care, broadly eliminating practices that were shown not to be effective or beneficial. The committee considered this Alternative an extreme approach for addressing a very specific issue and recognized that it had not been developed to its full logical extent. The committee considered an advantage to this approach is that it could improve minimal standards and define the goals of safety and high quality care. However, such a centralized system would mean a large increase in bureaucracy and reduce provider incentives and responsibility.

3) Assessment of Alternatives

The committee documented its consideration of the above alternatives by examining the extremes and moving toward its preferred alternative. It rejected Alternative A, Continue the Existing Situation, because it did not address the committee's concern that all ionizing radiation in medicine be administered and regulated more consistently. It rejected Alternative B, Laissez-Faire, because many committee members were not convinced that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. The committee rejected Alternative G, Health Finance Agency, because it was an all-encompassing and overwhelming solution to a very specific problem. The committee rejected Alternative F, Centralized Federal Regulation, because from a cost-benefit perspective the committee as a whole saw little reason to pursue this alternative. Thus the committee focussed on Alternatives C, State Regulation Only, D, State Regulation with Federal Guidance, and E, State Regulation with Reserve Federal Authority.

While the committee found Alternative C, State Regulation Only, attractive, it was concerned that State regulation evolve with technical advances, that Non-Agreement States be assisted in any transition from NRC regulation, and that information sharing be enhanced, so it rejected this alternative. The

committee found that Alternative E, State Regulation with Reserve Federal Authority, could result in a program very much like NRC's present Agreement State program which would not resolve the committee's concerns about that program's funding characteristics and practical drawbacks. The committee therefore arrived at its preferred choice, Alternative D, State Regulation with Federal Guidance.

As discussed above, Alternative D would give regulatory authority over medical uses of byproduct material to the States. The States would expand their existing radiation control programs that apply to NARM to include byproduct material as well. The committee recommends that a Federal agency, DHHS, exercise a leadership role in the radiation safety community. The leadership role would be non-regulatory and would assist in developing recommended state laws and regulations, acting as an information clearinghouse, and distributing resources for training and research. The Federal agency would work in conjunction with the CRCPD and other professional organizations to develop recommended state laws and regulations for all ionizing radiation in medicine. The NRC would retain responsibility for the manufacture and distribution of byproduct material (including sealed sources and devices) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State.

IV IOM REPORT - RECOMMENDATIONS

To implement its preferred alternative, the committee made a total of eight specific recommendations; two to Congress, three to the NRC, and three to the CRCPD and States. First, the committee recommended that Congress: 1) eliminate all aspects of the NRC's medical use program to include 10 CFR Part 35 and applicable activities conducted under 10 CFR Part 20; and 2) direct the Secretary of Health and Human Services to support, coordinate, and encourage activities involving regulation of all ionizing radiation in medicine including support the operation of the CRCPD, assist States in implementation of regulations, oversight of State programs, enhance training and standards for health care personnel, and investigate future significant radiation medicine incidents.

The recommendations to the NRC were to: 1) immediately relax enforcement of 10 CFR 35.32 and 35.33; 2) if Congress fails to act within 2 years to the committee's recommendations above, initiate formal steps under the Administrative Procedures Act to revoke 10 CFR Part 35 in its entirety; and 3) separate the costs of formulating regulations from costs of administering those regulations.

The recommendations to the CRCPD and the States were to: 1) incorporate into the SSRCR any relevant concepts from 10 CFR Part 35; 2) enact legislation to incorporate the regulation of reactor-generated byproducts into existing state

regulatory programs; and 3) continually reevaluate regulations and procedures to ensure congruence with evolving scientific understanding of radiation bioeffects and associated risks and benefits.

The committee did not reach total unanimity on the final recommendations. A committee member stated that federal regulatory authority should be reformed, not repealed. This dissenting opinion is included as a separate Appendix to the report.

The following sections discuss the recommendations individually. Each section contains a brief description of the recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal concerns, and some pertinent public comments.[4]

A RECOMMENDATIONS TO CONGRESS

A1. *The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.*

DESCRIPTION

By this action, Congress would relinquish responsibility for regulation of byproduct material used in medicine to each state. NRC would retain regulatory authority over manufacturers of byproduct material used in medicine. Other federal agencies, such as the FDA, the DOT, and the EPA, would retain their regulatory authority over radiation.

IOM RATIONALE

The intensity with which the byproduct area of radiation medicine is being regulated at the federal level far exceeds the rest of ionizing radiation used in medicine and most of the rest of medical practice and has little if any justification. In fact, the concentration of resources spent to reduce adverse events involving byproduct material, although seemingly effective, appears to have gone beyond the point at which the additional dollar spent on regulation achieves an equivalent dollar benefit.

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[4] A list of commentors organized by commentor affiliation, a list of commentors by general view, and a summary of specific comments appear in Appendices 1, 2 and 3, respectively.

All ionizing radiation, with the exception of byproduct material, is currently regulated or subject to regulation at the State level. States have the ability to regulate radiation effectively. Although the committee cannot guarantee that states will effectively regulate byproduct material, it believes they will. Further, States with insufficient resources could join a consortium of states for the purposes of implementation and oversight.

Rescission of authority at the federal level for regulation of the medical use of byproduct material has three benefits: 1) it eliminates prescriptive and costly regulations that yield marginal risk reduction; 2) it shifts responsibility, by giving state governments authority over the health and safety of their citizens; and 3) it promotes uniform treatment, in that radionuclides and machine-produced radiation are regulated by a single level of government at equal intensity, regardless of their source.

NRC STAFF ISSUES

1. The committee recognizes that not all states currently have strong regulatory programs in place for NARM and machine-produced radiation. In fact, not all States currently regulate ionizing radiation used in medicine. What assurance does the committee, or Congress or the NRC, have that all States will assume the responsibility for medical use of byproduct material?

2. This recommendation assumes that federal facilities will expand the scope of their existing regulations to cover all ionizing radiation in medicine - what existing regulations currently apply to federal facilities (other than those of the NRC)?

3. How would the goal of "uniform treatment" and regulation by a single level of government at "equal intensity" be achieved through legislation and rulemaking giving responsibility to the States.

PUBLIC COMMENTS

NRC has received 47 comments on the committee's report. About one third of the commentors support this recommendation and the rest of the committee's recommendations as well. These commentors included the Department of Veteran's Affairs, several State agencies, four professional societies associated with the use of radiation in medicine and six individuals. Several of these commentors not only supported this recommendation, but believed that NRC should discontinue all of its regulation of byproduct materials, and give that responsibility to the States.

A second third of the commentors supported the concept of regulatory reform, but with retention of Federal authority. These commentors included three Federal agencies, three professional societies involved in radiation in medicine, 10 States and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). Nine of these commentors favored continued regulation by the NRC, eight were not specific on which Federal agency should have authority, and two, the State of California and the ACMUI would vest authority with DHHS.

Four commentors, including the State of New Jersey favored regulatory reform, but only after additional analysis.

Nine commentors supported the concept of uniform regulation for all radioactive materials, including NARM, with Federal oversight.

Several specific comments are of interest. The EPA felt that the report reflected the concerns of the regulated community more than those of the public at large. The Department of Defense indicated that the Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished. The States of Utah and Virginia were concerned that State legislatures might view this as an unfunded mandate and would need additional Federal support. The CRCPD does not support the recommendation. "CRCPD is concerned that elimination of the entire program, as recommended, could have immediate and undesirable consequences on citizens in non-Agreement States which cannot or will not have developed a state program consistent with the national model prior to Congressional action. In addition, the absence of federal authority in the medical use area may also have long term consequences for Agreement States as they try to maintain a nationally consistent program in the face of budget cutbacks and a changing regulatory philosophy."[5] Several non-Agreement States indicated that they had neither the resources nor the capability to develop a program to adequately protect public health and safety.

A2. Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:

a. supporting the operation of the CRCPD;
b. providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation;

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[5] CRCPD position on the NAS report, reached at their meeting in Albuquerque, New Mexico, on May 8, 1996

c. assisting states in implementation of their regulations;
d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;
e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;
f. monitoring the effects of deregulation;
g. enhancing training and standards for health care personnel; and
h. investigating future significant radiation medicine incidents.

DESCRIPTION

In addition to the above, DHHS would educate the public for the primary purpose of "... putting radiation risk in a more accurate and balanced perspective." Adverse events for investigational drugs and blood products must be reported to FDA as are adverse events involving radiation devices resulting in serious injury or death.

As noted in the previous recommendation, NRC and Agreement States would continue to regulate the manufacture of byproduct material for use in radiation devices and radiopharmaceuticals; thus manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states.

IOM RATIONALE

A Federal agency, such as DHHS, would assist states to establish regulatory programs; train state radiation control personnel; build liaisons between smaller states that wish to share regulatory systems; develop survey methodology; and monitor the success of regulatory programs.

DHHS has an extensive history in regulating radiation in medicine. Within DHHS, FDA exercises direct authority to determine the safety and effectiveness, and to approve the marketing, labelling, and manufacture of all radiation products used in medicine. FDA has promulgated regulations establishing quality control standards and a certification program for medical facilities that provide mammography services. FDA has issued guidelines and recommendations regarding public exposure to ionizing and non-ionizing radiation.

The NRC should not regulate the education and training of health care personnel - it should be done by professional organizations and by the states.

NRC STAFF ISSUES

1. Would DHHS have any regulatory responsibility for Federal facilities other than the Public Health Service? If not, who would have authority over Federal facilities?

2. Current reporting requirements for FDA are not identical to those of NRC - they only require reporting adverse events resulting in serious bodily injury (to manufacturer) or death (to FDA). There are no reporting requirements for radiopharmaceuticals other than investigational drugs except on a voluntary basis. To what extent should administration errors be reported?

3. In view of the overall reduction in federal spending, whether DHHS would be provided any appropriations to carry out these additional responsibilities cannot be predicted. With the reduction in federal spending and with the knowledge that the NRC is supported by user fees rather than taxpayer dollars, would Congress appropriate sufficient funds for even the minimal expenses of this agency?

4. How would the effects of deregulation be monitored? The report states that the committee did not possess the requisite expertise to address the issue of appropriate criteria for measuring the effectiveness of regulatory programs.

PUBLIC COMMENTS

As mentioned above, about a third of the commentors support this recommendation along with all the committee's recommendations. A number of commentors support the role of a Federal agency described in this recommendation, but do not necessarily endorse DHHS. Many of these latter commentors believe that the Federal agency should have at least some authority and that it should be responsible for at least NARM as well as byproduct material. The CRCPD view is illustrative. CRCPD supports the concept of a single federal agency with a strong leadership role, and believes that consolidation of authority presently found in several agencies including NRC, DHHS, OSHA, and EPA is very desirable. However, CRCPD, in addition to several states, do not support the automatic selection of DHHS as the lead agency, but consider that radiation protection should be a major responsibility of the lead agency. The OAS[6] recommended a revision to recommendation A2 to include that a single federal agency should be directed (by Congress) to support, coordinate, and oversee specified activities involving regulation of all ionizing radiation in medicine. The OAS did not reach consensus on which agency should have the responsibility.

The agency most affected by this recommendation is DHHS, who does not support it. DHHS does not find the committee's arguments compelling and does not consider the legislation recommended by the committee likely. Further, in the

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[6] The OAS comment provided the recommendations of and consensus reached at a NRC and Agreement State technical workshop conducted on March 6, 1996.

event of such legislation, DHHS considers the probability low that it would receive funding from Congress commensurate with its additional responsibilities.

B RECOMMENDATIONS TO THE NRC

B1. *The NRC should immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.*

DESCRIPTION

NRC's 10 CFR Part 35.32, Quality Management Program, requires, among other things, that medical licensees have written procedures to ensure that direction for a therapeutic administration is made in writing, that the patient's identity is verified by more than one method, that unintended deviation from the written directive is evaluated, and that the licensees review this program at least once every 12 months.

NRC's 10 CFR Part 35.33, Notifications, Reports, and Records of Misadministrations, requires, in part, that medical licensees notify the NRC within one calendar day of the discovery of a misadministration, and that they submit a written report within 15 days, and that they retain a record of each misadministration for five years.

The information required by 10 CFR 35.33 would not be entirely abandoned. NRC could continue to cooperate with the FDA as provided in their MOU to obtain data on devices, drugs, and biological products that relate to device malfunction, serious injury, or death.

IOM RATIONALE

NRC's Quality Management (QM) rule lacks the basic elements of a QM program: comprehensive process and outcomes data, feedback mechanisms for health care providers, education of clinicians to achieve continuous improvement, and follow-up measurement to monitor change/improvement.

The regulation of byproduct material greatly exceeds the regulation of chemotherapy, surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

A lower rate of adverse incidents in radiation medicine is not a result of stricter regulatory oversight. The more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public.

The level at which the NRC currently enforces 10 CFR 35.32 and 35.33, through detailed and voluminous documentation, reporting, and penalties, is inconsistent with the NRC's Medical Policy Statement, which favors minimum regulatory intrusion into the practice of medicine.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has a performance standard which requires intensive assessment when performance varies from recognized standards, but does not specifically require reporting of medication errors except in accordance with written procedures of the hospital.

Elimination of the QM rule would not lessen the radiation protection of the public, occupational worker, or the patient.

The regulated community has expressed reservations about seeking advice from the NRC, fearing that they might become the target of punitive reprisals.

When the NRC levies a fine, the agency also issues a press release describing the violation and the fine. Licensees assert that adverse economic impact of such press releases is considerable.

NRC STAFF ISSUES

1. The lack of data for comparing byproduct material, NARM and machine-produce radiation limited the scientific basis of the committee's findings. How can we achieve improved data collection on actual incidence and rates of adverse incidents and misadministrations? Is there a need for improved databases?

2. What is the rationale or basis for the necessity for immediate action?

3. Assuming that NRC were to immediately relax enforcement, NRC would be in the position of having a regulation for which there would have been no monitoring or enforcement. If NRC were to follow this recommendation, what followup actions should NRC conduct in the event of a misadministration resulting in serious injury or death?

4. If NRC lacked statutory or regulatory authority governing the medical and biomedical research use of byproduct material, why should NRC continue to gather data on user errors, drugs, and biological products to share with FDA under the MOU (unless reimbursed by another Federal agency)?

PUBLIC COMMENTS

A number of commentors supported the concept that many of NRC's requirements are overly prescriptive and burdensome. CRCPD supports relaxation of these requirements because it finds them overly prescriptive and unnecessarily burdensome. The Organization of Agreement States believes that NRC should immediately relax enforcement of these requirements, and further considers that the Quality Management Rule should not be an item of Agreement State compatibility.

B2. *The committee recommends that the NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.*

DESCRIPTION

NRC's 10 CFR Part 35, Medical Use of Byproduct Material, contains technical and administrative requirements that apply specifically to medical applications. It sets quality management and reporting requirements, and establishes training and experience criteria for users of byproduct material. It sets requirements including dose calibration, leak testing, source inventory, patient release, instructions to nurses, and survey requirements as well as use of syringe shields and storage of waste for decay.

IOM RATIONALE

In addition to NRC's overly stringent enforcement, the regulations themselves are excessive and duplicative. 10 CFR Part 35 covers areas that either are already regulated at the institutional level or are best left to the states, to professional societies, and to patients in consultation with their doctors.

States regulate the medical uses of other forms of ionizing radiation and, could easily fold byproduct material into their regulatory programs.

The CRCPD could add byproduct material to its suggested state regulations. These additions could incorporate relevant concepts currently in Part 35.

Doctors have ethical obligations, codified in professional standards, for informing patients of medical errors. The relatively low misadministration rate could be maintained by less stringent programs that are administered at the state level by professional societies, and by existing liability law.

The FDA collects data on adverse effects of radiopharmaceuticals and incidents of failure of radiation-emitting medical devices, and it could assume the monitoring responsibilities of the NRC.

Public safety in the medical use of ionizing radiation would yet exist in the fact that the NRC would still retain responsibility for the licensing of manufacturers and, consequently could ensure that byproduct material was withheld from any state that failed to license users and regulate the use and safety of byproduct material.

The committee strongly endorses the formal route of notice and comment rulemaking, subject to the Administrative Procedure Act, to accomplish the rescission of all of Part 35.

NRC STAFF ISSUES

1. This recommendation presupposes Congress will not act, and therefore will not vest DHHS with a leadership role. This could result in the laissez faire or state control regulatory structures, both of which were rejected by the committee. How would this recommendation achieve the goal of the preferred alternative?

2. With the lack of data cited in the report, on what scientific basis might NRC make a finding that there is no unreasonable risk to public health and safety, and thereby exempt medical use of byproduct material from the requirements of a license, as set forth in Section 81 of the Atomic Energy Act?

PUBLIC COMMENTS

Many commentors, to include professional organizations, State agencies, and individuals, were in favor of the need to revise Part 35. While CRCPD considers that a major revision to 10 CFR Part 35 is needed, it does not support this recommendation. OAS believes that 10 CFR Part 35 should be revised significantly, but that it should not be revoked in the absence of legislation. OAS believes that a minimum level of radiation protection must be available.

B3. *The committee recommends that the NRC separate the costs of formulating regulations from the cost of administering those regulations.*

DESCRIPTION

The Omnibus Budget Reconciliation Act of 1990 requires NRC to recover 100% of its budget by charging fees to NRC applicants and licensees. As a result, NRC licensees bear all of the agency's costs both of developing its regulations and of administering them. Separating these costs would enable NRC to recover development costs from its licensees differently than it recovers its administrative costs.

IOM RATIONALE

Only NRC-licensed institutions should bear the NRC's costs of licensing and inspection, whereas the costs of developing standards should be borne by all institutions, whether or not they are located in NRC-regulated states.

Licensing fees charged to health care facilities to meet the cost of the existing NRC program are becoming more expensive as more states become Agreement States.

Several individuals interviewed during site visits voiced concern that excessive costs force laboratories to stop using radionuclides, which in turn delays or prohibits the development and implementation of new uses of radionuclides in medicine.

NRC STAFF ISSUE

If NRC were to separate the costs of formulating regulations from the cost of administering these regulations, how would the Agreement State licensees bear the cost of developing standards?

PUBLIC COMMENTS

CRCPD supports this recommendation and recommends that Congress provide general funds to support development of essential regulatory standards. OAS identified the issue of how Agreement States would bear the costs of developing standards if NRC were to accept this recommendation.

C RECOMMENDATIONS TO THE CRCPD AND THE STATES

C1. *The committee recommends that the Conference of Radiation Control Program Directors incorporate into its Suggested State Regulations for Control of Radiation any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.*

IOM RATIONALE

All states will be able to provide regulatory oversight for AEA material in a manner similar to that provided for non-AEA material through the adoptions of CRCPD's Suggested State Regulations for the Control of Radiation. "[T]he committee expects that byproduct materials can be accommodated in the state systems."

Although State laws, regulations, and administrative practices vary, States can and do achieve a level of uniformity in many areas through cooperative, voluntary, and informal arrangements.

Although States cannot be compelled to accept the voluntary guidelines or the SSRCR, a variety of forces can greatly influence them to do so such as a collaborative effort, professional peer pressure, consumer groups and the media, and State medical societies.

CRCPD will continue to provide SSRCRs of the current level of quality without the assistance of the NRC, but with another federal agency providing "voluntary guidelines and model regulations for states"

NRC would continue to fund the CRCPD's efforts with respect to all nonmedical uses of byproduct material.

NRC STAFF ISSUES

1 Will the states voluntarily adopt the CRCPD's SSRCR in the absence of any real compelling mandate placed on either CRCPD or the states? For example, in the case of the recently passed mammography law, Congress provided a compelling reason for hospitals and clinics to meet the quality standards: i.e., in order to be reimbursed for mammography services, the hospital or clinic must be certified as meeting the standards.

2 The level to which the states currently adopt the SSRCR varies from state to state. Would there be greater uniformity under the proposed recommendation?

PUBLIC COMMENTS

CRCPD considers that it already has accomplished this.

C2. *The committee recommends that all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.*

IOM RATIONALE

States have effectively regulated naturally-occurring and NARM in the past and continue to do so. Therefore all States can regulate the medical use of byproduct material effectively.

Congress will modify the AEA to revoke the NRC's authority to regulate the medical use of byproduct material, give another Federal agency the responsibility for providing guidance, and allow all States, at their option, to exercise regulatory authority over the medical use of byproduct materials.

All States will devote the additional necessary resources to provide adequate protection of the public health and safety related to the medical use of byproduct materials with "little", if any, additional federal funding.

The possibility of precluding users from obtaining byproduct material from manufacturers in those "states that did not include byproduct material into their existing regulatory programs" would be acceptable to Congress and the public.

NRC STAFF ISSUE

Will all States in fact have the will, the resources, and the competence to regulate the medical use of all sources and uses of ionizing radiation safely?

PUBLIC COMMENTS

OAS endorses this recommendation, but as applied to all ionizing radiation. CRCPD endorses the recommendation, although it recognizes that not all States will choose to establish comprehensive programs that include byproduct materials. However, the CRCPD continues to support consistent application of radiation protection standards nationwide and believes that this can be best accomplished by having all radiation programs in a single state agency which can deal comprehensively with all forms of ionizing radiation within the state.

C3. *The committee recommends that the Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.*

IOM RATIONALE

Continual reevaluation and maintaining congruence is a necessary step for providing adequate protection of the public health and safety.

The CRCPD and all states will devote the necessary resources to maintain congruence with evolving scientific understanding of radiation bioeffects and be in accord with advances in knowledge regarding the benefits and risks of the medical use of ionizing radiation.

NRC STAFF ISSUE

Many states have adopted regulations for non-AEA materials that are similar to those that NRC implements for AEA materials and requires Agreement States to adopt as items of compatibility (e.g., NRC's QM rule for cobalt teletherapy versus State regulations for accelerator teletherapy). Will the CRCPD be able to effectively "ensure congruence" of the States' regulations and procedures to "be in accord with advances in knowledge regarding benefits and risks ..." by using voluntary mechanisms in the absence of the regulatory presence and resource support of NRC?

PUBLIC COMMENTS

Both OAS and CRCPD endorse this recommendation.

V NRC ACTIONS AND COMMENT SUMMARY

A NRC Actions to Date

The IOM provided NRC with a prepublication copy of the committee's report in December 1995. The NRC provided copies of the report to all Agreement States and non-Agreement States and Territories, appropriate Federal agencies, CRCPD, OAS, Congressional Oversight Committees and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, the NRC published a Federal Register notice (61 FR 1648) on January 22, 1996, and issued a press release acknowledging receipt of the report and requesting comments on the possible impacts of the report, to include any views on policy, legislative, rulemaking, and guidance issues. The Commission directed the staff to consider the report and comments received within its Strategic Assessment and Rebaselining efforts. While the report is being considered, the NRC is continuing to implement the ongoing medical use program.

Several public meetings have been held to discuss the report. The ACMUI met on February 21-22, 1996 and subsequently briefed the Commission on May 3, 1996 to discuss their recommendations. Briefly, the ACMUI did not recommend any of specified alternatives. They reached consensus that the medical use regulatory program should be rebuilt, reassessing the objectives of the regulations and encompassing all uses of ionizing radiation in medicine, and that States should be federally mandated to administer the program, with appropriate incentives to encourage States to comply. State programs should be monitored by a Federal agency with an overall medical use perspective (e.g., DHHS).

The OAS and the members of the IOM committee briefed the Commission on February 26 and 27, 1996, respectively. In addition, the report was discussed at a joint NRC and Agreement State technical workshop on March 5-6, 1996. The workshop included representatives of 18 Agreement States and two non-Agreement States. More recently, the report was discussed with the Conference of Radiation Control Program Directors on May 6, 1996.

B COMMENTS ON IOM REPORT

As of the end of August 1996, the staff had received 47 written comments on the report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the

merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized above under the specific recommendations to which they apply.

The NRC will continue to evaluate comments as part of the strategic assessment and rebaselining efforts. A summary of the comments is provided in Attachments 1-3.

Categories of Responses Received on IOM Report

Federal Agencies:

Department of Defense (DOD) - consolidates views for three services
Department of Health and Human Services (DHHS)
Department of Labor, Occupational Safety and Health Administration (OSHA)
Department of Veterans Affairs (DVA)
Environmental Protection Agency (EPA)

Agreement States:

Arkansas
California
Florida (Office Radiation Control) - R
Florida (State Health Office) - H
Illinois
Kentucky
Maryland
New Mexico
New York (Dept. Environmental Conservation) - E
New York (Dept. Health) - H
New York (Dept. Labor) - L
Tennessee
Texas
Utah
Vermont
Washington

Non-Agreement States/Territories:

Alaska
American Samoa
Delaware
Hawaii
Massachusetts
New Jersey
Virginia
Wyoming

Organizations/Committees:

American Association of Physicists in Medicine (AAPM)
American College of Cardiology (ACC)
American College of Medical Physics (ACMP)
American College of Nuclear Physicians/Society of Nuclear Medicine (ACNP/SNM)
American College of Nuclear Physicians - California chapter (ACNP-CA)
American College of Radiology (ACR)
American Pharmaceutical Association (APhA)
American Society of Nuclear Cardiology (ASNC)
Conference of Radiation Control Program Directors (CRCPD)
NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI)
Organization of Agreement States (OAS)[7]

Other Respondents:

CBeasley, St. John's Regional Health Center, Springfield, MO
MHafermann, Virginia Mason Cancer Center, Seattle, WA
DJones, Northwest Medical Physics Center, Lynnwood, WA
CMarcus, University of California, Los Angeles, CA
CPerez, Washington University, St. Louis, MO
GPoteat, OH
JRieke, Virginia Mason Cancer Center, Seattle, WA
DSchumacher, Northwest Medical Physics Center, Lynnwood, WA
MSelikson, RSO, University of Pennsylvania, Philadelphia, PA
St. John's Hospital, Jackson, WY

[7] The OAS comment provided the recommendations of and consensus views reached at the NRC and Agreement State Technical workshop. The session on the NAS report included representatives from 18 Agreement States (CA, NY, SC, NV, IL, WA, TX, MS, TN, GA, NE, CO, KY, KS, NYC, FL, AR, AZ) and two non-Agreement States (OH, PA).

General Comments on IOM Report

Respondents in favor of IOM recommendations:

Support IOM report/recommendations as written:

AAPM
ACNP/SNM
ASNC
DVA
NM
MHafermann (Virginia Mason Cancer Ctr)
DJones (Northwest Medical Physics Ctr)
CMarcus (UCLA)
CPerez (Washington Univ)
JRieke (Virginia Mason Cancer Ctr)
DSchumacher (Northwest Medical Physics Ctr)

Support IOM report/recommendations, but as applied to all materials:

FL (R)
NY (H)
NY (L)
ACNP-CA

Respondents not in agreement with IOM recommendations:

Support concept of regulatory reform[8] but retain Federal authority[9]:

DHHS oversight: ACMUI, CA

NRC oversight: EPA, ACMP, ACR, HI, KY, NY(E), UT, WA, GPoteat(OH)

Unspecified oversight: DHHS[10], DOD, ACC, AK, DE, TN, VA, WY

Support concept of regulatory reform, but after additional analysis:

CBeasley (St John's Regional Health Center)
MSelikson (RSO, Univ. of Pennsylvania)
NJ
St. John's Hospital

Support concept of uniformity for all radioactive materials regulation with Federal oversight:

CRCPD
OAS
APhA
AR (NRC as lead agency)
FL (H)
IL
MA
MD
TX

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[8] It should be pointed out that the degree of regulatory reform perceived to be necessary by different respondents varied from recognizing the concerns raised by the IOM to a drastic change in the approach to regulation of medical uses.

[9] Some States (e.g., VA, WY, DE) were primarily concerned with the substantial financial impact of the NAS recommendations and the issue of unfunded Federal mandates, rather than more specific concerns on the overall approach for regulation.

[10] DHHS did not address the issue of regulatory reform, Federal authority, or concerns raised by the IOM, but focussed on the implications of the recommendation to DHHS.

Respondents indicating report under review

DOL
AS
VT

Specific Comments on IOM Report

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DVA	The Veterans Health Administration generally concurs with and endorses the findings and recommendations of IOM. Principal concern is lack of specifics regarding regulation of Federal entitities and also the regulation of medical research programs.
	New Mexico	Agrees with IOM recommendation that Congress remove regulation of possession and use of material subject to AEA from NRC's purview. Supports leadership role of DHHS so long as all states maintain regulatory programs that measure comprehensive standards of performance and effectiveness.
	AAPM	AAPM fundamentally supports position, conclusions, and recommendations of the IOM report. NRC should be removed from its current regulatory role for medical use. Establish programs for implementing States' regulations monitored by appropriate federal health agency with assistance of user community and professional organizations.
	ACNP/SNM	The ACNP and SNM believe the report proposes a sound and thoughtful approach to the regulation of nuclear medicine and urges NRC to implement the IOM recommendations, allowing for comment on specific means to achieve implementation.
	ASNC	Concur with the IOM's conclusions and support their recommendations for a uniform policy to be set at Federal level which can be enforced by the States. DHHS should include medical radiation safety as part of its health care management plan.
	Hilafermann	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	BJones	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	CMarcus	Supports the IOM report and expresses disagreement with statements made by Robert Adler in his supplemental statement (Appendix L)
	CPerez	Expresses strong support for many of recommendations.
	JRieke	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	DSchumacher	Supports recommendations proposed by IOM committee.
Support IOM report/ recommendations, but as applied to all materials	Florida (Rad. Control)	Support idea of delegating regulation of medical byproduct material to states in addition to all agreement materials.
	New York (Dept. Health)	Support the IOM's conclusion that the regulation of medical use of byproduct materials should be carried out at the state level. Encourages the NRC to not limit its response to the IOM report to the narrow medical focus of the report.
	New York (Dept. Labor)	Supports the IOM's recommendation that NRC discontinue regulation of medical use of byproduct materials, but considers it illogical to limit the recommendation to this one area (should include nuclear pharmacies, manufacturers, distributors, and industrial users)
	ACNP-CA	NRC's entire materials program should be given to the States and Federal entities

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support concept of regulatory reform but retain Federal authority	ACMUI	ACMUI indicated a preference for a variant of the IOM preferred alternative in which there would be substantial Federal oversight of State programs with a mechanism to ensure compliance of States and users. State programs should be monitored by a Federal agency with overall medical use perspective (DHHS).
	DHHS	Report does not make a compelling public health argument for DHHS taking on a substantial new role. The probability is low that Congress would provide adequate resources. DHHS does not support the recommendation.
	DOD	Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished in favor of a voluntary or State-operated system.
	EPA	Report reflects the concerns of the regulated community more than the public at large. There may be aspects of NRC's program that can be improved, but NRC should continue to assure public is protected.
	ACC	Transfer of oversight of the medical use of isotopes to the States seems reasonable. However, strongly encourage Federal oversight of this state initiative. An obvious drawback would be if all States had separate regulations for licensure and compliance.
	ACMP	Supports the need for a drastic change in regulation of radiation in medical use including use of Advisory Panels (comprised of users, manufacturers, and public) to determine the regulatory framework to be applied uniformly in medical profession. Current regulations should be modified.
	ACR	In lieu of Congressional action to eliminate NRC's medical use program, the ACR believes that NRC's medical use program must be rebuilt and its objectives thoroughly reassessed.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH ION RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Alaska	This would not be a cost effective nor efficient reform for Alaska. It is in the best interest of the State to support the existing method of regulating nuclear medicine licensees by a Federal agency.
	California	In view of split regulatory authority at federal level and apparent reluctance of NRC to expand jurisdiction, agree that Congress remove NRC's authority. DHHS should be given authority to ensure that every state maintains a radiation program that meets minimum, comprehensive, consensus standards of performance and effectiveness.
	Delaware	The impact of the ION recommendations would be substantial in terms of our increased need for funding, staffing, training and infrastructure requirements.
	Hawaii	Does not have resources or capability to adequately implement regulation of byproduct materials. Without assistance (training and development) to States, the removal of NRC's authority may significantly jeopardize public health and safety.
	Kentucky	A better approach would be to have NRC revise its medical program to go along with the recommendations the Institute has given in preferred alternative D.
	New York (Dept. Environ. Conservation)	Many unforeseen consequences may occur if AEA is modified. Commission should proceed cautiously in pursuing ION recommendations that may alter the present AEA.
	Tennessee	While the findings of the Committee have some merit, there is no conclusive support provided to document them. Sweeping changes are not well thought out and may result in chaos.
	Utah	State legislatures may view this as another unfunded Federal mandate and may provide no additional support to the State program. Medical community should work with NRC, States, and other parties to resolve the regulation issue.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH ION RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Virginia	The Commonwealth is in no position to assume any additional unfunded Federal mandates. Could only assume regulatory responsibility if NRC provides funds to defray cost of implementing the program.
	Washington	NRC should focus on radiation safety of worker and non-patient public (oversight of production, distribution, and handling of byproduct materials) while protection of patient is best handled through State boards of medicine and pharmacy.
	Wyoming	The conclusions of the report neglect the considerable hardship to be incurred by smaller, less populous, and less affluent States. Only through continued Federal regulatory participation can the goals of uniformity and public access to safe medical procedures be achieved.
	GPoteat	Potential decrease in safety may result from a transfer to State regulators of NRC's authority. Minor changes are necessary but overall NRC's regulations balance the need to protect workers, patient and the public with the requirements of medical practice.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform, but after additional analysis	New Jersey	If NJ chose not to become an Agreement State, public may not be assured of adequate protection. If adopting the recommendations, NRC and Congress should not act precipitously, but allow the States to prepare for assuming regulatory programs in orderly fashion.
	University of Pennsylvania	Before moving in the direction of a State-based decentralized system, a better evaluation of potential both for increased risk to the public and increased cost to the medical industry is necessary.
	St. John's Hospital	Urges NRC to give every consideration to IOM report, particularly the review of risk assessment.
	CBeasley	The report missed part of its stated intended goal to review the current system of regulation (the issues of uniformity among states was not fully explored). Proposes review in more detail the regulation of non-nuclear medicine radiology and question of uniformity between states.
Support concept of uniformity for all radioactive materials regulation with Federal oversight	OAS	At NRC/Agreement State Technical Workshop, consensus was reached that all radiation use (regulated currently under NRC, FDA, EPA, and OSHA) should be consolidated under a single Federal agency.
	CRCPD	Absence of federal authority in medical use area may have immediate and undesirable consequences on citizens in non- Agreement States and long term consequences for Agreement States trying to maintain a nationally consistent program. CRCPD does not support automatic selection of DHHS as the agency to provide leadership role.
	APhA	All ionizing radiation should be grouped together under a uniform regulation. Transfer responsibility for medical uses of any ionizing radiation to the States. Some Federal authority should remain over the medical uses of ionizing radiation (NRC or a similar federal agency).

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of uniformity for all radioactive materials regulation with Federal oversight (continued)	Arkansas	The NRC should consider alternative A2 (status quo modified). If major changes are to be made, centralization of regulation within one Federal agency (NRC) would be the best approach for all uses of radiation. Congress would be required to expand the role of NRC and a change in the agency would be necessary. Expand current Agreement State program.
	Florida (Health Office)	Support idea that regulatory authority of all agreement materials be turned over to the states with consolidation of federal radiation oversight, guidance, and regulatory functions into one agency, not necessarily DHHS.
	Illinois	Prefer CRCPD proposed new organizational concept that recommends some consolidation of all radiation regulatory functions at federal level. Revise QM and pharmacy rules. Prepare white paper to use as a policy basis to clearly delineate the respective authority and responsibilities of various Federal and State agencies.
	Maryland	Rather than revoke NRC's authority and repeal the Federal regulations, such authority should be expanded to incorporate NARM, and the Federal regulations should be thoroughly reviewed and amended to clarify regulatory responsibility. DHHS does not have necessary expertise.
	Massachusetts	Do not support elimination of all aspects of NRC's medical program, but support relaxation of overly prescriptive and unnecessarily costly requirements. Support intent of single Federal agency providing a single leadership role but do not support automatic selection of DHHS.
	Texas	The basis for the report's recommendations do not seem to be substantiated. The merging of all federal radiation control oversight into a single regulatory program should be considered. The NRC should enhance the partnership with the States to jointly determine compatibility requirements.

Attachment E

DSI No. 12, "Risk-Informed, Performance-Based Regulation"

STRATEGIC ASSESSMENT ISSUE PAPER

DSI 12: RISK-INFORMED, PERFORMANCE-BASED REGULATION

INTRODUCTION

In August 1995, the Nuclear Regulatory Commission (NRC) staff initiated a Strategic Assessment and Rebaselining Project. This project was intended to take a new look at the NRC by conducting a reassessment of NRC activities in order to redefine the basic nature of the work of the agency and the means by which that work is accomplished, and to apply to these redefined activities a rigorous screening process to produce (or rebaseline) a new set of assumptions, goals, and strategies for the NRC. The results of this project are intended to provide an agency-wide Strategic Plan which can be developed and implemented to allow the NRC to meet the current and future challenges.

A key aspect of this project was the identification and classification of issues that affect the basic nature of NRC activities and the means by which this work is accomplished. These issues fall into three categories. The first category includes broad issues defined as Direction-Setting Issues (DSIs). DSIs are issues that affect NRC management philosophy and principles. The second category includes subsumed issues. Subsumed issues are those that should be considered along with the DSIs. The third category includes related issues. These are issues that should be considered after the Commission makes a decision on the option(s) for a DSI. Also, as part of the project, other issues of an operational nature were identified. These are not strategic issues and are appropriately resolved by the staff, and are not discussed in the issue papers.

Following the reassessment of NRC activities, issue papers were prepared to provide a discussion of DSIs and subsumed issues, and to obtain a review of these broad, high-level issues. These papers are intended to provide a brief discussion of the options as well as summaries of the consequences of the options related to the DSIs. Final decisions related to the DSIs will influence the related issues which are listed, but not discussed, in each issue paper. As part of the Strategic Assessment and Rebaselining Project, the issue papers are being provided to interested parties and to the public. Following distribution of the issue papers, a series of meetings are planned to provide a forum to discuss and receive comment on the issue papers. After receiving public comment on the issue papers, the Commission will make final decisions concerning the DSIs and options. These decisions will then be used to develop a Strategic Plan for the NRC. In summary, the Strategic Assessment and Rebaselining Project will analyze where the NRC is today, including internal and external factors, and outline a path to provide direction to move forward in a changing environment.

I. SUMMARY

A. Direction-Setting Issue

The Commission has established the policy that, to the extent practical, risk insights shall be incorporated into all nuclear regulatory activities. As a result of this policy, the staff has developed a framework for applying probabilistic risk assessment (PRA) methods and techniques in reactor regulation (SECY-95-280, "Framework for Applying Probabilistic Risk Analysis in Reactor Regulation") in order to ensure consistent and appropriate application of PRA methods. The staff has also identified a number of regulatory applications associated with reactor regulation that appear amenable to the expanded use of PRA - such as inservice testing of pumps and valves, inservice inspection, technical specifications, and graded quality assurance. In these areas, the staff is developing PRA standards and guidance to help clarify and facilitate the use of risk-informed, performance-based regulation for both the NRC and the industry.

Industry and NRC efforts to develop and apply similar approaches to nuclear materials programs are not as advanced as reactor programs. The complexity of power reactors and the potentially severe consequences of a reactor accident led to the development of analysis methods to provide better estimates of risk. The consequences of an accident in the nuclear materials area would be less severe and the event sequences would be less complex than the consequences of an accident in the reactor area. The need for a better understanding of risk for commercial power reactors resulted in detailed development of reactor risk analysis methodology before such methodology was developed for the relatively simpler, but more diverse, nuclear materials area. Also, power reactor risk analysis techniques are more developed than nuclear materials risk analysis techniques because the commercial nuclear power industry is actively seeking regulatory relief in numerous areas using risk-informed, performance-based insights to help justify the request for relief.

Considering the general direction provided by the Commission and Congressional directives to various Government agencies to proceed to use risk-based and cost-benefit criteria, and recognizing the resources needed to implement risk-informed, performance-based approaches to regulation the following direction setting-issue (DSI) was identified:

> What criteria should NRC use in expanding the scope in applying a risk-informed, performance-based approach to rulemaking, licensing, inspection, and enforcement?

The Commission's decision on this issue will be used to establish the overall framework for "how fast" and "how far" the agency will go in expanding activities in the application of risk-informed, performance-based regulatory approaches. This paper provides four options for moving toward more risk-informed, performance-based regulatory approaches.

Sample criteria for expanding the scope within the context of the strategic direction are discussed in Appendix A.

B. Options.

Option 1: Continue Current Process

The current process for pursuing risk-informed, performance-based regulation could be characterized as an incremental process. Priority and scope in applying risk-informed, performance-based regulatory approaches are determined by balancing external and internal goals and available resources. Priority criteria (Appendix A) are applied and the scope of activities is primarily determined by considering the industry demand, the safety benefit, the ease of implementation, and available resources. This approach covers both reactor and nuclear materials areas but there is more activity associated with risk-informed regulatory approaches for reactor applications as outlined in the PRA Implementation Plan (SECY-95-079).

Option 2: More Rigorously Assess Relationship to Public Health and Safety

Before pursuing risk-informed, performance-based approaches, this option would require that for new initiatives, the NRC determine that there is the potential for a substantial increase in overall protection to public health and safety that would justify the level of resources necessary to pursue additional risk-informed, performance-based regulatory initiatives. Priority and scope in applying risk-informed, performance-based regulatory approaches are primarily determined by the projected cost of the initiative compared to benefit to the public health and safety. Many intangibles would have to be qualified before proceeding. Priority criteria are weighted toward greatest safety benefit. The scope of risk-informed, performance-based approaches would be primarily determined by considering the cost/benefit, the overall impact on the NRC and regulated industry, and available resources. This option would provide additional focus for moving toward risk-informed, performance-based regulation and potentially move more slowly toward risk-informed, performance-based regulation than the current process.

Option 3: Perform a Comprehensive Assessment of NRC Regulatory Approaches

This is a proactive, aggressive option for moving toward risk-informed, performance-based regulation. This option would maximize internal self-assessment and include exploring all regulatory areas to determine whether risk-informed, performance-based regulation should be pursued in that area. This approach would require a comprehensive review of our regulations and regulatory processes to determine areas that could be improved through risk-informed, performance-based regulatory approaches. Priority for regulatory activities are established based on consideration of the cumulative impacts on safety, burden reduction, and efficiency. The scope of risk-informed regulatory approaches under this option would be determined by considering agency responsiveness to stakeholder initiatives, the safety benefit/significance of the approach, and the effect on NRC and licensee efficiency. Ease of implementation and available resources are secondary scoping considerations (i.e., if the activity is determined to be a high priority then resources will be made available and efforts made to improve the state-of- the-art to the level necessary to support the desired goal).

Option 4: Consider Risk-Informed, Performance-Based Approaches Primarily in Response to Stakeholder Initiatives

This option is the most responsive to industry and stakeholder initiatives. Priority and scope in applying risk-informed, performance-based regulatory approaches would be primarily determined by stakeholder demand and ease of implementation. Priority would be weighted toward industry initiatives to use risk-informed, performance-based approaches to reduce regulatory burdens. The scope of risk-informed regulatory approaches under this option would be primarily determined by nature of the initiative. Ease of implementation and cost/benefit play a major role in defining the scope of the regulatory approach.

II. DESCRIPTION OF ISSUES

A. Background

Since the early 1970s, the NRC has expended significant resources in the development and application of PRA technology. This included the ground-breaking work of the Reactor Safety Study (documented in WASH-1400) in 1975. On January 18, 1979, the NRC issued a policy statement entitled "NRC Statement of Risk Assessment and the Reactor Safety Study Report (WASH-1400) in Light of the Risk Assessment Review Group Report" [Risk Assessment Review Group Report, NUREG/CR-0400]. In addition to addressing specific criticisms of WASH-1400, the 1979 policy statement articulated limitations in the use of PRA in the regulatory arena. Many of these limitations have been addressed, however, some still remain pertinent today. Primary among these limitations is the

characterization of uncertainties associated with calculated probabilities of reactor accidents. PRA methodologies have, however, provided a better means for identifying and characterizing the range of uncertainty.

The Three Mile Island accident in 1979 substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. In addition, both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional nonprobabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

In early 1991, the NRC published NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In NUREG-1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants. This study was a significant turning point in the use of risk concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance given core damage initiation and subsequent accident progression. The methods developed for, and results from, these studies provided a valuable foundation in quantitative risk techniques.

PRA methods have been applied successfully in several regulatory activities and have proved to be a valuable complement to traditional deterministic engineering approaches. This application of PRA represents an extension and enhancement of traditional regulation rather than a separate and different technology. Several recent Commission policies or regulations have been based, in part, on PRA methods and insights. These include the Backfit Rule (10 CFR 50.109, "Backfitting"), the Policy Statement on "Safety Goals for the Operation of Nuclear Power Plants," (51 FR 30028; August 21, 1986), the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138; August 8, 1985), and the Commission's "Final Policy Statement on Technical Specifications Improvement for Nuclear Power Reactors" (58 FR 39132; July 22, 1993). PRA methods also were used effectively during the anticipated transient without scram (ATWS) and station blackout (SBO) rulemakings, and have been used extensively in the generic issue prioritization and resolution process. Additional benefits have been found in the use of "Risk-Based Inspection Guides" to focus NRC reactor inspector efforts and make more efficient use of NRC inspection resources. Probabilistic analyses were extensively used in the development of the recently proposed rule change to reactor siting criteria in 10 CFR Part 100 (59 FR 52255; October 17, 1994), especially in the area of estimating the Safe Shutdown Earthquake ground motion for a nuclear reactor site.

Currently, the NRC is using PRA techniques to assess the safety importance of operating reactor events and as an integral part of the design certification review process for advanced reactor designs. In addition, the Individual Plant Examination (IPE) program and the Individual Plant Examination - External Events (IPEEE) program (an effort resulting from the implementation of the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants") have resulted in commercial reactor licensees using risk- assessment methods to identify any vulnerabilities needing attention.

The Commission has been developing performance assessment methods for low-level and high-level waste since the mid-1970s, and these activities intensified using performance assessment techniques in the 1980s and early 1990s. This work involved the development of conceptual models and computer codes to model the disposal of waste. Because waste disposal systems are passive, certain analysis methods used for active systems in PRA studies for power reactors had to be adapted to provide scenario analysis for the performance assessment of the potential geologic repository at Yucca Mountain, Nevada. In regard to high- level waste, the NRC staff participates in a variety of international activities (e.g., the Performance Assessment Advisory Group of the Organization for Economic Cooperation and Development, Nuclear Energy Agency) to ensure that consistent performance assessment methods are used to the degree appropriate.

In mid 1994, the NRC staff proposed a PRA policy statement to the Commission in SECY-94- 218, "Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities." In that Commission paper, the staff proposed that an overall policy on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities should be established and that the use of PRA technology in NRC regulatory activities should be increased. The staff also forwarded SECY-94-219, "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)," to the Commission.

The NRC established its regulatory requirements to ensure that nuclear facilities can be operated and nuclear materials can be used without undue risk to the health and safety of the public. These requirements are largely based on deterministic engineering criteria, involving the use of multiple barriers and application of a defense-in-depth philosophy. Beyond its deterministic criteria, for commercial power reactors, the NRC has additionally formulated guidance, as in the safety goal policy statement, that utilizes quantitative, probabilistic risk measures. The safety goal policy statement establishes top-level objectives to help ensure safe operation of nuclear power plants. The safety goals provide guidance on where plant risk is sufficiently low so that further regulatory action is not necessary. Also,

as noted above, the Commission has been using PRA in performing regulatory analyses for backfit of cost-beneficial safety improvements at operating reactors (as required by 10 CFR 50.109) for a number of years.

The application of PRA to nuclear regulatory activities has evolved with improvements in PRA techniques and data bases. PRA techniques can be used to derive valuable insights, perspectives, and general conclusions as a result of the integrated and comprehensive examination of the plant design and a structured examination of plant and operator response to events. For a nuclear power plant, a plant-specific PRA can be used to derive plant-specific insights and conclusions where appropriate plant-specific modeling and data are available and used appropriately. PRA sensitivity studies are particularly useful in focusing designers, operators, and regulators on important aspects of design, operation, and maintenance.

The Commission has considered recent improvements in nuclear technology and accumulated experience with risk assessment methods, and concluded that increased use of these techniques as an integral part of the regulatory decision-making process is now justified. Consequently, in its policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622, August 16, 1995), the Commission adopted the policy that the use of PRA should be encouraged and the scope of PRA applications in nuclear regulatory matters should be expanded to the extent supported by the state-of-the-art methods and data.

Bases

The bases for rules and standards issued by the NRC are the Atomic Energy Act of 1954 (AEA), the Energy Reorganization Act, the Administrative Procedures Act, and other legislation. The AEA generally requires that the NRC establish regulatory standards to govern its licensing determinations. The AEA (section 161(b)) provides NRC with broad authority regarding the standards and processes that the NRC must apply in exercising its licensing and regulatory responsibilities.

In the reactor area, the AEA (sections 101 and 103) requires a license for each utilization facility and requires technical specifications (section 182) to be part of the license. The AEA allows for amendments to the licenses (section 187) and includes requirements for holding hearings in the amending of licenses (section 189). Under the Energy Reorganization Act of 1974, NRC is responsible for these licensing and regulatory functions. The procedures and requirements governing issuance and modification of these licenses are contained in the NRC's regulations (primarily in 10 CFR Parts 2 and 50).

In the nuclear materials area, the AEA requires general or specific licensing for distribution and use of special nuclear material (section 53), source material (sections 62 and 63), and byproduct material (section 81). As a consequence of the statutory responsibilities for licensing the distribution and use of nuclear materials and the use of utilization and production facilities, the NRC regulates medical, industrial, academic, and other commercial uses of nuclear materials.

The AEA provides the broad authority for inspection to ensure compliance with the provisions of the Act. NRC inspections provide an independent verification of licensees' activities to ensure that the activities are in compliance with agency regulations. Inspections are primarily discussed in 10 CFR Parts 19, 30, and 50.

The AEA authorizes the NRC to undertake enforcement activities relating to violations of the licensing requirements, such as notices of violations and the imposition of civil monetary penalties. The NRC is also authorized to issue Orders that may lead to the suspension, revocation, or amendment of licenses. 10 CFR Part 2 describes the procedures for issuing notices of violation and Orders, and imposing civil penalties.

B. External Factors

1. Executive Branch and Congress

Congressional and Executive requirements regarding regulatory reform, changes in international standards, and advances in understanding risk and the biological effects of radiation may affect the regulation of the nuclear industry. As late as 1995, Congress was considering legislation concerning risk assessment (Title III of H.R. 9, the Risk Assessment and Communication Act of 1995).

2. Standards-Setting Organizations

International and national standards-setting committees may influence the transition toward risk- informed, performance-based regulations. Translations between dose and risk usually use international consensus factors. In the nuclear materials area, NRC has traditionally used radiological dose as the endpoint for rulemaking and compliance assessment. That is, in certain nuclear materials areas, regulatory decisions are related to the acceptability of dose as a surrogate for risk. The International Commission on Radiological Protection (ICRP) dose limits reflect ICRP recommendations for acceptable risk selections for radiation workers and the public. The NRC makes use of recommendations from the ICRP, the National Council on Radiation Protection, and the National Academy of Sciences.

3. Federal Agencies

The Environmental Protection Agency (EPA) has undertaken a number of regulatory initiatives under its authorities that affect activities licensed or otherwise regulated by the NRC. Substantial differences have arisen between the two agencies and have included the underlying bases and approaches used to develop standards. In 1995, the NRC and the EPA developed a joint paper entitled "White Paper on Risk Harmonization" to help explore ways to "harmonize" risk goals and to develop mutually agreeable approaches for risk assessment methodologies to assess radiological risk.

As previously discussed, the Paperwork Reduction Act of 1995 is the basis for agency and OMB activities related to information collections. It requires controls to limit and reduce the burden on the public for collecting agency information. In 5 CFR 1320, which implements the Paperwork Reduction Act, OMB requires agencies to submit plans for new, revised, and extended information collections to OMB for approval. However, the NRC, as an independent regulatory agency, may override OMB decisions.

4. Nuclear Industry

In the reactor area, commercial nuclear power utilities and industry organizations are using risk insights to identify and reduce unnecessary burdens. Where NRC review and approval is necessary before reducing the burden, the industry is actively engaging the staff to seek relief. In the nuclear materials area, there is less demand for regulatory change based on risk insights than in the reactor area. In some instances the nuclear materials industry may not be supportive of risk-informed, performance-based initiatives due to perceived high cost, impact on small number of licensees, and little perceived additional safety benefit.

5. Public

The public will likely play a substantial role in the transition to risk-informed, performance-based regulation. In order to maintain public confidence, the bases for and implications associated with risk-informed, performance-based regulatory approaches should be well defined and easily understood.

C. Internal Factors

1. Nuclear Materials Initiatives

The Commission's decision on the future role and scope of the NRC's nuclear materials program (in particular NRC's regulation of the medical use of nuclear material) will potentially affect the priority and scope for pursuing

risk-informed, performance-based regulatory approaches in nuclear materials program areas. The National Academy of Sciences recommended that the NRC reduce or eliminate its oversight of the medical uses of nuclear material. The basis for a decision regarding NRC oversight of the medical uses of nuclear material may affect the oversight and regulation of other material licensees and, consequently, the extent to which the agency may pursue risk-informed, performance-based approaches. The Business Process Reengineering effort is examining ways to gain efficiencies in licensing of nuclear materials and the results of this effort may affect the extent to which risk-informed, performance-based approaches could improve the effectiveness and efficiency of the licensing process.

2. Commission's PRA Policy Statement

The Commission's PRA Policy Statement encourages the use of PRA and seeks to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state- of-the-art in terms of methods and data. Performance-based regulation is an implicit element of the Policy Statement. Depending on the Commission's decision for proceeding toward risk- informed, performance-based regulatory approaches (e.g., more aggressive (Option 3) or less aggressive (Option 4)), activities associated with the PRA Policy Statement and the companion PRA Implementation Plan may be refocused and staff resources may be redirected.

3. Defense-in-Depth

The Commission has recognized that reliance for safety should not be placed on any single element of design, construction, operation, maintenance, training or other activity associated with nuclear facilities or the use of nuclear materials. Our current regulations are generally deterministic and were constructed around this concept of defense-in-depth. Risk insights provide a more structured way to assess relative importance of the levels of defense-in-depth and can lead to enhanced defense-in-depth. Risk-informed, performance-based regulations may need to consider the potential adverse cumulative effect of reducing conservatism and providing additional flexibility on defense-in-depth. Performance-based initiatives are considered for activities where failure to meet the performance criteria results in tolerable conditions for which appropriate corrective action will be taken. Therefore, a key element of a transition toward risk-informed, performance-based regulation is maintaining "defense-in-depth" for risk-informed, performance-based approaches by appropriately balancing deterministic- based and performance-based requirements so that defense-in-depth is not compromised.

4. Policy and Legal Issues: Compliance with Performance-Based Regulations

Substantive policy and legal issues are likely to emerge as increased reliance is placed on probabilistic- and performance-based approaches to support regulatory requirements and licensing decisions. Issues such as using risk to assess the severity level of an enforcement action or determining compliance with performance-based regulations will need to be addressed to ensure that there is an appropriate balance between deterministic-based and performance-based regulations so that defense-in-depth is not compromised.

III. DISCUSSIONS

A. Discussion of Direction-Setting Issue

The Commission's decision on this direction-setting issue will be used to establish the overall framework for expanding agency activities in applying risk-informed, performance-based regulatory approaches. After deciding on the overall approach for pursuing risk-informed, performance-based regulation, criteria for expanding the scope in applying a risk-informed, performance-based approach to rulemaking, licensing, inspection, and enforcement activities can be applied in the context of the overall Commission direction. In order to provide agency focus, these criteria can be sufficiently broad so that the criteria can be applied to both the reactor and nuclear materials areas. However, given the diverse nature of nuclear materials applications and the differences between commercial nuclear power and other nuclear materials areas in regard to their amenability for risk-informed, performance-based regulations, these criteria may need to be applied differently for different regulatory activities. Appendix A contains sample "priority and scoping" criteria that can be applied to better focus agency activities once the Commission decides the overall approach for pursuing risk-informed, performance-based regulatory approaches.

B. Discussion of Subsumed Issues

After the Commission decides on the overall approach for pursuing risk-informed, performance- based regulation, six subsumed strategic issues will be resolved in the context of the overall direction. Four of these subsumed issues can be directly resolved through resolution of the direction-setting issue. The resolution for the two other subsumed issues will be greatly influenced by the Commission decision on this direction setting issue.

The four issues most directly resolved through implementation of the Commission decision for "how fast" and "how far" the agency will go in expanding activities in the application of risk- informed, performance-based regulatory approaches are:

- What should be NRC"s strategy and philosophy with respect to changing NRC"s responsibilities and authority in areas of little public risk?
- What approach should NRC take in modifying the materials regulations to move toward risk-informed, performance-based regulation, recognizing the requirements will vary as a result of the range of products and the divergence of the licensees that use or possess byproduct nuclear material?
- Should NRC revise its regulations to address the uses of materials resulting from technological advances and changing human factors? If so, to what extent should NRC articulate objectives to prevent or limit the effects of equipment failures and human factors/human performance?
- What should be the approach for licensing material uses with various levels of inherent risks?

The first two issues should be completely resolved by the Commission's decision on this direction-setting issue and the Commission's decision on the direction-setting issue concerning the future role and scope of the NRC's nuclear materials program (in particular, NRC's regulation of the medical use of nuclear material).

The agency is required by the Atomic Energy Act of 1954 (AEA), as amended, to provide reasonable assurance of an adequate level of protection of the public health and safety, as well as to promote the common defense and security, in its regulatory activities. Although the scope of actions necessary to attain this level of protection from the use of AEA materials is relatively clear in areas of high risk, it is not so easily defined for those activities and types of material that generate a relatively small risk to the public from their use. Such areas include, but not limited to, the use of generally licensed devices, exempt distribution of consumer products, the definition and regulation of source material, review of formerly licensed sites and stabilization and long-term control of uranium mill tailings. As the agency seeks to improve the efficiency and effectiveness of its regulatory programs, these low risk activities will be scrutinized in order to make informed decisions about how the agency should proceed.

The Commission's philosophy for considering changes to its regulatory activities, including areas of responsibilities and authorities for areas of little public risk is, in part, contained in the Commission's Final Policy Statement on the use of probabilistic risk assessment in nuclear regulatory activities. In the Final Policy Statement, the Commission conveys an open-minded approach for considering strategic-type changes associated with using risk insights and states that two explicit implications associated with the policy statement are:

First, that the NRC staff, licensees, licensee applicants, and Commission must be prepared to consider changes to regulations, to guidance documents, to the licensing process, and to the inspection program. Second, the NRC staff and the Commission must be committed to a shift in the application of resources over a period of time based on risk findings.

The current agency-wide strategy for increasing the use of risk assessment and risk management in regulatory decision-making is captured in the agency's PRA Implementation Plan. Therefore, the Commission decision on "how fast" and "how far" the agency should go in expanding activities associated with the application of risk-informed, performance-based regulatory approaches will further define the approach and support the bases for considering changes to regulations, responsibilities and authorities.

The third issue explicitly recognizes the diverse nature of nuclear materials applications and the differences between reactor and nuclear materials areas in regard to their amenability for risk- informed, performance-based regulations. For example, events associated with industrial and medical uses of nuclear materials generally involve a simple system, involve radiation overexposures, and result from human error, not equipment failure. Because of these characteristics of medical and industrial events, analysis of these events using relatively simple techniques may yield useful results. These results may lead to the establishment of standards with broad risk-informed, performance-based objectives and criteria. Conversely, these results may lead to a conclusion that more prescriptive requirements for equipment design and procedural compliance are appropriate. In these cases, risk insights lead to risk-informed, deterministic regulations not risk-informed, performance-based regulations. Similar to the first subsumed issue, this subsumed issue will also be resolved by the Commission's decision on this direction-setting issue and the aforementioned direction-setting issue concerning regulation of nuclear materials.

The fourth subsumed issue concerns licensing for nuclear materials when there is determined to be a wide range of inherent risks because of the diverse use of the materials. These risks vary from very low-risk smoke detectors to relatively high-risk irradiators. Although the Commission must license all of these uses in response to the AEA, the Commission has flexibility in how it approaches the licensing. Currently, the Commission provides for three types of licensing: (1) exempt distribution, (2) general licenses, and (3) specific licenses. For exempt distribution devices (e.g., smoke detectors), the Commission oversees and controls their manufacture and distribution by issuing specific licenses to the manufacturers and distributors. The individual users of these low-risk devices are not licensed. A review of the internal and external factors and ongoing activities has not identified any strategic issues associated with exempt distribution devices.

The generally licensed devices consist of radioactive material contained in sealed sources that are designed with inherent radiation safety features. Approximately 1.5 million generally licensed devices are under the jurisdiction of the Agreement States and the NRC. NRC's regulation of these devices is essentially limited to the maintenance of a general license database, which contains the names of the general licensees and the products they possess. For general licenses, issues associated with control and accountability were discussed in SECY- 95-139, which reports that many general licensees are not aware of their responsibilities under the general license.

The staff has previously noted that there are inconsistencies in terms of risk, both among and across these three levels of activities. For example, in SECY-90-175, the staff identified certain generally licensed gauges that may be better controlled through specific licensing and also identified certain generally licensed devices that are suitable for exemption from regulation. In this regard and in accordance with recommendations contained in SECY-95-139, the staff has established a joint Agreement State-NRC working group to evaluate the current regulations concerning generally and specifically licensed devices. A report from the working group is expected in June 1996.

As previously mentioned, issues associated with determining an approach for considering risk in the licensing of material uses will also be resolved in the context of the overall Commission decision on this direction-setting issue and the direction-setting issue concerning the future role and scope of the NRC's nuclear materials program (in particular, NRC's regulation of the medical use of nuclear material).

A fifth subsumed issue concerns the information necessary for developing and implementing risk-informed, performance-based regulation. The subsumed issue is stated as follows:

- Given the new Government-wide goals for reducing Federal information collections, how should the agency prepare for possible reductions in its budget ceiling for information collection without compromising public health and safety?

The Paperwork Reduction Act of 1995 is the basis for agency and OMB activities related to information collections. It requires controls to limit and reduce the burden on the public for collecting agency information. In 5 CFR 1320, which implements the Paperwork Reduction Act, OMB requires agencies to submit plans for new, revised, and extended information collections to OMB for approval. However, the NRC, as an independent regulatory agency, is not bound by OMB decisions. By majority vote, the Commission can choose not to abide by an OMB decision.

The new Paperwork Reduction Act sets a goal of 10-percent annual reduction in information collections for 1996 and 1997 followed by a 5-percent reduction each year in 1998, 1999, 2000, and 2001. It is uncertain how OMB will implement this goal. Depending on individual agency plans to achieve the reductions, OMB could assign specific reduction goals to each agency. NRC could be required to reduce its information collection burden before imposing any additional burden through new or amended collections. This could affect the rulemaking process, especially since risk-informed, performance-based regulatory approaches may well require licensees to collect more information for the NRC.

The Commission's decision on expanding agency activities in applying risk-informed, performance-based regulatory approaches will influence the extent and impact of additional information requirements. In response to several comments concerning the potential data collection implications of the Commission"s PRA Policy Statement, the Commission agreed that it should make every effort to avoid any unnecessary regulatory burdens in connection with collecting reliability and availability data (60 FR 42622 at 42626). The Commission also indicated that, in the context of risk-informed regulation, this was an implementation issue and that data and information collection will be addressed in connection with proposed data collection requirements when the requirements are published for comment.

In a strategic sense, information collection requirements and burdens should not define the direction that the agency takes regarding risk-informed, performance-based approaches. Regardless of the option selected for proceeding toward risk-informed, performance-based regulatory approaches, the Commission could consider information collection options independently. The Commission may (1) look for efficiencies in information collection and storage methods and identify areas that could be made more efficient, (2) wait until OMB publishes its guidance to agencies for implementing the provisions of the new Paperwork Reduction Act and address any issues on a case-by-case basis with each rulemaking, or (3) report NRC"s case to OMB now and request a level or increased ceiling to accommodate future information collection needs associated with risk-informed, performance-based regulatory approaches.

Finally, a sixth subsumed issue concerns interagency implications associated with moving toward a more risk-informed, performance-based regulatory framework. Specifically:

- How should a risk-informed, performance-based regulatory philosophy influence NRC's handling of dual regulation?

As previously mentioned, the Environmental Protection Agency (EPA) has undertaken a number of regulatory initiatives under its authorities that affect activities licensed or otherwise regulated by the NRC. Substantial

differences have arisen between the two agencies and have included differences associated with the underlying bases and approaches used to develop regulatory standards and acceptable methods for meeting these standards. In 1995, the NRC and the EPA developed a joint paper entitled "White Paper on Risk Harmonization" to help explore ways to "harmonize" risk goals and to develop mutually agreeable approaches for risk assessment methodologies to assess radiological risk.

As the NRC and other government agencies move toward more risk-informed, performance-based regulatory approaches, the use of risk insights should help promote a common understanding of the technical bases for regulatory approaches. The common desire for increasing the use of risk in all government agencies helps define the common goals, but there is substantial interagency work necessary to ensure that there is a systematic interrelatedness among approaches and mutual understanding and agreement on the underlying bases for the regulatory approach, including agreement on key policy issues, such as agency safety goals, and technical issues confronting the agencies. The Commission decision on "how fast" and "how far" the agency should go in expanding activities associated with the application of risk-informed, performance-based regulatory approaches will further influence the level of agency resources devoted to reconcile differences in conflicting interagency regulatory approaches.

C. Important Aspects of Risk-Informed, Performance-Based Regulation

Three important aspects of expanding agency activities in applying risk-informed, performance- based approaches concern establishing a common understanding of what is meant by "risk- informed, performance-based," dealing with uncertainties in regulatory decision-making, and strategically considering how to ensure regulatory coherence during the transition from deterministic-based regulations to risk-informed, performance-based regulations.

1. Discussion of terms "Deterministic-Based," "Risk-Informed, Deterministic-Based," "Performance-Based," and "Risk-Informed, Performance-Based"

Deterministic-based. The NRC has generally regulated the use of nuclear material (including nuclear materials and reactors) based on deterministic approaches. Deterministic approaches to regulation consider a set of challenges to safety and specify how those challenges should be mitigated. Simply stated, the deterministic approach establishes requirements for use of nuclear materials and for engineering margin and quality assurance in design, manufacture, construction, and operation of nuclear facilities.

The NRC established its regulatory requirements to ensure that a facility is designed, constructed, and licensed to operate without undue risk to the health and safety of the public. These requirements are largely based on deterministic engineering criteria. In addition, this approach assumes that adverse conditions can exist (e.g., equipment failures and human errors) and establishes a set of design basis events. It then requires that the licensed facility design include safety systems capable of preventing and/or mitigating the consequences of those design basis events to protect the public health and safety. The deterministic approach contains implied elements of probability. For example, reactor vessel rupture is considered too improbable to be included as an accident to be analyzed. However, the likelihood that a single emergency core cooling system or system train would not function was considered high enough that safety train redundancy and protection against single failure where required.

Risk-informed, deterministic-based. A risk-informed, deterministic approach to regulation enhances and extends this traditional, deterministic approach, by: (a) allowing consideration of a broader set of potential challenges to safety, (b) providing a logical means for prioritizing these challenges based on likelihood and risk significance, and (c) allowing consideration of a broader set of resources to defend against these challenges. A risk-informed approach can be used to focus deterministic regulations by considering risk in a more coherent and comprehensive manner. By considering risk insights, operating experience, and engineering judgment, the NRC and its licensees can focus regulatory approaches and licensee activities on those items most important to public health and safety. Where appropriate, a risk-informed regulatory approach can be used to reduce unnecessary conservatism in deterministic approaches or can be used to identify areas with insufficient conservatism and provide the bases for additional requirements. Deterministic-based regulations have been successful in protecting the public health and safety and risk insights are most valuable when they serve to focus the deterministic- based regulations and support the defense-in-depth philosophy.

Performance-based. A performance-based regulatory approach requires at least four key elements:

- There are measurable parameters to monitor acceptable plant and licensee performance.
- Objective performance criteria are established to assess performance.
- There is licensee flexibility to determine how to meet established performance criteria.

- Failure to meet a performance criterion must not result in unacceptable consequences.

In theory, a performance-based approach can be implemented without the use of risk insights. This type of performance-based approach would require that objective performance criteria be based on deterministic analysis and performance history. This approach would provide additional flexibility to the licensee to determine how to meet performance criteria. However, the net impact on public health and safety would be difficult to determine.

Risk-informed, performance-based. Risk-informed, performance-based approaches use risk insights, together with deterministic analyses and performance history, to develop measurable parameters for monitoring plant and licensee performance, as well as for developing criteria for performance assessment, and focus on the results as the primary means of regulatory oversight. Similar to a risk-informed, deterministic-based approach, a risk-informed, performance-based regulatory approach can be used to reduce unnecessary conservatism in deterministic approaches or can be used to support additional regulatory requirements. In addition, a risk-informed, performance-based approach can further focus performance-based approaches by defining the goal or purpose of the approach in terms of performance characteristics and safety significance and permitting the licensee additional flexibility in meeting the regulation. Performance-based initiatives can be considered for activities where objective performance criteria can be established for performance monitoring. Additional evaluation of performance-based approaches may result in a determination that a number of functional areas are not amenable to performance-based treatment.

The NRC Inspection Manual has tailored the concepts of "risk-informed" and "performance- based" for inspections into a single definition of "performance-based inspection." According to Inspection Manual Chapter 0610, performance-based inspection is inspection that focuses on issues of safety and reliability, with an emphasis on field observation rather than in-office procedural or records review. The emphasis on safety and reliability borrows from risk studies, incorporating PRA and individual plant examination insights to structure inspections that focus on systems or components most important to plant safety. In addition, performance-based inspection tends to focus more on results than on process and method.

2. Uncertainties in Regulatory Decision-Making

The treatment of uncertainties is an important issue for regulatory decisions. Uncertainties exist in any regulatory approach and these uncertainties are derived from knowledge limitations. These uncertainties and limitations existed during the development of deterministic regulations and attempts were made to accommodate these limitations by imposing prescriptive, and what was

hoped to be, conservative regulatory requirements. A probabilistic approach has exposed some of these limitations and provided a framework to assess their significance and assist in developing a strategy to accommodate them in the regulatory process.

Human performance is an important consideration in both deterministic and probabilistic approaches. Assessing the influence of errors of commission and organizational and management issues on human reliability is an example that illustrates where current PRA methods are not fully developed. Although this lack of knowledge contributes to the uncertainty in estimated risks, the PRA framework offers a powerful tool for logically and systematically evaluating the sensitivity and importance to risk of these uncertainties. Improved PRA techniques and models to address errors of commission and the influence of organizational factors on human reliability are currently being developed.

Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission has recognized that a single approach for incorporating risk analyses into the regulatory process may not be appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-informed decision-making. Activities that lead to regulatory coherence will also reduce uncertainty in regulatory decision-making.

3. Regulatory Coherence

Regulatory coherence is essential in order to ensure that the direction the Commission takes in expanding agency activities in applying risk-informed, performance-based regulatory approaches promotes a stable and predictable regulatory environment. Regulatory coherence is achieved when the regulatory programs or processes are well understood and proceed in a logical and orderly fashion. In this paper "regulatory coherence" means:

(a) integration of risk-informed, regulatory approaches based on a consistent pattern or framework

(b) implementation of risk-informed, performance-based approaches in a suitable or orderly way that promotes and ensures mutual understanding

(c) development of risk-informed, performance-based approaches that are governed by rational principles and that ensure systematic interrelatedness.

The Commission has recognized the importance of coherence for increasing the use of PRA and the Commission's policy statement on the use of probabilistic risk assessment methods in nuclear regulatory activities (60 FR 42622)

promotes regulatory coherence. Through the "PRA Implementation Plan" the staff monitors PRA-related activities and helps ensure consistent application of PRA methods and techniques. The PRA Implementation Plan explicitly contains activities that have, as a principal goal, the achievement of regulatory coherence. Recently, the schedule for completing several activities in the PRA Implementation Plan dealing with regulatory guides and standard review plans (SRPs) for reactor pilot applications have been accelerated to improve and promote regulatory coherence. Arguably, the increased use of PRA methods and techniques itself promotes regulatory coherence by integrating regulatory decisions using risk, allowing systematic comparisons of approaches, and enhancing mutual understanding of those items that are most important to safety.

Another way that the Commission is promoting regulatory coherence for operating reactors is through the safety goal policy statement. The safety goal policy statement uses quantitative, probabilistic risk measures and establishes top-level objectives to help ensure safe operation of nuclear power plants. The safety goals provide guidance on where risk is sufficiently low that further regulatory action is not necessary. The concept of a "safety goal" has not been firmly established for NRC licensees, other than commercial power reactor licensees.

Eventually, the Commission could consider rulemaking, adoption of a national standard for performing PRAs, or more detailed regulatory guidance to help ensure uniformity in the quality and application of risk-informed, performance-based regulatory approaches. The Commission and senior NRC management could define staff requirements more precisely for moving toward risk-informed, performance-based regulatory approaches and could more strongly articulate its expectations for industry use of risk-informed, performance-based approaches to support regulatory decision-making.

Finally, regulatory coherence for a risk-informed, performance-based approach may not be achieved unless there is a cohesive approach that can be used as guidance for both the NRC and the regulated industry. The Commission could encourage industry/stakeholders to develop solutions or processes that help ensure regulatory coherence. To help ensure regulatory coherence for industry processes or industry application of a risk-informed, performance-based approach, a part of the burden could be assumed by the regulated industry. For example, if the varying levels of quality for individual PRAs contribute to regulatory incoherence, the industry could develop a PRA "certification" process or develop criteria for detailed peer reviews.

As discussed above, regulatory coherence is essential in order to ensure that the direction the Commission takes to expand agency activities in applying risk-informed, performance-based regulatory approaches promotes a stable and predictable regulatory environment.

IV. OPTIONS

Option 1: Continue Current Process

This option would continue the current process for determining priority and scope of risk- informed, performance-based activities. The Commission's final policy statement on "Use of Probabilistic Risk Assessment in Nuclear Regulatory Activities" establishes an overall policy on the use of PRA methods in nuclear regulatory activities so that the many potential applications of PRA can be implemented in a consistent and predictable manner that would promote regulatory stability and efficiency. The priority and scope for regulatory activities under this policy statement are captured in the agency's PRA Implementation Plan.

There is flexibility associated with the PRA Implementation Plan. NRC Program Offices principally determine the priority and scope in applying risk-informed, performance-based regulatory approaches. The PRA Implementation Plan is periodically updated to reflect progress for plan activities, to indicate areas that are determined to be not yet amenable to risk- informed approaches, or to add new areas where the staff is pursuing risk-informed approaches. Under the current process, the priority and scope in applying risk-informed, performance-based approaches are determined by balancing external and internal goals with available resources. Priority criteria are applied and the scope of activities is primarily determined by considering the industry demand, the safety benefit, the ease of implementation, and available resources.

The current process is responsive to industry initiatives in reactor-related areas. In part, this is because the potential benefits for reducing unnecessary industry burden, enhancing safety decision-making, and improving staff efficiency are more readily apparent. Consequently, resources in the reactor area are focused on developing additional regulatory guidance and supplementing the Standard Review Plan to address areas such as inservice inspection, inservice testing of pumps and valves, graded quality assurance, and technical specifications.

There is no widespread industry demand to consider risk-informed approaches in many of the nuclear material areas and it is not apparent whether some nuclear material areas will significantly benefit from implementation of risk-informed approaches. As a result, in the PRA Implementation Plan, there is less emphasis on incorporating risk-informed approaches in the nuclear materials areas.

A performance-based approach is an implicit element for some PRA Implementation Plan activities and a necessary element for other activities in the plan. For example, there have been several performance-based initiatives

discussed in the PRA Implementation Plan, such as risk- informed, performance-based changes to containment leakage requirements, fire protection requirements, and maintenance rule implementation. The PRA Implementation Plan pilot applications dealing with inservice testing of pumps and valves and inservice inspection contain performance-based aspects. As data from performance monitoring of structures, systems and components are accumulated and made available to the agency, the staff evaluates the performance data, where appropriate, to determine the effectiveness of the approach.

Under this option, the modification of rules and regulations to move toward performance-based regulation would proceed at a pace consistent with the activities under the PRA Implementation Plan. As areas amenable to risk-informed, performance-based regulation are identified and as resources become available, the staff may initiate rulemaking. In the nuclear materials areas, technological changes and changing human factors may affect the speed and scope of risk- informed, performance-based revisions to regulations. In areas involving dual regulation, the current emphasis and level of activity devoted to resolving issues affected by dual regulation would continue and the pace of these activities would be consistent with the safety benefit, the ease of implementation, and available resources.

Since this option is the current process, no change in resource allocation is necessary to implement it. The resource and programmatic consequences are gradual and incremental.

Option 2: More Rigorously Assess Relationship to Public Health and Safety

Similar to the Continue Current Process option discussed above, this option would primarily continue the current approach for moving toward more risk-informed, performance-based regulatory approaches. However, under this option, the relationship of new activities to public health and safety would need to be more rigorously assessed. The results of this safety assessment would determine whether the agency would pursue the activity. In other words, those activities where there could be a substantial increase in overall protection to public health and safety will be given the highest priority.

Underlying both this option and the Continue Current Process option is the assumption that our regulations and current regulatory processes are adequate, and will continue to be adequate, to protect public health and safety. The Continue Current Process option pursues enhancement to current regulatory processes through risk-informed approaches to regulation, is exploratory in nature and applies a threshold for pursuing such activities. This option also pursues enhancements to our current regulatory processes through risk-informed approaches to regulation. However, this option is more narrowly focused than Option 1 and applies a higher threshold for pursuing activities.

Under Option 2, priority and scope in applying risk-informed, performance-based regulatory approaches would be primarily determined by the projected cost of the approach compared to benefit to the public health and safety. Many intangibles would have to be analyzed, at least qualitatively, and a methodology developed in order to provide a meaningful assessment. Priority criteria are weighted toward greatest safety benefit. The scope of risk-informed, performance-based approaches is primarily determined by considering the cost/benefit, the overall impact on the NRC and regulated industry, and available resources.

For example, consider some of the current activities in the reactor regulation area. Several of these activities are in response to industry demand and have as a principal goal to reduce unnecessary burden. The safety benefit of these activities is not well defined. There has been an assumption that, once burden has been reduced, those resources made available through that reduction in burden would be made available to focus on activities that are of greater safety importance. However, this safety benefit is difficult to quantify.

In the nuclear materials area, there is less industry demand to reduce unnecessary burden through risk-informed, performance-based approaches to regulation than in the reactor area. The nature of the interaction between the NRC and its materials licenses is different from the interaction between the NRC and commercial power reactor licensees. Material licensees often deal with simple systems and the primary contributor to risk is human error. Any safety benefit associated with a risk-informed, performance-based approach may also be difficult to quantify. Under Option 2, the current emphasis on reconciling regulatory differences arising from dual regulation may be reduced.

Priority criteria for new initiatives are used as a threshold but weighted toward greatest safety benefit. Scoping criteria from Appendix A most useful in this approach are cost/benefit, safety significance, largest impact, and available resources.

Option 3: Perform a Comprehensive Assessment of NRC Regulatory Approaches

This approach would involve a comprehensive review of our regulations and regulatory processes to determine areas that could be improved through risk-informed, performance- based regulatory approaches. The agency priority for activities would be established based on consideration of the cumulative impacts on safety, burden reduction, and efficiency.

This is the most proactive, aggressive option for moving toward risk-informed, performance- based regulation. This option would maximize internal self-assessment and include exploring all regulatory areas to determine whether risk-informed, performance-based regulation should be pursued in that

area. The purpose for the review under Option 3 is not just to enhance our deterministic regulations. The purpose of this assessment is to fundamentally change, in a comprehensive manner, the bases to our regulations and process for those areas that are amenable to a risk-informed, performance-based approach.

Under Option 3, priority for regulatory activities would be established based on consideration of the cumulative impacts on safety, burden reduction, and efficiency. The scope of risk-informed regulatory approaches under this option would be determined by considering agency responsiveness to stakeholder initiatives, the safety benefit/significance of the approach, and the effect on NRC and licensee efficiency. Ease of implementation and available resources are secondary scoping considerations (i.e., if the activity is determined to be a high priority then resources will be made available and efforts made to improve the state-of-the-art to the level necessary to support the desired goal).

In the reactor area, the staff and industry have already identified several areas that may be conducive to risk-informed, performance-based regulatory approaches. The Commission has already performed a systematic review of the many current rules and regulations to identify opportunities for eliminating unnecessary regulations. In 1993, the NRC established the Regulatory Review Group (RRG) to conduct a structured review of power reactor regulations with special attention on the opportunity to reduce unnecessary regulatory burdens. The RRG recommendations to reduce the regulatory burden included the suggestion to use more risk- based approaches in quality assurance, inservice inspection, and inservice testing. The RRG recommendations were documented in SECY-94-003. Option 3 would build on the RRG review results with a more tightly focused assessment on the bases of those regulations and on identifying and prioritizing regulations that are amenable to a risk-informed, performance-based approach.

In the nuclear materials area, a similar systematic assessment of rules and regulations has not been conducted. However, several recent initiatives, including an materials licensee regulatory impact study and the Business Process Reengineering initiative, may result in changes to nuclear materials regulatory approaches. Option 3 would initiate a thorough review of the bases for nuclear materials regulations and process and would identify and prioritize those areas that are amenable to a risk-informed, performance-based approach. As a result of this assessment, a framework, similar to the framework for applying PRA in reactor regulation in SECY-95-280, could be developed for other nuclear materials uses.

Because the purpose of Option 3 is to change the bases of our regulations and process for those areas that are amenable to a risk-informed, performance-based approach, this option is the most resource intensive option.

Additional resources would be needed to train the staff, develop a strategy for review, complete the assessment, and implement rulemaking or procedural changes.

Under Option 3, the staff would likely intensify its efforts to resolve issues associated with dual regulation. The agency would more aggressively pursue a systematic interrelatedness among approaches and mutual understanding and agreement on the underlying bases for the regulatory approaches, including agreement on key policy issues, such as agency safety goals, and technical issues confronting the agencies.

Because it is the most resource intensive, this option would also be the most costly to licensees in the form of fees to pay for the reviews, guidance development, and rulemakings to be undertaken. Their participation in and support for such activities could well depend on the extent to which they perceived near term, concrete benefits accruing to their own operations.

Option 4: Consider Risk-Informed, Performance-Based Approaches Primarily in Response to Stakeholder Initiatives

This option is the most responsive to stakeholder interests. The agency would determine for new initiatives the priority and scope in applying risk-informed, performance-based regulatory approaches through consideration of stakeholder demand and ease of implementation. The scope would be primarily established to meet the demand or request.

Under this option, reducing industry burden would be the primary result. The safety review for proposed risk-informed, performance-based approaches would be to ensure that the proposed approach maintains an acceptable level of safety. Staff and industry efficiency may be collateral benefits of this approach.

Another potential consequence of selecting this option is that the agency could be perceived to be reactive and not making the best use of available information and technology to reach decisions. The agency's expertise in risk-informed regulatory approaches may be limited by the demand for that expertise. Therefore, in the future there might be a substantial burden associated with "ramping-up to speed" to deal with emerging safety issues.

V. RELATED ISSUES

After the Commission has made decisions concerning the Direction-Setting Issue discussed above, additional issue(s) such as those related to implementation details will be addressed as the Strategic Plan is implemented. The related issues are listed in this section to provide a more complete understanding of the higher level Direction-Setting Issue.

- What is the appropriate level of resources that the NRC should devote over the next few years to reduce the number of licensing requirements no longer required for safety and to develop risk-informed, performance-based approaches in order to achieve long-term reductions in the resource burden of both the licensee and the NRC?

- What levels of residual radioactivity are acceptable for decommissioning a materials licensed facility?

VI. COMMISSION'S PRELIMINARY VIEWS

Staff actions regarding the various options should be held in abeyance pending the Commission's final decision on this issue paper. The Commission's preliminary views are:

The Commission recognizes that, in order to accomplish the principal mission of the NRC in an efficient and cost effective manner, it will in the future have to focus on those regulatory activities that pose the greatest risk to the public. This can be accomplished by building upon probabilistic risk assessment concepts, where applicable, or other approaches that would allow a risk-graded approach for determining high and low risk activities. In general, those activities that are of a higher risk should be the primary focus of the agency's efforts and resources. The level of staff activity associated with lower risk activities should be determined based on a consideration of the cumulative impacts on safety, stakeholder initiatives and burden reduction, and the effect on agency and licensee efficiency.

The staff should continue with the current efforts, in cooperation with the industry (Option 1), including pilot programs. The objective of this initiative is to obtain additional information regarding the appropriateness of a risk-informed, performance-based approach for the subject activities. These activities and their schedule, are presently captured in the agency's PRA Implementation Plan. As data from performance monitoring of structures, systems and components are accumulated, the staff should evaluate the performance data to determine the effectiveness of the approach on the subject activity.

The staff should proceed in the direction of enhancing the PRA Implementation Plan (i.e., moving towards implementation of elements of Option 3) by building on the Regulatory Review Group's (RRG) results, which were initially focused on reducing the regulatory burden, with a more focused assessment of those regulations which are amenable to a risk-informed, performance-based approach. In determining the priority and scope of regulatory activities to be included in moving in the direction of partial implementation of option 3, the staff should consider the cumulative impacts on safety, stakeholder initiatives and burden reduction, and the effect on NRC and licensee efficiency. This

approach should result in a further focusing of resources, on the various areas that the Commission regulates, that is commensurate with its risk significance, potential burden reduction and effect on efficiency.

The staff should evaluate and clarify any technical and/or administrative issues associated with performance-based approaches to regulation (e.g., inspection activities, enforcement, etc.). The staff should also perform a thorough review of the basis for nuclear materials regulations and process, and should identify and prioritize those areas that are either now, or can be made with minimal additional effort/resources, amenable to a risk-informed, performance-based approach. This assessment should eventually lead to the development of a framework for applying PRA to nuclear material uses, similar to the one developed for reactor regulation (SECY-95-280), where appropriate.

In the public comments on this issue, the NRC particularly solicits how NRC should deal with dual regulation when applying a risk-informed, performance-based regulatory philosophy.

Appendix A

Sample Criteria for Determining the Priority and Scope Within the Context of the Strategic Direction

I. Applying the Criteria

The weighting of criteria to determine the priority and scope associated with applying a risk- informed, performance-based approach to rulemaking, licensing, inspection, and enforcement for new initiatives will be governed by the option that the Commission chooses for proceeding toward a risk-informed, performance-based regulatory framework.

Several sample criteria for establishing the scope and priority in applying a risk-informed, performance-based regulatory are discussed under this issue paper. Except as noted, the criteria can be applied to reactor and nuclear materials areas.

The staff notes that the expected benefit of an activity may elevate its priority. However, if the scope of the activity necessary to explore that expected benefit is resource intensive, then the priority may be lowered.

II. Priority Criteria

Priority criteria can be broadly defined by the relationship of the activity or proposed activity to the agency's commitment to good regulation. Priority criteria also reflect a balance between the need for a revised approach and an assessment of whether the revised approach is achievable. The priority for applying a risk-informed, performance-based regulatory approach can be illustrated by assessing an activity or proposed activity using the following high-level criteria:

Safety Impact:	To what extent will the activity result in enhanced safety decision- making or increase the level of public health and safety? Conversely, to what extent will the activity potentially reduce the level of public health and safety?
Burden Reduction:	To what extent will the activity reduce unnecessary burdens on the staff or the industry by eliminating unnecessary requirements?
Efficiency:	To what extent will the activity promote a better use of staff or industry resources by focusing on those activities that are more important to safety?

III. Scoping Criteria

Scoping criteria can be broadly defined by the extent and,timing of the resource commitment necessary to achieve a certain goal. The scope defines the nature and character of the activity and conveys an agency resource commitment. The scope in applying a risk-informed, performance-based regulatory approach for new initiatives can be determined using a criterion or combinations of criteria. Sample criteria are listed below.

Responsive to Stakeholders:	Scope is determined by the extent needed to be responsive to stakeholder initiatives.
Safety Benefit:	Scope is determined by the extent needed to achieve the desired impact on reduction in risk or positive impact on public health and safety.
Efficiency:	Scope is determined by the extent needed to achieve the desired impact on staff efficiency.
Cost/Benefit:	Scope of an activity is pursued to the extent that is supported by a cost/benefit analysis. The scope of an activity may be established to optimize the cost/benefit ratio.
Public Confidence:	Scope of an activity is limited to those areas that the public is willing to support.
Largest Impact:	Scope is determined by the extent needed to provide a large-scale programmatic or systemic impact.
Available Resources:	Scope is determined by the extent supported by available NRC and licensee resources.
Ease of Implementation:	Scope is determined by the maturity of the technology and how easily the technology can be incorporated into the regulatory framework.

ACRONYMS

AEA	Atomic Energy Act of 1954
ATWS	anticipated transient without scram
BPR	business process reengineering
DSI	direction-setting issue
EPA	Environmental Protection Agency
ICRP	International Commission on Radiological Protection
IPE	Individual Plant Examination
IPEEE	Individual Plant Examination-External Events
OMB	Office of Management and Budget
PRA	probabilistic risk assessment
RRG	Regulatory Review Group
SBO	station blackout
SNM	special nuclear material
SRP	standard review plan

General Discussion of Comments on IOM Report

NRC has sought a broad range of public comments on the report. NRC provided prepublication copies of the report to all Agreement States, non-Agreement States, and U.S. Territories; appropriate Federal agencies (U.S. Departments of Health and Human Services, Veterans Administration, Defense, Labor, and Transportation, and Environmental Protection Agency); the Conference of Radiation Control Program Directors (CRCPD); the Organization of Agreement States (OAS); Congressional Oversight Committees; and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, we published a Federal Register notice (61 FR 1648) on January 22, 1996, and issued a press release acknowledging receipt of the report and requesting comments on the possible impacts of the report, to include any views on policy, legislative, rulemaking, and guidance issues. The NRC staff conducted an analysis of the conclusions and data used by the IOM to support its preferred alternative regulatory structure and the eight recommendations for its implementation. The staff discussed the report with the ACMUI on February 21-22, 1996, and at an NRC and Agreement State Technical Workshop conducted March 5-6, 1996. On February 27, 1996, members of the IOM committee, and on May 3, 1996, the ACMUI and Robert S. Adler (IOM committee member with dissenting view) briefed the Commission. The Commission has also directed the staff to consider the IOM report and comments received within its strategic assessment and rebaselining efforts.

To date, the NRC has received 50 letters, containing 47 comments on the report. Three of the letters stated that they would continue to consider the issues, and provide comments at a later time. A breakdown by category of respondent is attached. The staff has reviewed all the comments received and grouped them by broad category. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Department of Health and Human Services (DHHS), the Federal agency that would be most likely to assume more regulatory oversight if the IOM recommendations were implemented, indicated that the report does not make a compelling public health argument for DHHS to assume the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Specific comments are summarized in a table provided as Enclosure 3 to the letter. Four of the 14 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

Enclosure 2

Other comments varied widely in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to implement adequately the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation. For example, the OAS response provided a summary of the consensus opinions of the participants at the NRC and Agreement State technical workshop conducted March 5-6, 1996, which represented 18 Agreement States and two non-Agreement States. The CRCPD response expresses the concern that the absence of Federal authority in the medical use area may have immediate and undesirable consequences on citizens in non-Agreement States, and long-term consequences for Agreement States trying to maintain a nationally consistent program. CRCPD does not support automatic selection of the DHHS as the agency to provide a leadership role. The staff is continuing to evaluate the responses as they are received, and will consider them in the broader context of its agency-wide strategic assessment and rebaselining effort.

Categories of Responses Received on IOM Report

Federal Agencies:

Department of Defense (DOD) - consolidates views for three services
Department of Health and Human Services (DHHS)
Department of Labor, Occupational Safety and Health Administration (OSHA)
Department of Veterans Affairs (DVA)
Environmental Protection Agency (EPA)

Agreement States:

Arkansas
California
Florida (Office Radiation Control) - R
Florida (State Health Office) - H
Illinois
Kentucky
Maryland
New Mexico
New York (Dept. Environmental Conservation) - E
New York (Dept. Health) - H
New York (Dept. Labor) - L
Tennessee
Texas
Utah
Vermont
Washington

Non-Agreement States/Territories:

Alaska
American Samoa
Delaware
Hawaii
Massachusetts
New Jersey
Virginia
Wyoming

Organizations/Committees:

American Association of Physicists in Medicine (AAPM)
American College of Cardiology (ACC)
American College of Medical Physics (ACMP)
American College of Nuclear Physicians/Society of Nuclear Medicine (ACNP/SNM)
American College of Nuclear Physicians - California chapter (ACNP-CA)
American College of Radiology (ACR)
American Pharmaceutical Association (APhA)
American Society of Nuclear Cardiology (ASNC)
Conference of Radiation Control Program Directors (CRCPD)
NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI)
Organization of Agreement States (OAS)[1]

Other Respondents:

CBeasley, St. John's Regional Health Center, Springfield, MO
MHafermann, Virginia Mason Cancer Center, Seattle, WA
DJones, Northwest Medical Physics Center, Lynnwood, WA
CMarcus, University of California, Los Angeles, CA
CPerez, Washington University, St. Louis, MO
GPoteat, OH
JRieke, Virginia Mason Cancer Center, Seattle, WA
DSchumacher, Northwest Medical Physics Center, Lynnwood, WA
MSelikson, RSO, University of Pennsylvania, Philadelphia, PA
St. John's Hospital, Jackson, WY

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[1] The OAS comment provided the recommendations of and consensus views reached at the NRC and Agreement State Technical workshop. The session on the NAS report included representatives from 18 Agreement States (CA, NY, SC, NV, IL, WA, TX, MS, TN, GA, NE, CO, KY, KS, NYC, FL, AR, AZ) and two non-Agreement States (OH, PA).

General Comments on IOM Report

Respondents in favor of IOM recommendations:

Support IOM report/recommendations as written:

AAPM
ACNP/SNM
ASNC
DVA
NM
MHafermann (Virginia Mason Cancer Ctr)
DJones (Northwest Medical Physics Ctr)
CMarcus (UCLA)
CPerez (Washington Univ)
JRieke (Virginia Mason Cancer Ctr)
DSchumacher (Northwest Medical Physics Ctr)

Support IOM report/recommendations, but as applied to all materials:

FL (R)
NY (H)
NY (L)
ACNP-CA

Respondents not in agreement with IOM recommendations:

Support concept of regulatory reform[2] but retain Federal authority[3]:

DHHS oversight: ACMUI, CA

NRC oversight: EPA, ACMP, ACR, HI, KY, NY(E), UT, WA, GPoteat(OH)

Unspecified oversight: DHHS[4], DOD, ACC, AK, DE, TN, VA, WY

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[2] It should be pointed out that the degree of regulatory reform perceived to be necessary by different respondents varied from recognizing the concerns raised by the IOM to a drastic change in the approach to regulation of medical uses.

[3] Some States (e.g., VA, WY, DE) were primarily concerned with the substantial financial impact of the NAS recommendations and the issue of unfunded Federal mandates, rather than more specific concerns on the overall approach for regulation.

[4] DHHS did not address the issue of regulatory reform, Federal authority, or concerns raised by the IOM, but focussed on the implications of the recommendation to DHHS.

Support concept of regulatory reform, but after additional analysis:

CBeasley (St John's Regional Health Center)
MSelikson (RSO, Univ. of Pennsylvania)
NJ
St. John's Hospital

Support concept of uniformity for all radioactive materials regulation with Federal oversight:

CRCPD
OAS
APhA
AR (NRC as lead agency)
FL (H)
IL
MA
MD
TX

Respondents indicating report under review

DOL
AS
VT

Enclosure 3

Specific Comments on IOM Report

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DVA	The Veterans Health Administration generally concurs with and endorses the findings and recommendations of IOM. Principal concern is lack of specifics regarding regulation of Federal entitities and also the regulation of medical research programs.
	New Mexico	Agrees with IOM recommendation that Congress remove regulation of possession and use of material subject to AEA from NRC's purview. Supports leadership role of DHHS so long as all states maintain regulatory programs that measure comprehensive standards of performance and effectiveness.
	AAPM	AAPM fundamentally supports position, conclusions, and recommendations of the IOM report. NRC should be removed from its current regulatory role for medical use. Establish programs for implementing States' regulations monitored by appropriate Federal health agency with assistance of user community and professional organizations.
	ACNP/SNM	The ACNP and SNM believe the report proposes a sound and thoughtful approach to the regulation of nuclear medicine and urges NRC to implement the IOM recommendations, allowing for comment on specific means to achieve implementation.
	ASNC	Concur with the IOM's conclusions and support their recommendations for a uniform policy to be set at Federal level which can be enforced by the States. DHHS should include medical radiation safety as part of its health care management plan.
	MHafermann	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DJones	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	CMarcus	Supports the IOM report and expresses disagreement with statements made by Robert Adler in his supplemental statement (Appendix L)
	CPerez	Expresses strong support for many of recommendations.
	JRieke	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	DSchumacher	Supports recommendations proposed by IOM committee.
Support IOM report/ recommendations, but as applied to all materials	Florida (Rad. Control)	Support idea of delegating regulation of medical byproduct material to states in addition to all agreement materials.
	New York (Dept. Health)	Support the IOM's conclusion that the regulation of medical use of byproduct materials should be carried out at the state level. Encourages the NRC to not limit its response to the IOM report to the narrow medical focus of the report.
	New York (Dept. Labor)	Supports the IOM's recommendation that NRC discontinue regulation of medical use of byproduct materials, but considers it illogical to limit the recommendation to this one area (should include nuclear pharmacies, manufacturers, distributors, and industrial users)
	ACNP-CA	NRC's entire materials program should be given to the States and Federal entities

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support concept of regulatory reform but retain Federal authority	ACMUI	ACMUI indicated a preference for a variant of the IOM preferred alternative in which there would be substantial Federal oversight of State programs with a mechanism to ensure compliance of States and users. State programs should be monitored by a Federal agency with overall medical use perspective (DHHS).
	DHHS	Report does not make a compelling public health argument for DHHS taking on a substantial new role. The probability is low that Congress would provide adequate resources. DHHS does not support the recommendation.
	DOD	Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished in favor of a voluntary or State-operated system.
	EPA	Report reflects the concerns of the regulated community more than the public at large. There may be aspects of NRC's program that can be improved, but NRC should continue to assure public is protected.
	ACC	Transfer of oversight of the medical use of isotopes to the States seems reasonable. However, strongly encourage Federal oversight of this state initiative. An obvious drawback would be if all States had separate regulations for licensure and compliance.
	ACMP	Supports the need for a drastic change in regulation of radiation in medical use including use of Advisory Panels (comprised of users, manufacturers, and public) to determine the regulatory framework to be applied uniformly in medical profession. Current regulations should be modified.
	ACR	In lieu of Congressional action to eliminate NRC's medical use program, the ACR believes that NRC's medical use program must be rebuilt and its objectives thoroughly reassessed.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Alaska	This would not be a cost effective nor efficient reform for Alaska. It is in the best interest of the State to support the existing method of regulating nuclear medicine licensees by a Federal agency.
	California	In view of split regulatory authority at federal level and apparent reluctance of NRC to expand jurisdiction, agree that Congress remove NRC's authority. DHHS should be given authority to ensure that every state maintains a radiation program that meets minimum, comprehensive, consensus standards of performance and effectiveness.
	Delaware	The impact of the IOM recommendations would be substantial in terms of our increased need for funding, staffing, training and infrastructure requirements.
	Hawaii	Does not have resources or capability to adequately implement regulation of byproduct materials. Without assistance (training and development) to States, the removal of NRC's authority may significantly jeopardize public health and safety.
	Kentucky	A better approach would be to have NRC revise its medical program to go along with the recommendations the Institute has given in preferred alternative D.
	New York (Dept. Environ. Conservation)	Many unforeseen consequences may occur if AEA is modified. Commission should proceed cautiously in pursuing IOM recommendations that may alter the present AEA.
	Tennessee	While the findings of the Committee have some merit, there is no conclusive support provided to document them. Sweeping changes are not well thought out and may result in chaos.
	Utah	State legislatures may view this as another unfunded Federal mandate and may provide no additional support to the State program. Medical community should work with NRC, States, and other parties to resolve the regulation issue.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Virginia	The Commonwealth is in no position to assume any additional unfunded Federal mandates. Could only assume regulatory responsibility if NRC provides funds to defray cost of implementing the program.
	Washington	NRC should focus on radiation safety of worker and non-patient public (oversight of production, distribution, and handling of byproduct materials) while protection of patient is best handled through State boards of medicine and pharmacy.
	Wyoming	The conclusions of the report neglect the considerable hardship to be incurred by smaller, less populous, and less affluent States. Only through continued Federal regulatory participation can the goals of uniformity and public access to safe medical procedures be achieved.
	GPoteat	Potential decrease in safety may result from a transfer to State regulators of NRC's authority. Minor changes are necessary but overall NRC's regulations balance the need to protect workers, patient and the public with the requirements of medical practice.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform, but after additional analysis	New Jersey	If NJ chose not to become an Agreement State, public may not be assured of adequate protection. If adopting the recommendations, NRC and Congress should not act precipitously, but allow the States to prepare for assuming regulatory programs in orderly fashion.
	University of Pennsylvania	Before moving in the direction of a State-based decentralized system, a better evaluation of potential both for increased risk to the public and increased cost to the medical industry is necessary.
	St. John's Hospital	Urges NRC to give every consideration to IOM report, particularly the review of risk assessment.
	CBeasley	The report missed part of its stated intended goal to review the current system of regulation (the issues of uniformity among states was not fully explored). Proposes review in more detail the regulation of non-nuclear medicine radiology and question of uniformity between states.
Support concept of uniformity for all radioactive materials regulation with Federal oversight	OAS	At NRC/Agreement State Technical Workshop, consensus was reached that all radiation use (regulated currently under NRC, FDA, EPA, and OSHA) should be consolidated under a single Federal agency.
	CRCPD	Absence of federal authority in medical use area may have immediate and undesirable consequences on citizens in non-Agreement States and long term consequences for Agreement States trying to maintain a nationally consistent program. CRCPD does not support automatic selection of DHHS as the agency to provide leadership role.
	APhA	All ionizing radiation should be grouped together under a uniform regulation. Transfer responsibility for medical uses of any ionizing radiation to the States. Some Federal authority should remain over the medical uses of ionizing radiation (NRC or a similar federal agency).

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of uniformity for all radioactive materials regulation with Federal oversight (continued)	Arkansas	The NRC should consider alternative A2 (status quo modified). If major changes are to be made, centralization of regulation within one Federal agency (NRC) would be the best approach for all uses of radiation. Congress would be required to expand the role of NRC and a change in the agency would be necessary. Expand current Agreement State program.
	Florida (Health Office)	Support idea that regulatory authority of all agreement materials be turned over to the states with consolidation of federal radiation oversight, guidance, and regulatory functions into one agency, not necessarily DHHS.
	Illinois	Prefer CRCPD proposed new organizational concept that recommends some consolidation of all radiation regulatory functions at federal level. Revise QM and pharmacy rules. Prepare white paper to use as a policy basis to clearly delineate the respective authority and responsibilities of various Federal and State agencies.
	Maryland	Rather than revoke NRC's authority and repeal the Federal regulations, such authority should be expanded to incorporate NARM, and the Federal regulations should be thoroughly reviewed and amended to clarify regulatory responsibility. DHHS does not have necessary expertise.
	Massachusetts	Do not support elimination of all aspects of NRC's medical program, but support relaxation of overly prescriptive and unnecessarily costly requirements. Support intent of single Federal agency providing a single leadership role but do not support automatic selection of DHHS.
	Texas	The basis for the report's recommendations do not seem to be substantiated. The merging of all federal radiation control oversight into a single regulatory program should be considered. The NRC should enhance the partnership with the States to jointly determine compatibility requirements.

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 10—HUMAN USES OF BYPRODUCT MATERIALS

Regulation of the Medical Uses of Radioisotopes; Statement of General Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the FEDERAL REGISTER (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 FEDERAL REGISTER notice. The comments are discussed in Section II. Copies of the comments may be examined in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:[1]

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public *and* the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific

[1] NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term *byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term *source material* means (1) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. *Special nuclear material* means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, or (2) any material artificially enriched by any of the foregoing, but does not include source material.

Enclosure 5

to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of *policy* not *authority*, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of *authority*, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of *policy*, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.[1] This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

[1]The term general public in this statement specifically excludes patients.

The NAS-BEIR[2] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgment. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

[2]National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences—National Research Council*, Washington, D.C. (1972).

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical devices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to

those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. Discussion of Public Comments

A. Comments on the Policy Statement

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diagnosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. Comments on Specific Issues

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the Federal Register for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

(FR Doc. 79-4148 Filed 2-8-79; 8:45 am)

[8010-01-M]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33-6020, IC-10571]

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

Short Form for the Registration of Securities

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission is adopting amendments to the short form S-16 in order to further expand its use for primary offerings by subsidiaries of certain issuers. The amendments will enable certain subsidiary issuers who otherwise satisfy the general requirements of the form to use the form for primary offerings of securities if they have outstanding securities held by non-affiliates with an aggregate principal amount or market value of at least $250 million, the offer or sale of which has been registered pursuant to the Securities Act of 1933, and at least 1,000 security holders who receive annual reports containing certified financial statements of the issuer.

EFFECTIVE DATE: March 15, 1979; however, persons desiring to use the revised form prior to that date may do so, provided they comply with all applicable provisions of the new form.

FOR FURTHER INFORMATION CONTACT:

Steven J. Paggioli, Office of Disclosure Policy and Proceedings, Division of Corporation Finance, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549, (202/376-8090).

SUPPLEMENTARY INFORMATION: On September 7, 1978, the Commission authorized for publication proposed amendments to Form S-16 (17 CFR 239.27), a form for the registration of certain securities under the Securities Act of 1933 ("Securities Act") (15 U.S.C. 77a et seq. as amended by Pub. L. No. 94-29 (June 4, 1975)). Securities Act Release No. 5974 (43 FR 41052) invited comments on these proposed amendments which would generally expand the class of subsidiary issuers eligible to use the form for primary offerings to include those whose parents do not guarantee their securities as to principal and interest and also allow the use of the form for the registration of equity securities of such issuers. In addition to the general requirements for the use of Form S-16 and the market capitalization requirement of the parent, the eligibility criteria proposed in Release 33-5974 for subsidiaries included (1) the existence of outstanding debt or equity securities held by nonaffiliates, with an aggregate principal amount or market value of at least $250 million, the offer or sale of which has been registered pursuant to the provisions of Section 6 of the Securities Act, (2) compliance with certain specified earnings to fixed charges ratios (varying according to industry) for the most recent fiscal period reported, and (3) the existence of at least 2,500 security holders who receive annual reports from the issuer containing certified financial statements.

This release contains a general discussion of the background and purpose of the amendments proposed in Release No. 33-5974, the comments received on the proposal,[1] and the Commission's response to those comments. The text of the amendments should be consulted for a complete understanding of the new provisions.

BACKGROUND AND PURPOSE

On April 11, 1973, the Commission in Securities Act Release No. 5923 (43 FR 16672) announced the adoption of amendments making Form S-16 available for the first time for primary offerings by issuers under certain specified conditions. The amendments reflected in part the recommendation of the Advisory Committee on Corporate Disclosure ("Advisory Committee") that Form S-16 be available for the registration of securities to be offered directly to the public by a "small top tier of companies * * * which usually provide high quality corporate communication documents, including 1934 Act reports, * * * whose corporate information is widely disseminated * * * (and) which are widely followed by debt and equity analysts."[2] One of the major conditions ultimately adopted in furtherance of identifying a category of such issuers was the requirement that an issuer have outstanding voting stock held by nonaffiliates with an aggregate market value of at least $50 million, the relation of this requirement to the issuer's voting stock, however, was criticized by several commentators who noted that many companies with no publicly held voting stock may be better established than those with such stock.[3] Accordingly, the amendments that were adopted in Release 33-5923 allow the use of Form S-16 by issuers with no publicly held voting stock when the issuer is a majority owned subsidiary and its parent meets the $50 million market capitalization requirement and guarantees the securities as to principal and interest.

As noted in Release 33-5974, subsequent to the adoption of these amendments, further comments were received to the effect that several subsidiary issuers, such as finance and utility companies, are among the largest and best established business concerns and frequently finance externally. Substantial public information is available regarding these issuers in view of their previous issuance of securities and reporting history. It was further suggested that, in view of the quality of these subsidiary issuers, parent companies generally need not and do not guarantee their securities. In light of these concerns, the Commission in Release 33-5974 proposed amendments to the form that would enable subsidiary issuers to use the form for primary offerings in the absence of a parent guarantee provided that they meet certain criteria intended to assure the satisfaction of similar standards of information dissemination and significant interest by securities professionals that must be met by their parent companies. These additional criteria proposed in Release 33-5974, the comments received thereon, and the Commission's response as reflected in the final amendments are discussed immediately below.

ADOPTION OF REQUIREMENT OF $250 MILLION AGGREGATE PRINCIPAL AMOUNT OR MARKET VALUE OF OUTSTANDING SECURITIES

In addition to the general requirements that the issuer satisfy the rules for the use of Form S-7[4] and that its

[1] See comments collected at File No. S7-754.

[2] Report of the Advisory Committee on Corporate Disclosure to the Securities and Exchange Commission ("Report"), House Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess., Committee Print 95-29 at 433-34.

[3] See comments collected at File No. S7-725.

[4] Generally, an issuer may use Form S-16 if it meets the conditions for use of Form S-7, which require an issuer (a) to have a class of securities registered under section 12 or be subject to the reporting requirements of section 15(d) of the Securities Exchange Act of 1934; (b) to have been subject to the requirements of sections 12 or 15(d) and to have filed all applicable reports for 36 calendar months prior to filing the registration statement and have timely filed all required reports for the past 12 calendar months; (c) to have had no default in payments on preferred stock, indebtedness for borrowed money or long-term leases during the past 36 months; and (d) to have had consolidated net income of at least $250,000 for 3 of the last 4 fiscal years, including the most recent fiscal year. See 17 CFR 239.26.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 8 1996

The Honorable Shirley Ann Jackson
Chairman
Nuclear Regulatory Commission
Washington D.C. 20555-0001

Dear Ms. Jackson:

This is in response to your letters to me and to Commissioner Kessler requesting the Department's review of the report of the Institute of Medicine (IOM) entitled "Radiation in Medicine: A Need for Regulatory Reform." We appreciate the opportunity to comment as your Commission assesses its Medical Use Program. I regret the delay in responding.

The report examines several alternatives to your agency's current regulation of the medical use of radioactive materials generated by nuclear reactors ("byproducts"). It recommends that the states take on this obligation in addition to their current range of regulatory responsibilities for the medical use of other radiation sources. It suggests that this Department provide leadership and collaboration as the States develop new guidelines and model state regulations for this purpose.

We do not believe, however, that the report makes a compelling public health argument for this Department's taking on such a substantial new role. We would also comment that, in the unlikely event that new legislation for such a purpose should be enacted, the probability is low that the Congress would provide the Department with resources commensurate with such responsibilities. Therefore, we cannot support the recommendation.

We trust these comments are helpful and that the process of public comment and review of the IOM report will prove useful.

Sincerely,

Donna E. Shalala

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