UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 20, 1996

IA 96-105

Thomas Keys, M.D.
[Home Address Deleted
10 CFR 2.790]

SUBJECT: NRC INSPECTION REPORT NO. 030-02649/96001(DNMS) AND OI INVESTIGATION REPORT NO. 3-96-025

Dear Dr. Keys:

This refers to the NRC inspection completed on August 6, 1996, and to the investigation conducted by the NRC Office of Investigations (OI) at the Cleveland Clinic Foundation facilities (CCF) in Cleveland, Ohio. The inspection report was sent to CCF on September 16, 1996. A copy of the synopsis of the OI investigation was included with the inspection report. On October 22, 1996, a transcribed predecisional enforcement conference was held with you and other CCF staff members to discuss the violations, their causes, and corrective actions.

Based on the inspection and OI investigation findings, and the information presented during the predecisional enforcement conference, the NRC has determined that two deliberate violations of NRC requirements occurred. The violations are described in detail in the subject inspection report (Enclosure 1). As Director of Quality Management, you were aware that the annual refresher training for laboratory personnel and the senior management program audit had not been conducted, but failed to assure that prompt and effective action was taken to correct these deficiencies. At the enforcement conference, it was apparent that the violations were not addressed because the available resources were used to manage more pressing safety significant issues in your licensed program. The former radiation safety officer (RSO), who occupied a position that reports to you, identified the violations and the resource issue to you and, subsequently, to the other members of the Radioisotope & Radiation Safety Committee (RRSC) as well; however, the RRSC allowed the violations to continue without taking immediate corrective action. Therefore, the violations are deliberate on the part of yourself and other CCF managers.

These violations are of regulatory concern because of their willful nature and because licensee officials allowed them to continue. Incumbent upon the licensee's management staff is the responsibility to protect public health and safety, and the health and safety of Cleveland Clinic Foundation employees, by ensuring that all NRC requirements are met. Because this was not done, CCF was cited with a Severity Level III problem accompanied by a proposed civil penalty of $5,000 (Enclosure 2).

PUBLIC IE-07

In addition to the circumstances noted above, the NRC acknowledges your cooperation and candor during the inspection, investigation, and the conference and is not initiating an enforcement action against you in this matter. While formal enforcement action is not being taken against you, you should be aware that the NRC's regulations allow enforcement actions to be taken directly against persons who, through their deliberate misconduct, cause a licensee to be in violation of NRC requirements. Deliberate misconduct includes an intentional act or omission that the person knows constitutes a violation of a requirement, procedure or training instruction. An order may also be issued to an individual to prevent him or her from engaging in licensed activities at all NRC-licensed facilities. A violation of these requirements, as set forth in 10 CFR 30.10, "Deliberate Misconduct" (Enclosure 3), may also lead to criminal prosecution. Similar failures in the future could lead to formal NRC enforcement action against you.

You are not required to respond to this letter. However, if you choose to provide a response, please submit it to me within 30 days of the date of this letter at U. S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, records or documents compiled for enforcement purposes are placed in the NRC Public Document Room (PDR). A copy of this letter, and your response if you chose to submit one, will be placed in the PDR with your home address removed.

If you have any questions or comments, please contact Mr. Bruce Burgess of my staff at (630) 829-9666.

Sincerely,

/s/ W. L. Axelson (for)

A. Bill Beach
Regional Administrator

Enclosures: 1. Inspection Report
No. 030-02649/96001
2. Notice of Violation and Proposed
Imposition of Civil Penalty
3. 10 CFR 30.10

cc w/o encl: Cleveland Clinic Foundation

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SYNOPSIS

This investigation was initiated by the Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region III (RIII), on May 13, 1996, to determine whether the Radiation Safety Officer (RSO) at the Cleveland Clinic Foundation (CCF), deliberately violated conditions of the CCF's NRC material license by failing to timely conduct a senior management audit and did not conduct annual refresher training for laboratory radiation workers from July 1993 through April 1996. Additionally, the investigation was to determine to what extent CCF management were aware of the alleged violations.

Based on the evidence developed during the investigation, it is concluded that the RSO and the CCF Director of Quality Management deliberately failed to conduct an annual senior management audit for 1995 and deliberately failed to conduct annual refresher training as required by conditions of the NRC material license.

September 16, 1996

EA 96-289

Floyd D. Loop, M.D.
Chairman of the Board of Governors
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

SUBJECT: NRC INSPECTION REPORT NO. 030-02649/96001 (DNMS)
AND INVESTIGATION REPORT NO. 3-96-025

Dear Dr. Loop:

This refers to the inspection conducted on March 19-22, 1996, with continuing NRC review through August 6, 1996, at the Cleveland Clinic Foundation facility, Cleveland, Ohio. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with those members of your staff identified in the enclosed report.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

This also refers to an investigation conducted by the NRC Office of Investigations (OI) to determine if your Director of Quality Management and Director of Radiation Safety deliberately violated NRC requirements pertaining to annual refresher training and annual senior management audits. A synopsis of the results of the investigation is enclosed.

Based on the results of the inspection and investigation, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (60 FR 34381; June 30, 1995). Two apparent violations pertain to the failure to implement annual refresher training for radiation workers from 1993 to 1996, and to perform an annual senior management audit in 1995. These apparent violations are of significant concern because they were apparently caused by two of your management officials who were knowledgeable of Cleveland Clinic Foundation's NRC-licensed requirements regarding refresher training and audit programs and who deliberately violated those requirements. The third apparent violation pertains to failure to secure from unauthorized removal or limit access to licensed materials that were stored in unrestricted areas.

Three additional violations were also identified during this inspection but are not being considered for escalated enforcement at this time.

The apparent violations are described in the enclosed report and will be discussed with your staff in a transcribed predecisional enforcement conference. Consequently, a Notice of Violation is not presently being issued for these inspection findings. The number and characterization of the apparent violations may change as a result of further NRC review.

The transcribed predecisional enforcement conference has been scheduled for October 8, 1996, at 1:00 p.m. in the Region III office, 801 Warrenville Road, Lisle, IL. The decision to hold an enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The purposes of this conference are to discuss the apparent violations, their causes and safety significance; to provide you the opportunity to point out any errors in our inspection report; and to provide an opportunity for your staff to present your proposed corrective actions. In particular, we expect you to address specific action to ensure licensed activities are conducted in full compliance with all NRC requirements and license commitments. In addition, this is an opportunity for you to provide any information concerning your perspectives on: (1) the severity of the violations, (2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.B.2 of the Enforcement Policy, and (3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In addition to the NRC findings identified in the March 1996 inspection, we would like to discuss during the predecisional enforcement conference the violations identified and your subsequent corrective actions regarding an iodine-131 contamination incident which occurred on August 27, 1996. The incident resulted in the uptake of iodine-131 to three Cleveland Clinic Foundation employees and off-site contamination at several locations. Consequently, you will be receiving an inspection report for your review describing NRC's findings prior to the October 8, 1996 conference.

To assist you in preparing for the predecisional enforcement conference, we are enclosing a copy of the NRC Enforcement Policy and an Information Notice which provides guidance on the development and implementation of corrective actions.

Please contact Mr. Michael LaFranzo at telephone number (630) 829-9865 if you have any questions.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and enclosures 1 and 2 will be placed in the NRC Public Document Room.

Sincerely,

Original signed by Cynthia D. Pederson

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

License No. 34-00466-01
Docket No. 030-02649

Enclosures: 1. Inspection Report
No. 030-02649/96001 (DNMS)
2. OI Synopsis
3. Enforcement Policy (NUREG-1600)
4. Information Notice 96-28

cc w/encls: Judy McKenna, RSO
Dr. Thomas Key, Director
of Quality Management

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02649/96001(DNMS) Program Code 02110

Docket No. 030-02649

EA No. 96-296

License No. 34-00466-01 Priority 1 Category G1

Licensee: Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

Inspection Conducted: March 19-22, 1996, with continuing NRC review through August 6, 1996.

Inspectors: B. J. Holt for
Michael LaTranzo
Radiation Specialist
Date 9/16/96

B. J. Holt for
Wayne Slawinski
Senior Radiation Specialist
Date 9/16/96

Approved By: B. J. Holt
B. J. Holt, Chief
Nuclear Materials Inspection
Branch 1
Date 9/16/96

Inspection Summary:

Inspection during the period March 19-22, 1996, with continuing NRC review through August 6, 1996 (Report No. 030-02649/96001(DNMS))
Areas Inspected: This was an unannounced routine inspection of the licensee's radiation safety program with primary focus on research related activities. The inspection included a review of the following: organizational and management controls, radiation safety training, management audits, security, receipt, distribution and inventory of radioactive materials, radioactive effluent and waste disposal program, internal and external radiation monitoring program, storage facilities, and the laboratory audit program. The inspection also included a limited review of the radiopharmaceutical therapy Quality Management Program (QMP) and the licensee's use of two cesium-137 irradiators.

Results: Six apparent violations of NRC requirements were identified and consist of: (1) failure to conduct annual refresher training for laboratory radiation workers from July 1993 through March 1996 (License Condition 37); (2) failure to conduct an annual senior management audit in 1995 (License Condition 37); (3) failure to secure radioactive material from unauthorized removal or access (10 CFR 20.1801); (4) failure to fully establish and implement a system for ordering and receiving radioactive material (License Condition 37); (5) failure to limit authorized user possession of radioactive material to quantities authorized by the Radioisotope and Radiation Safety Committee (License Condition 37); and (6) failure to evaluate the solubility of radioactive material prior to discharge to the sanitary sewerage system (10 CFR 20.1501).

NOTE: License Condition 37 referred to in this report is referenced in Amendment No. 62 of License No. 34-00466-01. This was the license Condition in effect at the time of the on site inspection.

DETAILS

1. Persons Contacted

* Penelope Ott, Administrator, Office of Quality Management
*+ Thomas Keys, M.D., Director of Quality Management
*+ Donald Neuman, M.D., Ph.D., Chairman of the Radiation Safety Committee
*+ Judy McKenna, Director of Radiation Safety/Radiation Safety Officer
* Mark Mettler, Radiation Safety Coordinator
* David Burkett, Medical Health Physicist
* Jill Stanley, Research Administrative Coordinator
* Guy Chisolm, Ph.D., Staff, Department of Cell Biology/Radiation Safety Committee Member
* Gopal Saha, Director of Nuclear Chemistry and Pharmacy
* Jim Shores, Supervisor, Police
* Doug Koman, Police/Security, Protective Services

* Denotes those individuals present during the site exit meeting conducted on March 22, 1996.
\+ Denotes those individuals contacted by telephone for additional inspection related information between March 22 and May 14, 1996.

In addition, NRC inspectors interviewed numerous Cleveland Clinic Foundation staff which included radiation safety staff, authorized users, supervisors of various departments, laboratory technicians and other radiation workers, nuclear medicine technicians, engineers, and maintenance personnel.

2. Program Summary and Inspection History

The Cleveland Clinic Foundation (licensee) is authorized by NRC License No. 34-00466-01 to possess and use byproduct material for medical use as described in 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500, and iridium-192 sealed sources for use in a High Dose Rate (HDR) remote afterloading brachytherapy device for the treatment of cancer in humans. The license also authorizes use of byproduct material with Atomic Numbers 1 through 83, including increased possession limits for several specifically listed radionuclides for research and development as defined in 10 CFR 30.4, instrument calibration, and animal studies. The license also authorizes use of cesium-137 sealed sources in irradiator devices for non-human irradiator studies.

On July 19, 1991, the NRC issued a Notice of Violation and a $7,500 civil penalty to the licensee for violations involving a phosphorus-32 spill that resulted in radiation exposures to individuals and off-site contamination. The incident was indicative of a programmatic breakdown, in that the NRC found 14 violations related to ineffective control, assessment, and oversight of the radiation safety program by the management of Cleveland Clinic Foundation, members of the Radioisotope Committee and the Radiation Safety Officer.

In January 1992, a special inspection was conducted to review a licensee's reported brachytherapy misadministration. No violations were identified; however, several areas of concern were noted.

In August 1992, a routine safety inspection identified four violations: (1) failure to use absorbent pads when working with radioactive materials (repeat violation), (2) failure to provide training to individuals who used the J. L. Shepherd and Associates Mark I series irradiator (repeat violation), (3) failure to perform bioassays of individuals who used I-125 in excess of 1 millicurie (repeat violation), and (4) failure to determine the annual average concentration of radioactive material in air discharged to unrestricted areas. In addition, the licensee made a commitment to revise the laboratory radiation safety procedures manual to delineate appropriate requirements for surveys, bioassays and other good health physics practices. This revision was to have been completed by the end of 1992.

In January 1993, a special safety inspection identified two violations: (1) failure to properly implement the licensee's Quality Management Program and (2) failure to include written policies and procedures for identifying, evaluating, and correcting unintended deviations from written directives.

In September 1993, a routine safety inspection identified two violations: (1) failure to fully implement the Quality Management Program and (2) failure to calculate the amount of time needed after a spill of radioactive gas to reduce concentration levels in the room to acceptable levels.

In January 1995, a routine safety inspection identified one violation for failure to evaluate an extremity dose to a worker to demonstrate compliance with regulatory dose limits. In addition, an area of concern was identified regarding the completion and distribution of a Radiation Safety Manual for the licensee's research laboratories as committed by the licensee to the NRC in August 1992. The licensee committed to completing and distributing the Radiation Safety Manual by June 1995.

In August 1995, a special inspection was conducted to review a brachytherapy incident. No violations were identified.

3. Organization and Management Controls

Research and development activities are reviewed and approved by the Radioisotope and Radiation Safety Committee (RRSC). The Director of Radiation Safety (hereafter known as the Radiation Safety Officer (RSO)) reports to the Director of Quality Management and the RRSC. The RSO and Director of Quality Management meet at least monthly to review policy and procedures and evaluate the status of the radiation safety program.

The RSO's staff consists of 9 full time staff members. The radiation safety office performs several services for the research laboratories

including approval, receipt and distribution of radioactive materials, and quarterly lab audits.

The RRSC is also responsible for oversight of the nuclear medicine and radiation oncology programs at the Cleveland Clinic Foundation and is supported by the radiation safety office.

4. Training Program

The licensee is required to perform initial and annual refresher training for all research laboratory workers. Specifically, Condition 3 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 8 of the letter dated May 12, 1992, states that training for individuals who handle radioactive material other than Part 35 material, will be performed as outlined in Appendix A, Regulatory Guide 10.8, Revision 2, commensurate with their responsibilities. In addition, Item 8 also states that laboratory workers will receive training at least annually which will include lecture, discussion and demonstration.

The licensee has implemented an initial training program for all new laboratory workers that consists of a 2-3 hour lecture and discussion provided by the radiation safety office. The inspectors independently verified during laboratory audits that laboratory workers had an adequate working knowledge of practices and procedures regarding the safe use and handling of radioactive material. However, at the time of the inspection in March 1996, the licensee had not implemented a refresher training program as required by License Condition No. 37 which references letter dated May 12, 1992. The RSO confirmed the retraining program had not been implemented since July 1992, and indicated the reasons were due to inadequate staff resources and other more pressing safety needs. According to the RSO, the RRSC was informed in December 1994 that the annual refresher training had not been implemented. Although no timetable was provided to the RRSC at that time, the licensee planned to implement the retraining program in 1995. In December 1995, the RSO informed the RRSC that implementation of the annual refresher training was postponed until 1996. According to the licensee, the first refresher training session was to take place in March 1996; however, scheduling problems further delayed the implementation of the program.

Failure to provide annual refresher training to laboratory workers is an apparent violation of License Condition 37.

In April 1996, the radiation safety office provided retraining to authorized users and their designees as described in Appendix A of Regulatory Guide 10.8. Authorized users and their designees were requested to retrain those laboratory workers whom they supervise. The licensee stated that starting in 1997, all laboratory radiation workers will receive annual refresher training by the radiation safety office. As of May 9, 1996, approximately 85% of the authorized users and their designees had been trained by the radiation safety office.

One apparent violation of NRC regulatory requirements was identified.

5. Management Audits

Three of the licensee's senior management representatives are required to perform an audit of the radiation safety program annually. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 7.1 of the letter dated May 12, 1992 states that the Director of Quality Management, Director of Radiation Safety and Administrator of Quality Management will, at least annually, conduct a facility tour/audit with a summary of all findings and recommendations presented to the RRSC for review, discussion, and appropriate actions.

Programs required to be audited by senior management include the nuclear medicine department, radiation oncology department, research laboratories and the radiation safety department. During each program audit, senior management is required to review various records, postings, implementation of radiation safety practices by radiation workers and compliance with reporting requirements. Audits were performed by senior management annually in 1992 through 1994; however, no audit was performed in 1995.

According to the RSO, senior management audits have historically been scheduled for the end of the calendar year. Although an audit was scheduled for December 1995, the RSO and Director of Quality Management determined there was insufficient time to conduct the audit as planned. Additionally, the RSO and Director of Quality Management determined that the senior management audit, in its current form, was not significantly contributing to the radiation safety program. Therefore, the licensee decided not to conduct the audit in 1995 but rather to amend its NRC license to remove or modify the senior management audit requirement. At the time of the inspection in March 1996, an audit by senior management had not been conducted since 1994, nor had the licensee requested an amendment to its NRC license to revise the audit requirement.

Failure of the Director of Quality Management, Director of Radiation Safety and Administrator of Quality Management to perform an audit of the radiation safety program in 1995 is an apparent violation of License Condition 37.

In July 1996, the licensee hired an independent contractor to perform the audit, as authorized by License Condition No. 37 and letter dated May 12, 1992.

The licensee plans to remove or modify the requirement for the annual senior management audits in a future amendment request to the NRC.

One apparent violation of NRC regulatory requirements was identified.

6. Security

The licensee is required to secure licensed material from unauthorized use. Specifically, 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

The NRC inspectors performed a security tour of research building (FF) at Cleveland Clinic Foundation between 5:30 and 6:20 p.m. on Tuesday, March 19, 1996. A licensee representative accompanied the inspectors during the security tour. The tour included walking through hallways to determine if rooms were properly posted for radioactive material and radioactive material was secure or otherwise attended by authorized personnel. If the laboratories were posted, unlocked and a laboratory worker could not be located by the inspectors, the inspectors attempted to determine if locks or securing devices were evident on containers (refrigerators, cabinets, etc.) to prevent access to radioactive material. The inspectors noted several unattended, unlocked or open laboratories posted as radioactive material use areas, containing unknown quantities of radioactive material housed in unlocked refrigerators and freezers.

At approximately 6:20 p.m., the inspectors and licensee representative exited the building through the west ground floor door. Upon exiting, the inspectors noticed the door's electronic key card security system, which was to have locked the door after 6:00 p.m. with key card access only, was not functioning. As a result, a key card was not necessary to enter the building.

On March 20, 1996, the inspectors requested from the radiation safety office a listing of radioactive material in each laboratory which was found posted, unlocked and unattended by laboratory workers. According to the radiation safety office, five laboratories contained unsecured radioactive material in refrigerators or freezers which were accessible to the inspectors as listed below:

Building/Room	Licensed Material	Activity
FF5-12	Chromium-51	5.00 millicuries
FF4-62	Phosphorus-32	1.36 millicuries
	Calcium-45	0.87 millicuries
FF3-01	Hydrogen-3	10.37 millicuries
	Iodine-125	0.28 millicuries
	Phosphorus-32	1.00 millicuries
	Sulfur-35	0.61 millicuries
FF2-19	Iodine-125	2.65 millicuries
FF2-51	Iodine-125	0.78 millicuries
	Chromium-51	1.36 millicuries

Failure to secure from unauthorized removal or limit access to licensed materials in storage is an apparent violation of 10 CFR 20.1801.

During NRC audits of approximately 30 research laboratories, authorized users and technicians indicated after normal working hours, the last person leaving the lab is responsible for locking the laboratory doors. However, many of these individuals also stated that they have relied on the electronic key card security system, which controls access to the building, as the security mechanism to comply with licensee and NRC security requirements.

During the licensee's routine quarterly laboratory audits, the radiation safety staff reviews security procedures and practices with laboratory radiation workers and determines if radioactive material is attended and/or secured. However, these audits are performed during normal working hours when labs are normally attended by authorized personnel.

The radiation safety office's policy on security is outlined in the licensee's radiation safety manual. The manual indicates that laboratory radiation workers may leave radioactive material unattended and unsecured for up to 10 minutes. If laboratory radiation workers believe they will be out of the laboratory for longer than 15 minutes, the radioactive material must be secured. The licensee was informed by the inspectors that NRC requirements require that licensed material to be controlled at all times and that a "10 minute rule" is not adequate to comply with NRC requirements.

The RSO contacted each authorized user in the laboratories where radioactive material was found to be unsecured and informed them of the security violations. The remaining users have been or will be informed during annual retraining sessions which are being held this year.

During the site inspection in March 1996, the radiation safety office had contacted Cleveland Clinic Foundation's security division and informed them of the malfunctioning key card system. According to the licensee, the key card security system was repaired for building FF in April 1996.

Following the site inspection, the RSO indicated that the radiation safety office was in the process of developing procedures to perform security spot checks throughout the licensee's facilities where radioactive material is used to verify compliance with NRC security requirements. In addition, the licensee is considering other security mechanisms, e.g. locks on refrigerators and freezers containing radioactive material.

One apparent violation of NRC regulatory requirements was identified.

7. Receipt of Radioactive Material

The licensee is required to establish and maintain a system for the ordering and receiving of radioactive material which shall include the authorized user or department, isotope, chemical form, and activity. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with

statements, representations and procedures contained in a letter dated May 12, 1992. Item 10.6 of the letter dated May 12, 1992, states that the licensee will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2. Item 2 of Appendix K states that the radiation safety office will establish and maintain a system for ordering and receiving radioactive material and that system will include written records that identify the chemical form and activity for each authorized user.

The licensee has a computer database in place which identifies the authorized user, isotope and maximum activity per package that the authorized user is permitted to order. However, the database does not include the chemical form and maximum possession limits which are limited by an authorized users Radioactive Material Authorization form, approved by the RRSC. The radiation safety staff, which approves each order for radioactive material and receives and distributes packages to the various authorized users, does not check to ensure the chemical form of the licensed material ordered is as authorized by the RRSC and that authorized users do not exceed maximum possession limits per nuclide.

Failure to fully establish and maintain a system for ordering and receiving radioactive material is an apparent violation of License Condition 37.

The license plans to purchase and install a software package that will track licensed material, orders, use and disposal throughout the licensee's facility and improve radioactive material accountability practices.

One apparent violation of NRC regulatory requirements was identified.

8. Inventory

The licensee is required to limit the quantities of radioactive material possessed by authorized users to those authorized and approved by the RRSC. Specifically, Condition 37 of License No. 34-00466-01 (Amendment 62) requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992. Item 10, Section 16.5, titled "Amendment Request to Radioactive Material Authorization," requires the licensee to limit an authorized users radioactive material possession to specific quantities as approved by the Radioisotope and Radiation Safety Committee (RRSC).

Inspector review of laboratory records and quarterly inventory reports for 1994, 1995 and 1996, identified several cases where authorized users possessed quantities of licensed material greater than that authorized by the RRSC. Examples are provided below:

Authorized User	Isotope	Maximum Inventory Limit(RRSC)	Actual Inventory	Date of Actual Inventory
Dr. Philip Howe	Sulfur-35	25 mCi	79 mCi	12/94
Dr. Ahsan Husain	Sulfur-35	0.5 mCi	1.1 mCi	9/95
Dr. Henry Hoff	Hydrogen-3	20 mCi	31 mCi	3/95
Dr. Alan Wolfman	Phosphorus-32	30 mCi	40 mCi	2/96
Dr. Edward Plow	Chromium-51	12 mCi	20 mCi	1/96

Failure to limit authorized users total possession of radioactive material to quantities approved by the Radioisotope and Radiation Safety Committee is an apparent violation of License Condition 37.

Quarterly inventory reports are received by the radiation safety office from each authorized user which includes the amount of radioactive material for each nuclide possessed by the authorized user as of the date of the inventory. As a self initiated action in January 1996, a radiation safety office staff member reviewed all quarterly inventory reports from all authorized users from the fourth quarter of 1995 and compared possession limits against the radionuclide limits requested by the authorized user and approved by the RRSC. The licensee's review identified that thirteen authorized users were in excess of their possession limits. These findings were summarized in a report dated January 24, 1996; however, the report was not provided to the RSO until a few days prior to the NRC inspection. The RSO did not review the report until the first day of the inspection.

The RSO stated that the licensee will inform the authorized users in excess of authorized possession limits to either dispose of the excess licensed material or request amended possession limits authorized through the RRSC. No timetable was provided to the NRC regarding the above licensee corrective actions.

The licensee plans to purchase the necessary equipment and develop a computerized database that will allow the radiation safety office to track radioisotopes ordered, received, possessed and disposed of throughout the licensee's facility. According to the RSO, the computer program will have the capability to track the amount of licensed material possessed at any one time by an authorized user. However, funding was not approved for this software package as of March 1996.

One apparent violation of NRC regulatory requirements was identified.

9. Radioactive Effluent and Waste Disposal Program

The licensee is required to insure liquid effluent is soluble or biologically dispersible when disposed of in the sanitary sewerage system. Specifically, 10 CFR 20.2003 states, in part, that a licensee may discharge licensed material into a sanitary sewerage if the material is readily soluble or dispersible biological material in water. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in

Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present. As defined by 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

During the inspection, the NRC determined the licensee was not supplying authorized users with the appropriate information regarding the disposal of licensed material into the sanitary sewerage system. Specifically, the licensee did not evaluate the solubility of chemicals tagged with licensed material that were disposed into the sanitary sewerage system. The licensee distributed a radiation safety newsletter where the authorized users were informed that non-soluble licensed material was not to be disposed of in the sanitary sewerage system. However, the licensee did not make a proper evaluation regarding the solubility of licensed material using the guidance equivalent to that in Information Notice 94-07 or other appropriate methodology.

Failure to evaluate the solubility of liquids containing licensed material discharged into the sanitary sewerage system is an apparent violation of 10 CFR 20.1501.

Between January 1994 and December 1995, the licensee has disposed of approximately 371.9 millicuries (13.7 GBq) of various NRC licensed nuclides into the sanitary sewerage system. The inspectors verified five of the most commonly used chemicals which are attached to the nuclides disposed of in the sanitary sewerage system are soluble or biologically dispersible. The licensee plans to add a section in the radiation safety manual regarding solubility of radioactive material disposed of in the sanitary sewerage system at an undisclosed date. The licensee did not indicate what type of information would be included in the revised radiation safety manual. However, as of May 1996, the licensee had not made a full evaluation regarding the solubility or the biological dispersibility of NRC licensed material disposed of via the sanitary sewerage system.

One apparent violation of NRC regulatory requirements was identified.

10. Other Areas Inspected

The inspection included review of other areas of the licensee's radiation safety program including, internal and external radiation monitoring program, storage facilities, cesium-137 irradiators, laboratory audit program, and a limited Quality Management Program (QMP) review.

No apparent violations of NRC regulatory requirements were identified.

11. Exit Summary

At the conclusion of the on-site inspection, the lead inspector conducted a site exit meeting with those individuals denoted in Section 1 of this report. The summary included a discussion of the preliminary findings of the inspection. On May 10 and 14, 1996, the lead inspector individually contacted those individuals denoted in Section 1 of this report regarding NRC findings at the licensee's facility after further NRC review. The licensee did not identify any information reviewed during the inspection as proprietary in nature.

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Cleveland Clinic Foundation
Cleveland, Ohio

Docket No. 030-02649
License No. 34-00466-01
EA 96-289

During an NRC inspection conducted on March 19-22, 1996, with continuing NRC review through August 6, 1996, and the investigation conducted by the NRC Office of Investigations from May 13, 1996 through August 6, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty Associated with Conduct of Training and Audits

Condition 37 of License No. 34-00466-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992.

A. Item 8 of the referenced letter dated May 12, 1992, states that laboratory workers will receive training at least annually which will include lecture, discussion and demonstration.

Contrary to the above, from 1993 through March 1996, laboratory workers did not receive annual training as required. (01013)

B. Item 7.1 of the letter dated May 12, 1992, states that the Director of Quality Management, Director of Radiation Safety and Administrator of Quality Management will, at least annually, conduct a facility tour/audit with a summary of all findings and all recommendations presented to the RRSC for review, discussion, and appropriate actions.

Contrary to the above, the Director of Quality Management, Director of Radiation Safety, and Administrator of Quality Management did not perform a facility tour/audit from December 1994 through June 1996. (01023)

These violations represent a Severity Level III problem (Supplement VI) Civil Penalty - $5,000.

II. Violation Not Assessed a Civil Penalty Associated with Securing and Limiting Access to Licensed Material

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on the evening of March 19, 1996, the licensee did not secure from unauthorized removal or limit access to licensed materials that were stored in unlocked containers (refrigerator freezers) within five unattended research laboratories in the FF Building. The laboratories and licensed materials were readily accessible to the inspectors; therefore, the areas were unrestricted. (02013)

This is a Severity Level III violation (Supplement IV).

III. Violations Not Assessed a Civil Penalty Associated with Possession Limits, Ordering and Receiving Licensed Materials and Surveys

A. Condition 37 of License No. 34-00466-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992.

Item 10, Section 16.5 of the referenced letter, entitled "Amendment Request to Radioactive Material Authorization," requires an Authorized User to limit total possession of requested radioisotopes to those types and quantities approved by the Radioisotope and Radiation Safety Committee.

Contrary to the above, on several occasions between December 1994 and February 1996, Authorized Users exceeded total possession limits for various radioisotopes as set forth by the Radioactive Material Authorization form requested by the Authorized User and approved by the Radioisotope and Radiation Safety Committee. For example, in January 1996, an Authorized User possessed 20 millicuries (740 Mbq) of chromium-51, which exceeded his inventory limit by 8 millicuries (296 MBq). (03014)

This is a Severity Level IV violation (Supplement VI).

B. Condition 37 of License No. 34-00466-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992.

Item 10.6 of the referenced letter, states that the licensee will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

Item 2 of Appendix K states that the radiation safety office will establish and maintain a system for ordering and receiving radioactive material and that system will include written records

that identify the chemical form and activity for each authorized user.

Contrary to the above, prior to March 19, 1996, the radiation safety office did not establish and maintain a system for ordering and receiving radioactive material that included written records that identify the chemical form and activity for each authorized user. (03024)

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.2003(a), which limits the disposal of licensed material by release into a sanitary sewerage system. Specifically, since January 1994, the licensee has discharged liquid containing licensed material into the sewerage system and failed to evaluate the solubility of the material prior to discharge (03034).

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Cleveland Clinic Foundation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the

authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request

withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at Lisle, Illinois,
this 20th day of December 1996

PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

[58 FR 52406]

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83, Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201 as amended, 202, 206, 68 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

GENERAL PROVISIONS

[58 FR 40684]

§ 30.1 Scope.

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by section 81 of the Act. This part also gives notice to all persons who knowingly provide to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 30.10.

[30 FR 8185]

§ 30.2 Resolution of conflict.

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

§ 30.3 Activities requiring license.

Except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in this chapter.

§ 30.4 Definitions.

"Act" means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

"Agreement State" means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. "Non-agreement State" means any other State;

"Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

"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;

"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

54 FR 14051

"Commission" means the Nuclear Regulatory Commission and its duly authorized representatives;

"Curie" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

"Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

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

"Department" and "Department of Energy" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

"Effective dose equivalent" means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

"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;

59 FR 7715

"License", except where otherwise specified means a license for byproduct material issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter;

59 FR 61767

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

54 FR 14051

"Microcurie" means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

"Millicurie" means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second;

"Person" means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244),[1] 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;

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

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

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[1] The Department facilities and activities identified in section 202 are:

(1) Demonstration Liquid Metal Fast Breeder reactors when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(2) Other demonstration nuclear reactors, except those in existence on January 19, 1975, when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(3) Facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from licensed activities.

(4) Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive waste generated by the Department, which are not used for, or are part of, research and development activities.

59 FR 36026

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

54 FR 14051

"Production facility" means production facility as defined in the regulations contained in Part 50 of this chapter;

"Radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;

"Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;

"Radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of byproduct materials;

"Research and development" means: (1) Theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and Parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

"Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

54 FR 14051

"Source material" means source material as defined in the regulations contained in Part 40 of this chapter;

"Special nuclear material" means special nuclear material as defined in the regulations contained in Part 70 of this chapter;

"United States", when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States;

"Utilization facility" means a utilization facility as defined in the regulations contained in Part 50 of this chapter;

58 FR 7715

§ 30.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and Parts 31 through 36 and 39 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 30.6 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in Parts 30 through 36 and 39 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

52 FR 8225

(1) By mail addressed to: Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

53 FR 43419

(2) By delivery in person to the Commission's offices to the Director, Office of Nuclear Material Safety and Safeguards at:

(i) 2120 L Street, N.W., Washington, D.C.; or

60 FR 24549

(ii) 11545 Rockville Pike, Two White Flint North, Rockville, Maryland.

52 FR 38391

(b) The Commission has delegated to the five Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted as specified in paragraph (b)(2) of this section.

58 FR 7715

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR Parts 30 through 36, 39, 40, and 70, to all persons for academic, medical, and industrial uses, with the following exceptions:

52 FR 38391

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in a room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproducts, source, or special nuclear material.

53 FR 2961

(2) *Submissions*—(i) *Region I.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All inquiries, communications, and application for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

52 FR 38391

(ii) *Region II.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement States and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to U.S. Nuclear Regulatory Commission, Region II, Material Radiation Protection Section, 101 Marietta Street, NW, Suite 2900, Atlanta, Georgia 30323.

58 FR 64110

(iii) *Region III.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region III non-Agreement States: Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 801 Warrenville Road, Lisle, Illinois 60532-4351.

59 FR 17464

(iv) *Region IV.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and a territory: Alaska, Hawaii, Montana, Oklahoma, South Dakota, Wyoming, and Guam. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

(v) [Removed 59 FR 17464.]

58 FR 52406

§ 30.7 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(2) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

58 FR 52406

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to Part 20 of this chapter or by calling the NRC Information and Records Management Branch at (301) 415–7230.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

49 FR 19623

§ 30.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq). OMB has approved the information collection requirements contained in this part under control number 3150–0017.

59 FR 61767

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, NRC Form 313 is approved under control number 3150–0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150–0028.

52 FR 49362

§ 30.9 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

52 FR 49362

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

56 FR 40664

§ 30.10 Deliberate misconduct.

(a) Any licensee or any employee of a licensee; and any contractor (including a supplier or consultant), subcontractor, or any employee of a contractor or subcontractor, of any licensee, who knowingly provides to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this part; may not:

(1) Engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Commission, or

(2) Deliberately submit to the NRC, a licensee, or a licensee's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Commission, or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, contractor, or subcontractor.

EXEMPTIONS

58 FR 7715

§ 30.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and Parts 31-36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) [Deleted 45 FR 6552]

45 FR 14139

search in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or (c) the use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel. In addition to the foregoing exemptions and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

58 FR 7715

(c) A manufacturer, processor, or producer of a product or material in an agreement State is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31, 32, 33, 34, 36 and 39 of this chapter to the extent that he transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

58 FR 7715

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to § 32.11 of this chapter or the general license provided in § 150.20 of this chapter.

48 FR 13971

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Part 60 of this chapter.

47 FR 57446

(d) Except as specifically provided in Part 61 of this chapter, any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Part 61 of this chapter.

45 FR 14139

§ 30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for: (a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of by-product material to or from such site and the performance of contract services during temporary interruptions of such transportation; (b) research in, development of, manufacture of, testing of, or transportation of atomic weapons or components thereof; or (c) activities licensed pursuant to the Energy Reorganization Act of 1974.

58 FR 7715

§ 30.13 Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and Parts 31-36 and 39 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

58 FR 7715

§ 30.14 Exempt concentrations.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31-36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

50 FR 8185

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

58 FR 7715

§ 30.15 Certain items containing byproduct material.

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece,

(ii) 5 millicuries of tritium per hand,

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,

(v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand,

(vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(vii) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(*a*) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(*b*) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(*c*) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(2) Lock illuminators containing not more than 15 millicuries of tritum or not more than 2 millicuries of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritum per balance part.

(4) Automobile shift quadrants containing not more than 25 millicuries of tritium.

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

(6) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(7) [Deleted 34 FR 6651.]

(8) Electron tubes: *Provided*, That each tube does not contain more than one of the following specified quantities of byproduct material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(ii) 1 microcurie of cobalt-60;

(iii) 5 microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) 5 microcuries of cesium-137;

(vi) 30 microcuries of promethium-147;

And provided further, That the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[3]

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material: *Provided*, That:

(i) Each source contains no more than one exempt quantity set forth in § 30.71, Schedule B, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

(10) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters per hour).

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

§ 30.16 Resins containing scandium-46 and designed for sand-consolidation in oil wells.

Any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand-consolidation in oil wells, and which have been manufactured or initially transferred for sale or distribution, in accordance with a specific license issued pursuant to § 32.17 of this chapter or equivalent regulations of an Agreement State. The exemption in this section does not authorize the manufacture or initial transfer for sale or distribution of any resins containing scandium-46.

[3] For purposes of this subparagraph "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30-34, 36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person who possesses byproduct material received or acquired prior to September 25, 1971, under the general license then provided in § 31.4 of this chapter is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30-34 of this chapter to the extent that such person possesses, uses, transfers, or owns such byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material, or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.22 of this chapter, which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.26 of this chapter, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

LICENSES

§ 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part and Parts 32-36, 39. General licenses are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

§ 30.32 Application for specific licenses.

49 FR 27923

(a) A person may file an application in duplicate on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

30 FR 8185

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license, should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

43 FR 6918

(d) An application for license filed pursuant to the regulations in this part and Parts 32-35 will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

36 FR 148

(e) Each application for a byproduct material license, other than a license exempted from Part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

49 FR 9352

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to Subpart A of Part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to Subpart A of Part 51 of this chapter.

52 FR 27782

(g) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either—

(1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter or with an Agreement State; or

(2) Contain the information identified in § 32.210(c).

53 FR 24018

(h) As provided by § 30.35, certain applications for specific licenses filed under this part and Parts 32 through 35 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

64 FR 14031

(i)(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in § 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(i) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph (i)(1)(i) of this section:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown § 30.72 due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in § 30.72;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in § 30.72; or

(vii) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (i)(1)(ii) of

this section must include the following information:

(i) Facility description. A brief description of the licensee's facility and area near the site.

(ii) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(iv) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(v) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

54 FR 14051

[1] These reporting requirements do not superceed or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

50 FR 8185

(4) The applicant satisfies any special requirements contained in Parts 32 through 36 and 39; and

58 FR 7715

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

49 FR 9352

30 FR 8185

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC 374, "Byproduct Material License").

55 FR 7715

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and the regulations in Parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b) No license issued or granted pursuant to the regulations in this part and Parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Commission pursuant to the regulations in this part and Parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and Parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

30 FR 8185

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

54 FR 14051

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

53 FR 23382

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test the generator eluates for molybdenum-99 breakthrough in accordance with §35.204 of this chapter. The licensee shall record the results of each test and retain each record for three years after the record is made.

52 FR 1292

(h)(1) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

58 FR 67657

§ 30.35 Financial assurance and recordkeeping for decommissioning.

(a) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^4 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^4 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(i) [Removed 59 FR 61767.]

53 FR 24018

(b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section shall either—

(1) Submit a decommissioning funding plan as described in paragraph (e) of this section; or

60 FR 38235

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (d) of this section using one of the methods described in paragraph (f) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section must be submitted to NRC before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

53 FR 24018

(c) (1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

60 FR 38235

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan as described, in paragraph (e) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 30.37 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

58 FR 67657

(d) Table of required amounts of financial assurance for decommissioning by quantity of material.

greater than 10^4 but less than or equal to 10^6 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a), divided by 10^4 is greater than 1 but R divided by 10^6 is less than or equal to 1.)	$750,000
greater than 10^6 but less than or equal to 10^8 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a), divided by 10^6 is greater than 1 but R divided by 10^8 is less than or equal to 1.)	$150,000
greater than 10^{10} times the applicable quantities of appendix B to part 30 for sealed sources or plated foils. (For a combination of isotopes, if R, as defined in § 30.35(a), divided by 10^{10} is greater than 1).	$75,000

60 FR 36235

(e) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

53 FR 24018

(f) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

59 FR 1618

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C of this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

53 FR 24018

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

53 FR 24018

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (f)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in paragraph (d) of this section, and indicating that funds for decommissioning will be obtained when necessary.

61 FR 24669

≫(g) Each person licensed under this part or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

53 FR 24018

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

58 FR 39628

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

58 FR 67657

(i) All areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

58 FR 39628

(ii) All areas outside of restricted areas that require documentation under § 30.35(g)(1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

58 FR 67657

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 10 CFR 20.2002.

58 FR 39628

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

§ 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a)(1) Except as provided in paragraph (a)(2) of this section, each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 30.37 not less than 30 days before the expiration date stated in the existing license (or, for those licenses subject to paragraph (a)(2) of this section, 30 days before the deemed expiration date in that paragraph). If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license (or, for those licenses subject to paragraph (a)(2) of this section, 30 days before the deemed expiration date in that paragraph), the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(2) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in paragraph (a)(3) of this section, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(3) The following specific licenses are not subject to, or otherwise affected by, the provisions of paragraph (a)(2) of this section:

(i) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with § 30.32(i);

(ii) Specific licenses whose holders are subject to the financial assurance requirements specified in 10 CFR 30.35, and on February 15, 1996, the holders either:

(A) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(B) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(iii) Specific licenses whose holders are listed in the SDMP List published in NUREG 1444, Supplement 1 (November 1995);

(iv) Specific licenses whose issuance, amendment, or renewal, as of February 15, 1996, is not a categorical exclusion under 10 CFR 51.22(c)(14) and, therefore, need an environmental assessment or environmental impact statement pursuant to Subpart A of Part 51 of this chapter;

(v) Specific licenses whose holders have not had at least one NRC inspection of licensed activities before February 15, 1996;

(vi) Specific licenses whose holders, as the result of the most recent NRC inspection of licensed activities conducted before February 15, 1996, have been:

(A) Cited for a Severity Level I, II, or III violation in a Notice of Violation;

(B) Subject to an Order issued by the NRC; or

(C) Subject to a Confirmatory Action Letter issued by the NRC.

(vii) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under 10 CFR 30.37 of this part.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of

61 FR 1109

61 FR 1109

59 FR 36026

roduct material until the
nmission notifies the licensee in
ting that the license is terminated.
ring this time, the licensee shall—
1) Limit actions involving byproduct
terial to those related to
commissioning; and
2) Continue to control entry to
tricted areas until they are suitable
release in accordance with NRC
uirements.

d) Within 60 days of the occurrence
any of the following, consistent with
administrative directions in § 30.6,
th licensee shall provide notification
the NRC in writing of such
currence, and either begin
commissioning its site, or any
parate building or outdoor area that
ntains residual radioactivity so that
building or outdoor area is suitable
release in accordance with NRC
quirements, or submit within 12
nths of notification a
commissioning plan, if required by
ragraph (g)(1) of this section, and
gin decommissioning upon approval
that plan if—

(1) The license has expired pursuant
paragraph (a) or (b) of this section; or
(2) The licensee has decided to
rmanently cease principal activities,
defined in this part, at the entire site
in any separate building or outdoor
ea that contains residual radioactivity
ch that the building or outdoor area
unsuitable for release in accordance
th NRC requirements; or
(3) No principal activities under the
ense have been conducted for a
riod of 24 months; or
(4) No principal activities have been
nducted for a period of 24 months in
y separate building or outdoor area
at contains residual radioactivity such
at the building or outdoor area is
suitable for release in accordance
th NRC requirements.

60 FR 38235

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 30.35 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1995.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to extend the time periods established in paragraph (d) if the Commission determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

60 FR 38235

61 FR 29836

(3) Procedures such as those listed in paragraph (g)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

61 FR 29836

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

60 FR 38235

(i) The Commission may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall—

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate—

(i) Report levels of gamma radiation in units of millisieverts (microroentgen)

per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters—removable and fixed—for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Byproduct material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with NRC requirements; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with NRC requirements.

60 FR 38235

(4) Records required by § 30.51 (d) and (f) have been received.

61 FR 24669

§ 30.37 Application for renewal of licenses.

(a) Application for renewal of a specific license must be filed on NRC Form 314 and in accordance with § 30.32.

59 FR 36026

(b) If any licensee granted the extension described in 10 CFR 30.36(a)(2) has a currently pending renewal application for the extended license, that application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded.

61 FR 1109

§ 30.36 Application for amendment of licenses.

Applications for amendment of a license shall be filed on Form NRC-313 in accordance with § 30.32 and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment.

49 FR 19623

§ 30.39 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 30.33 and Parts 32 through 36 and 39 of this chapter.

58 FR 7715

§ 30.41 Transfer of byproduct material.

(a) No licensee shall transfer byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer byproduct material:

(1) To the Department;

38 FR 33968

(2) To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under section 274 of the Act;

40 FR 8774

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

(5) To any person authorized to receive such byproduct material under terms of a specific license or a general license or their equivalents issued by the Atomic Energy Commission, the Commission, or an Agreement State;

38 FR 33968

(6) To a person abroad pursuant to an export license issued under Part 110 of this chapter; or

(7) As otherwise authorized by the Commission in writing.

43 FR 6915

(c) Before transferring byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: *Provided*, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the byproduct material.

38 FR 33968

RECORDS, INSPECTIONS, TESTS, AND REPORTS

56 FR 40757

§ 30.50 Reporting requirements.

(a) *Immediate report.* Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report.* Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001–20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001–20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

56 FR 40757

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

59 FR 14085

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

55 FR 40757

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC Regional office listed in appendix D of 10 CFR part 20. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72.

[1] The commercial telephone number for the NRC Operations Center is (301) 816-5100.

58 FR 7715

§ 30.51 Records.

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

53 FR 19240

(1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

58 FR 7715

(b) The licensee shall retain each record that is required by the regulations in this part and Parts 31 through 36 and 39 of this chapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part and Parts 31 through 36 and 39 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part and Parts 31 through 36 and 39 of this chapter, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and Parts 31 through 36 and 39 of this chapter for such records shall apply unless the Commission, pursuant to § 30.11, has granted a specific exemption from the record retention requirements specified in the regulations in this part or Parts 31 through 36 and 39 of this chapter.

61 FR 24669

≫ (d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981 [1]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with § 30.34(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981 [1]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by § 30.35(g) to the appropriate NRC Regional Office.

[1] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

§ 30.52 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

[30 FR 8185]

§ 30.53 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and Parts 31 through 36 and 39 of this chapter, including tests of:

[58 FR 7715]

(a) Byproduct material;

(a) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

[30 FR 8185]

§ 30.55 Tritium reports.

(a)-(b) [Reserved]

(c) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess tritium shall report promptly to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter by telephone and telegraph, mailgram, or facsimile any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year. The initial report shall be followed within a period of fifteen (15) days by a written report submitted to the appropriate NRC Regional Office which sets forth the details of the incident and its consequences. Copies of such written report shall be sent to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Subsequent to the submission of the written report required by this paragraph, the licensee shall promptly inform the Office of Nuclear Material Safety and Safeguards by means of a written report of any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of tritium.

(d) The reports described in this section are not required for tritium possessed pursuant to a general license provided in Part 31 of this chapter or for tritium contained in spent fuel.

[52 FR 31601]

Enforcement

§ 30.61 Modification and revocation of licenses.

(a) The terms and conditions of each license issued pursuant to the regulations in this part and Parts 31 through 35 of this chapter shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

[43 FR 6915]

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

[30 FR 8185]

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

§ 30.62 Right to cause the withholding or recall of byproduct material.

[40 FR 27741]

The Commission may cause the withholding or recall of byproduct 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 materials 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.

[30 FR 8185]

§ 30.63 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55062]

§ 30.64 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 30 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 30 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 30.1, 30.2, 30.4, 30.5, 30.6, 30.8, 30.11, 30.12, 30.13, 30.15, 30.16, 30.31, 30.32, 30.33, 30.37, 30.38, 30.39, 30.61, 30.62, 30.63, 30.64, 30.70, 30.71, and 30.72.

SCHEDULES

§ 30.70 Schedule A—Exempt concentrations.

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml[1]	Column II Liquid and solid concentration μCi/ml[2]
Antimony (51)	Sb 122	------	$3X10^{-4}$
	Sb 124	------	$2X10^{-4}$
	Sb 125	------	$1X10^{-3}$
Argon (18)	A 37	$1X10^{-3}$	------
	A 41	$4X10^{-7}$	------
Arsenic (33)	As 73	------	$5X10^{-3}$
	As 74	------	$5X10^{-4}$
	As 76	------	$2X10^{-4}$
	As 77	------	$8X10^{-4}$
Barium (56)	Ba 131	------	$2X10^{-3}$
	Ba 140	------	$3X10^{-4}$
Beryllium (4)	Be 7	------	$2X10^{-2}$
Bismuth (83)	Bi 206	------	$4X10^{-4}$
Bromine (35)	Br 82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd 109	------	$2X10^{-3}$
	Cd 115m	------	$3X10^{-4}$
	Cd 115	------	$3X10^{-4}$
Calcium (20)	Ca 45	------	$9X10^{-5}$
	Ca 47	------	$5X10^{-4}$
Carbon (6)	C 14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce 141	------	$9X10^{-4}$
	Ce 143	------	$4X10^{-4}$
	Ce 144	------	$1X10^{-4}$
Cesium (55)	Cs 131	------	$2X10^{-2}$
	Cs 134m	------	$6X10^{-2}$
	Cs 134	------	$9X10^{-5}$
Chlorine (17)	Cl 38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr 51	------	$2X10^{-2}$
Cobalt (27)	Co 57	------	$5X10^{-3}$
	Co 58	------	$1X10^{-3}$
	Co 60	------	$5X10^{-4}$
Copper (29)	Cu 64	------	$3X10^{-3}$
Dysprosium (66)	Dy 165	------	$4X10^{-3}$
	Dy 166	------	$4X10^{-4}$
Erbium (68)	Er 169	------	$9X10^{-4}$
	Er 171	------	$1X10^{-3}$
Europium (63)	Eu 152 (T/2=9.2 Hrs)	------	$6X10^{-4}$
	Eu 155	------	$2X10^{-3}$
Fluorine (9)	F 18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd 153	------	$2X10^{-3}$
	Gd 159	------	$8X10^{-4}$
Gallium (31)	Ga 72	------	$4X10^{-4}$
Germanium (32)	Ge 71	------	$2X10^{-2}$
Gold (79)	Au 196	------	$2X10^{-3}$
	Au 198	------	$5X10^{-4}$
	Au 199	------	$2X10^{-3}$
Hafnium (72)	Hf 181	------	$7X10^{-4}$
Hydrogen (1)	H 3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In 113m	------	$1X10^{-2}$
	In 114m	------	$2X10^{-4}$
Iodine (53)	I 126	$3X10^{-9}$	$2X10^{-5}$
	I 131	$3X10^{-9}$	$2X10^{-5}$
	I 132	$8X10^{-8}$	$6X10^{-4}$
	I 133	$1X10^{-8}$	$7X10^{-5}$
	I 134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir 190	------	$2X10^{-3}$
	Ir 192	------	$4X10^{-4}$
	Ir 194	------	$3X10^{-4}$
Iron (26)	Fe 55	------	$8X10^{-3}$
	Fe 59	------	$6X10^{-4}$
Krypton (36)	Kr 85m	$1X10^{-6}$	------
	Kr 85	$3X10^{-6}$	------
Lanthanum (57)	La 140	------	$2X10^{-4}$
Lead (82)	Pb 203	------	$4X10^{-3}$
Lutetium (71)	Lu 177	------	$1X10^{-3}$
Manganese (25)	Mn 52	------	$3X10^{-4}$
	Mn 54	------	$1X10^{-3}$
	Mn 56	------	$1X10^{-3}$
Mercury (80)	Hg 197m	------	$2X10^{-3}$
	Hg 197	------	$3X10^{-3}$
	Hg 203	------	$2X10^{-4}$
Molybdenum (42)	Mo 99	------	$2X10^{-3}$
Neodymium (60)	Nd 147	------	$6X10^{-4}$
	Nd 149	------	$3X10^{-3}$
Nickel (28)	Ni 65	------	$1X10^{-3}$
Niobium (Columbium) (41)	Nb 95	------	$1X10^{-3}$
	Nb 97	------	$9X10^{-3}$
Osmium (76)	Os 185	------	$7X10^{-4}$
	Os 191m	------	$3X10^{-2}$
	Os 191	------	$2X10^{-3}$
	Os 193	------	$6X10^{-4}$
Palladium (46)	Pd 103	------	$3X10^{-3}$
	Pd 109	------	$9X10^{-4}$
Phosphorus (15)	P 32	------	$2X10^{-4}$
Platinum (78)	Pt 191	------	$1X10^{-3}$
	Pt 193m	------	$1X10^{-2}$
	Pt 197m	------	$1X10^{-2}$
	Pt 197	------	$1X10^{-3}$
Potassium (19)	K 42	------	$3X10^{-3}$
Praseodymium (59)	Pr 142	------	$3X10^{-4}$
	Pr 143	------	$5X10^{-4}$
Promethium (61)	Pm 147	------	$2X10^{-3}$
	Pm 149	------	$8X10^{-4}$
Rhenium (75)	Re 183	------	$6X10^{-3}$
	Re 186	------	$9X10^{-4}$
	Re 188	------	$6X10^{-4}$

[1] Values are given only for those materials normally used as gases.

[2] μCi/gm for solids.

59 FR 5519

59 FR 5519

59 FR 5519

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml[1]	Column II Liquid and solid concentration μCi/ml[2]
Rhodium (45)	Rh 103m	------	$1X10^{-1}$
	Rh 105	------	$1X10^{-3}$
Rubidium (37)	Rb 86	------	$7X10^{-4}$
Ruthenium (44)	Ru 97	------	$4X10^{-3}$
	Ru 103	------	$8X10^{-4}$
	Ru 105	------	$1X10^{-3}$
	Ru 106	------	$1X10^{-4}$
Samarium (62)	Sm 153	------	$8X10^{-4}$
Scandium (21)	Sc 46	------	$4X10^{-4}$
	Sc 47	------	$9X10^{-4}$
	Sc 48	------	$3X10^{-4}$
Selenium (34)	Se 75	------	$3X10^{-3}$
Silicon (14)	Si 31	------	$9X10^{-3}$
Silver (47)	Ag 105	------	$1X10^{-3}$
	Ag 110m	------	$3X10^{-4}$
	Ag 111	------	$4X10^{-4}$
Sodium (11)	Na 24	------	$2X10^{-3}$
Strontium (38)	Sr 85	------	$1X10^{-3}$
	Sr 89	------	$1X10^{-4}$
	Sr 91	------	$7X10^{-4}$
	Sr 92	------	$7X10^{-4}$
Sulfur (16)	S 35	$9X10^{-6}$	$6X10^{-4}$
Tantalum (73)	Ta 182	------	$4X10^{-4}$
Technetium (43)	Tc 96m	------	$1X10^{-1}$
	Tc 96	------	$1X10^{-3}$
Tellurium (52)	Te 125m	------	$2X10^{-3}$
	Te 127m	------	$6X10^{-4}$
	Te 127	------	$3X10^{-3}$
	Te 129m	------	$3X10^{-4}$
	Te 131m	------	$6X10^{-4}$
	Te 132	------	$3X10^{-4}$
Terbium (65)	Tb 160	------	$4X10^{-4}$
Thallium (81)	Tl 200	------	$4X10^{-3}$
	Tl 201	------	$3X10^{-3}$
	Tl 202	------	$1X10^{-3}$
	Tl 204	------	$1X10^{-3}$
Thulium (69)	Tm 170	------	$5X10^{-4}$
	Tm 171	------	$5X10^{-3}$
Tin (50)	Sn 113	------	$9X10^{-4}$
	Sn 125	------	$2X10^{-4}$
Tungsten (Wolfram) (74)	W 181	------	$4X10^{-3}$
	W 187	------	$7X10^{-4}$
Vanadium (23)	V 48	------	$3X10^{-4}$
Xenon (54)	Xe 131m	$4X10^{-6}$	------
	Xe 133	$3X10^{-6}$	------
	Xe 135	$1X10^{-6}$	------
Ytterbium (70)	Yb 175	------	$1X10^{-3}$
Yttrium (39)	Y 90	------	$2X10^{-4}$
	Y 91m	------	$3X10^{-2}$
	Y 91	------	$3X10^{-4}$
	Y 92	------	$6X10^{-4}$
	Y 93	------	$3X10^{-4}$
Zinc (30)	Zn 65	------	$1X10^{-3}$
	Zn 69m	------	$7X10^{-4}$
	Zn 69	------	$2X10^{-2}$
Zirconium (40)	Zr 95	------	$6X10^{-4}$
	Zr 97	------	$2X10^{-4}$
Beta and/or gamma emitting byproduct material not listed above with half-life less than 3 years.	--------	$1X10^{-10}$	$1X10^{-6}$

[1] Values are given only for those materials normally used as gases.

[2] μCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of § 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in Product 1}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

36 FR 16898

§ 30.71 Schedule B.

Byproduct material	*Microcuries*
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000

Byproduct material	Microcuries
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2h (Eu 152 9.2h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 72 (Ga 72)	10
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorous 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulfur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct material	0.1

[Note removed 49 FR 19623]

25 FR 8425 25 FR 8245 25 FR 8425

10.72 Schedule C—Quantities of dioactive materials requiring nsideration of the need for an ergency plan for responding to a lease.

Radioactive material [1]	Release fraction	Quantity (curies)
inium-228	0.001	4,000
nericium-241	.001	2
nericium-242	.001	2
nericium-243	.001	2
timony-124	.01	4,000
timony-126	.01	6,000
rium-133	.01	10,000
rium-140	.01	[illegible]700
muth-207	.01	5,000
muth-210	.01	600
dmium-109	.01	1,000
dmium-113	.01	60
dium-45	.01	20,000
lifornium-252	.001	9 (20 mg)
rbon-14 (non-carbon dioxide)	.01	60,000
rium-141	.01	10,000
rium-144	.01	300
rium-134	.01	2,000
sium-137	.01	3,000
rbine-36	.5	100
romium-51	.01	300,000
balt-60	.001	5,000
pper-64	.01	200,000
rium-242	.001	60
rium-243	.001	3
rium-244	.001	4
rium-245	.001	2
sprosium-162	.01	600
sprosium-154	.01	400
sprosium-165	.01	3,000
rmanium-68	.01	2,000
ld-196	.01	30,000
ld-196	.01	30,000
nium-172	.01	400
nium-181	.01	7,000
mium-166m	.01	100
drogen-3	.5	20,000
dine-125	.5	10
dine-131	.5	10
dium-114m	.01	1,000
dium-192	.001	40,000
n-55	.01	40,000
n-59	.01	7,000
pton-85	1.0	6,000,000
ad-210	.01	6
nganese-56	.01	60,000
rcury-203	.01	10,000
lybdenum-99	.01	30,000
ptunium-237	.001	2
kel-63	.01	20,000
bium-94	.01	300
osphorus-32	.5	100
osphorus-33	.5	1,000
onium-210	.01	10
aseium-42	.01	9,000
rmethium-145	.01	4,000
rmethium-147	.01	4,000
uthenium-106	.01	200
amarium-151	.01	4,000
ndium-46	.01	3,000
enium-75	.01	10,000
ver-110m	.01	1,000
dium-22	.01	9,000
dium-24	.01	10,000
ontium-89	.01	3,000
ontium-90	.01	90
ulfur-35	.5	900
echnetium-99	.01	10,000
echnetium-99m	.61	400,000
ellurium-127m	.01	5,000
ellurium-129m	.01	5,000
erbium-160	.01	4,000
hulium-170	.01	4,000
n-113	.01	10,000
Tin-123	.01	2,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	6,000
Zirconium-93	.01	400
Zirconium-95	.01	6,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma [4]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [4]	.0001	20
Combinations of radioactive materials listed above [3]		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

[4] Waste packaged in Type B containers does not require an emergency plan.

61 FR 9901

Appendix A—Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and

(ii) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $10 million; and

(iv) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Commission of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

53 FR 24018

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Commission, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

53 FR 24018

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

Appendix B to Part 30

Material	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-126	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2 h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	10
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10

58 FR 67657

Material	Microcuries
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-106	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234	.01
Uranium-235	.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10

58 FR 67657

Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	.1

58 FR 67657

Note.—For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows. Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

[1] Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2] Based on alpha disintegration rate of U-238, U-234, and U-235.

Appendix C to Part 30—Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

59 FR 1618

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.